CLSA Access Agreement

This agreement is entered into this [Date] (the "**Effective Date**"), at Hamilton, Ontario.

McMaster University, a University incorporated by special act of the Province of Ontario, Canada, with a main address at 1280 Main Street West, McMaster Innovation Park, Suite 309A, Hamilton, Ontario, Canada, L8S 4K1 ("**McMaster**") is the host institution of the Canadian Longitudinal Study on Aging ("***CLSA***").

AND

[Insert User Institution Name], with a main address at **[insert address] ("Approved User *Institution*")**

WHEREAS:

A. Dr. Parminder Raina (McMaster University) is the Lead Investigator for the CLSA funded by a grant from the Canadian Institutes of Health Research (CIHR) and is responsible for the academic obligations under this Agreement

B. [Insert user scientist's name] (the "Approved User") is a <POSITION/FUNCTION>, at the Institution, where he/she carries or wishes to carry out a project entitled <TITLE OF RESEARCH PROJECT>, for which access to CLSA samples or data (or both) will be required.

C. The document titled "CLSA Data and Biospecimen Access Policy and Guiding Principles" attached, as Schedule A is an integral part of this agreement. All obligations contained therein are part of this agreement.

The parties hereto agree as follows:

1. Definitions

"Agreement" means this CLSA *Access Agreement.*

"DSAC" means the CLSA's Data and Sample Access Committee.

"**Project**" means the **CLSA Data and/or Biospecimen Request Application** described in Schedule B attached hereto.

"Transferred Materials," means the CLSA data, Metabolon Data, Regeneron Data and/or the biospecimens described in Schedule B attached hereto.

"**Metabolon Data**" means the metabolite biomarker signature data generated by Metabolon Inc. for CLSA described in Schedule B attached hereto.

"**Regeneron Data**" means the genomic data generated by the Regeneron Genetics Center for CLSA described in Schedule B attached hereto.

2. Sample and Data Security.

2.1 Security measures specified in Schedule C attached hereto will apply to all Transferred Materials. The Approved User and Institution undertakes to respect these security measures during the Project and afterwards, during storage of Transferred Materials where necessary.

2.2 The Approved User and Institution shall agree to the audit of their research facility by McMaster to ensure the security and confidentiality of Transferred Materials. These audits may be conducted with reasonable prior notice. Any discrepancies between the security measures specified in Schedule C and what is found at the Approved User and Institution's research facility will have to be corrected within sixty (60) days of notice by McMaster. McMaster will support the costs associated with these audits.

2.3 Transferred Materials, including any copies thereof, may only be used for the Project described in Schedule B and may not be disclosed, transmitted or shipped to anyone except employees working directly with the Approved User and Institution or co-investigators including co-applicants or other personnel from other institution(s), indicated in the Project who will require direct access to the CLSA Data and who agree to be bound by the terms of this

Agreement or to persons expressly designated in writing by McMaster. The Approved User shall retain control of the Transferred Material at all times. It is the responsibility of the Approved User and Institution to inform the staff and co-investigators, including co-applicants and other personnel at other third-party institution(s) entering into contact with the Transferred Materials of the obligations contained in the CLSA Data and Biospecimen Access Policy and Guiding Principles and this Agreement. As such, co-applicants and other personnel at other third-party institution(s) must submit a signed Schedule F attached hereto. Transfer of any CLSA biospecimens outside Canada is strictly prohibited. Data access will only be provided to institutional email addresses.

2.4 Any **Metabolon Data** provided hereunder are provided for Approved User's use solely in its non-commercial education and research activities, and may not be disclosed to, or used in research sponsored by, any for-profit entities, and/or transferred, directly or indirectly, to any for-profit entities, including any consortia that includes as one of its members or constituents a commercial entity or person acting on behalf of a commercial or for-profit entity.

2.5 Any **Regeneron Data** provided hereunder may not be used in research sponsored by for-profit entities and/or transferred to any for-profit entities.

3. Return of Derived Data. The Approved User undertakes to return to McMaster the results of the Project analyses as specified in Schedule D attached hereto within the timeframe and conditions specified therein.

4. Fees. The Institution shall pay to McMaster the access fees and transportation fees specified in Schedule E attached hereto within forty-five (45) days after receipt of the invoice.

5. Representations and Warranties of the Approved User and the Institution

5.1 The Approved User and the Institution represent and warrant that the Project has received ethical approval from the Institution's research ethics committee or, if no such committee exists within the Institution, from a recognized research ethics committee for the duration of the Project. All documents in the Approved User's possession concerning ethical approval of the Project, including any subsequent amendments/renewals that may be applicable, have been provided to McMaster.

5.2 The Approved User and the Institution represent that they have read and took note of their obligations under the CLSA Data and Biospecimen Access Policy and Guiding Principles attached hereto as Schedule A.

6. Property of Transferred Materials. Nothing in this Agreement will operate to transfer any property rights in the Transferred Material.

7. Exclusive Access: No exclusive access will be granted to any portion of the Transferred Materials. McMaster may grant access to the Transferred Materials to others and may use it for its own internal purposes.

8. Publications: Copies of all proposed publications using Transferred Materials from McMaster must be submitted to McMaster for review at least 15 working days prior to submission. This review will be limited to ensuring that participants cannot be identified in such publications, that results are presented in a scientifically accurate manner to prevent the stigmatization of participants and of the communities they belong to. Users are required to follow the process and conditions contained in the CLSA publication and promotion policy, which can be found on the CLSA Website: https://www.clsa-elcv.ca). For additional clarity, pursuant to clause 13.1, the Approved User's right to publish shall end upon termination of this Agreement

9. Archives and Peer Review. Approved User will be permitted to archive the Transferred Material for the period of time required for peer review and audit purposes but not to exceed 1 year following the termination of this Agreement. Once this period of time has elapsed, the Approved User undertakes to destroy all Transferred Materials and all copies thereof in his/her possession or his/her control. When requested by McMaster, the Approved User shall certify in writing that the Transferred Material and all copies thereof were destroyed (Schedule C).

10. Reporting Obligations: Approved Users shall comply with the following reporting obligations: i) a **Final Report** is to be submitted 60 days following the end date of this agreement; and ii) **notify** McMaster without delay for: a) incidents affecting the confidentiality of participants; b) incidents affecting the security or integrity of data/samples; c)

suspension or lapse of any relevant authorizations (e.g. Ethics approval), professional qualifications, funding or approvals.

11. Undertakings and Liability

11.1 The Institution and Approved User acknowledges that the biological samples contained in the Transferred Material may carry viruses, latent viral genomes, and other infectious agents. The Approved User undertakes to treat all such biological samples as if they are not free of contamination, and to ensure that all such biological samples are handled only by trained personnel under laboratory conditions that afford adequate biohazard containment. By accepting delivery of these biological samples, the Institution and Approved User assume full responsibility and risk for their safe and appropriate use, handling, storage, and/or disposal.

11.2 The Approved User and the Institution assume all liability or damages arising from the use, storage or disposal of the Transferred Material and further agrees to defend, indemnify and hold harmless McMaster and its agents and employees from any unauthorized use of or disclosure or transfer of the Metabolon Data or Regeneron Data pursuant to Section 2.4 and all liabilities, damages, demands, expenses and losses arising out of the acceptance, use for any purpose, handling or storage and/or disposal of the Transferred Materials or their by-products or modified or unmodified derivatives and in respect of all matters associated with the research results arising from the use of the Transferred Materials by the Approved User, the Institution or its employees.

12. Default of Approved User or Institution. Failure to comply with the terms of this Agreement may result, in addition to termination of this agreement pursuant to Section 13.2, in the disqualification of the Approved User or the Institution (or both) from receiving any additional data or biological samples from McMaster. McMaster reserves the right to institute and to take appropriate proceedings at law (or in equity, where applicable) against the Approved User or the Institution (or both) in connection with breaches of this Agreement.

13. Termination

13.1 This Agreement will terminate two years after the end date of the Project unless the parties agree in writing to renew it. Upon termination of the Agreement, the Approved Users will destroy all Transferred Materials in his or her possession. Following termination of the Agreement, Approved User's right to publish pursuant to Section 8 hereunder shall end.

13.2 McMaster may terminate this Agreement if the Approved User or the Institution are in default of any of the provisions of this Agreement and this default has not been remedied within sixty (60) days of written notice sent by McMaster to the Approved User or the Institution in respect of this default. Upon termination of this Agreement pursuant to this Section 13.2, the Approved User will return all Transferred Material in his or her possession to McMaster or destroy them and all copies thereof in possession or control of the Approved User or the Institution according to the instructions provided by McMaster. The Approved User will provide McMaster with a certificate attesting to such destruction, executed by him/her and an authorized representative of the Institution (Schedule C). In the event the Approved User is found to be in breach of this Agreement and such breach has not been remedied in accordance with this Section 13.2, the Approved User will not be entitled to publish the results of any Project except with the written agreement of McMaster.

14. No Warranties. The Transferred Materials accessed or delivered pursuant to this agreement are understood to be experimental in nature and are provided "as is". McMaster makes no representations and extends no warranties of any kind; either expressed or implied whatsoever in respect of the Transferred Materials. There are no express or implied warranties of merchantability, utility, efficacy, safety, identity, composition, non-toxicity and accuracy or fitness for a particular purpose or that the use thereof will not infringe any patent or other proprietary rights of any third party.

15. Notices. Any notice to be given by either party to the other shall be sent to the following:

For McMaster: CLSA Management Contact:	**For Legal Matters:**
Dr. Parminder Raina, PhD Lead Principal Investigator Canadian Longitudinal Study on Aging McMaster University 175 Longwood Rd. S. Suite 309A Hamilton, ON L8P 0A1 Tel: 905-525-9140, ext. 22197	Executive Director, McMaster Industry Liaison Office MIP – Rm. 305 175 Longwood Rd S, Hamilton, ON L8P 0A1 Tel: 905-525-9140, ext. 22176 Fax: 905-546-1372

Email: praina@mcmaster.ca	
If for Approved User:	If for Institution (add contact details)

16. General Provisions

16.1 This Agreement and the attached Schedules represent the entire understanding between the parties related to the Transferred Materials and the Project 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.

16.2 This Agreement is governed by and will be construed in accordance with the laws of the Province of Ontario, without regard to conflicts of laws principles.

16.3 The following provisions will survive termination of this Agreement: 5, 9, 10, 11, 12, 14, and 15.

16.4 This Agreement shall not be amended, modified, varied, or supplemented except in writing signed by each of the parties.

16.5 No party shall use, or authorize others to use, the name, symbols, or marks of another party hereto or its staff for any endorsement purposes without prior written approval from the party whose name, symbols or marks are to be used.

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

16.7 Nothing in this Agreement creates, implies, or evidences any partnership or joint venture between the parties, or the relationship between them of principal and agent. No party shall have the authority to act on behalf of any other party or to bind another party in any manner.

16.8 Each party represents that it is permitted to enter into this Agreement; to consent to its conditions and that each has authority to sign this Agreement. This Agreement may be executed in counterparts and may be executed and delivered by facsimile, digitally or electronically by PDF and all such counterparts, facsimiles and PDF copies shall together constitute one agreement. The parties agree that facsimile or PDF copies of signatures have the same effect as original signatures.

IN WITNESS WHEREOF, the parties hereto have signed this Agreement.

MCMASTER UNIVERSITY

Signature

Name: Gay Yuyitung, PhD

Title: Executive Director, MILO

Date:

Signature

Name: Parminder Raina, PhD

Title: Lead Investigator, CLSA

Date:

The Institution, through its authorized representative who has signed below, acknowledges that it is bound by this Agreement.

INSTITUTION

Signature

Name:

APPROVED USER

Signature

Name:

Title:
Date:

Title:
Date:

Schedule A:

Canadian Longitudinal Study on Aging (CLSA)

Data and Biospecimen Access
Policy and Guiding Principles

1. DEFINITIONS

1.1. Applicant: an investigator affiliated with a public research organization based in Canada or elsewhere who is applying to access data/biospecimens collected as part of the CLSA.

1.2. CLSA Bioanalysis and Biorepository Centre (BBC): the centre that stores the biological samples from CLSA participants and houses a research laboratory dedicated to undertaking detailed standardized biospecimen analysis of specialized biomarkers.

1.3. CLSA Access Agreement: an agreement developed by the CLSA and the lead investigator's institution which contractually binds the parties involved in accessing CLSA data/biospecimens. An executed Access Agreement is necessary to obtain access to data/biospecimens from the CLSA.

1.4. Lead Institution: McMaster University, where the National Coordinating Centre (NCC) is located.

1.5. Canadian Institutes of Health Research (CIHR) Advisory Committee on Ethical, Legal, and Social Issues (ELSI) for the CLSA: an independent advisory body under the governance of the Canadian Institutes of Health Research set in place specifically to address the various ELSI needs of the CLSA (hereafter "CIHR ELSI Advisory Committee").

1.6. CLSA Biomarker, Genetic and Epigenetics Centres: the centres where specified analyses for biomarkers are carried out on CLSA biospecimens to ensure standardized results.

1.7. CLSA Statistical Analysis Centre (SAC): the centre where data verification and preparation is carried out. The SAC also prepares alphanumeric datasets for users.

1.8. CLSA Scientific Management Team (SMT): the executive management body within CLSA.

1.9. Custodian: as per agreements between McMaster University (Lead Institution) and all CLSA Site institutions across Canada, McMaster University is deemed the legal custodian of the CLSA data and biospecimens, regardless of where the CLSA data and biospecimens were collected

1.10. Data and Biospecimen Access Committee (DSAC): a committee with the mandate to review data and biospecimen access applications to the CLSA. The DSAC makes recommendations for approval/rejection of access requests to the SMT.

1.11. Research: any systematic inquiry into the dimensions of adult development, health and aging using CLSA data and/or biospecimens.

1.12. Study Results: all analyses, including the results of laboratory testing, obtained from the analysis, manipulation, or testing of CLSA data and/or biospecimens.

1.13. Users: Applicants that have received the necessary approvals to access CLSA data and/or biospecimens.

2. DATA AND BIOSPECIMEN ACCESS POLICIES AND PRINCIPLES

2.1. Introduction

The Canadian Longitudinal Study on Aging (CLSA) is a scientific research program and research platform. Over the course of the conduct of the CLSA, a rich resource of data and biospecimens collected from study participants will be assembled. All participants in the CLSA have provided signed informed consent that includes the stipulation that the data and biospecimens collected from them will be treated according to strict security and confidentiality standards. In addition, CLSA participants are also informed that data and biospecimens collected from them will be made available to researchers under a set of conditions that respect the CLSA consent with particular attention to security and confidentiality of the data and biospecimens. Data

and biospecimen access in large-scale longitudinal studies is complex. Governance of access to the CLSA data must balance the interests of the CLSA, the custodian, Users and study participants.

The CLSA has implemented policies and procedures that create a fair and transparent process to access its data and biospecimens. The CLSA has developed principles to guide access to, and the use of, the CLSA data and biospecimens and these are described in this document. These principles, policies, and procedures apply to the access to all CLSA data and biospecimens for research purposes. All researchers, including CLSA investigators that are requesting access to data and/or biospecimens for research are required to follow the CLSA Data and Biospecimen Access Policies and Guiding Principles.

The CLSA includes as part of its governance structure the DSAC; the body responsible for the review of applications for access to, and use of, data and biospecimens, collected as part of the CLSA. The DSAC is composed of voting members selected from the research community (in Canada and overseas) in addition to an ex officio CLSA investigator and an ex officio observer from CIHR. The Committee functions in accordance with the CLSA policies, guidelines, and procedures for data and biospecimen access.

2.2. Guiding Principles

Access to, and use of, CLSA data and biospecimens are governed by the following principles:

- The rights, privacy and consent of participants must be protected and respected at all times (see CLSA Privacy Policy at www.clsa-elcv.ca).
- The confidentiality and the security of CLSA data and biospecimens must be safeguarded at all times.
- CLSA data and biospecimens are resources that will be used optimally to support research to benefit all Canadians.
- CLSA data and biospecimens will be made available for use in a timely and responsible manner taking into account the need to assure data validity and biospecimen integrity.
- CLSA biospecimens constitute a finite resource and procedures will be put in place to ensure that this resource is used optimally, according to the long-term research goals of CLSA, and in keeping with the informed consent.
- CLSA data and biospecimens will only be released to researchers once ethics approval for the research project has been obtained from the appropriate Research Ethics Board (REB) and the CLSA Access Agreement between the CLSA Custodian and the Applicant's institution has been executed. In addition, the biospecimens will only be released once evidence of funding to analyze the biospecimens is received.
- To meet data quality standards set by the CLSA documentation pertaining to biospecimen handling and analysis will be required. This includes standard operating procedures (SOP), lot-to-lot comparisons, quality control information and a temperature record.
- Exclusive access rights to CLSA data and biospecimens will not be granted to any Applicant for any Research.
- All Applicants will be required to follow the Access Procedures.
- Approved Applicants (Users) may be required to return derived variables and/or results to the CLSA within a timeframe specified in the CLSA Access Agreement noted above.
- Data and biospecimen management for access purposes will be cost neutral to the CLSA. The CLSA has a fixed charge for each biospecimen regardless of biospecimen type and a fixed cost for data regardless of number of participants or variables requested. These costs include administration, IT, retrieval, and shipping of consumables; the cost for shipping of biospecimens is additional and will vary depending on shipping location.
- The CLSA SMT team will have access to CLSA data and biospecimens for operational activities required for developing, managing and achieving overall success of the CLSA Platform. These are for

example: to conduct methodological analyses for the purposes of enhancing the design of the CLSA; enabling the development of communication materials to promote the CLSA Platform; and, facilitating partnerships in order to support long-term sustainability of the CLSA. The CLSA SMT is the decision making body for such operational activities and the CLSA will report on these activities to CIHR annually.

2.3. Limits on the Use of CLSA Data and Biospecimens

CLSA data and biospecimens can only be used by investigators affiliated with a public sector research organization[1]. Research projects must have received REB approval prior to the release of CLSA data and/or biospecimens.

In circumstances where CLSA links participant data and biospecimens to third party data holdings (e.g. provincial healthcare databases) the release of these data will be managed taking into account the terms and conditions of the third party data holdings, and thus may be subject to certain jurisdictional limitations with respect to the transfer and use of the linked data.

An important goal of the CLSA is to make the data and biospecimens available in a timely fashion for Research after data quality control and biospecimen integrity analyses are completed. If a User wishes to use CLSA data and/or biospecimens already received for a purpose other than the original purpose, then he/she must submit a new application to the DSAC. Any other change to the original application will require an amendment to the application and CLSA Access Agreement (as appropriate). CLSA Users are not permitted to share the data or biospecimens provided to them to others other than individuals identified as Users in the CLSA Access Agreement.

2.4. Access to CLSA Biospecimens

The Canadian Longitudinal Study on Aging (CLSA) collects blood and urine samples from consenting participants and stores the biospecimens in a Biorepository at McMaster University for future use. Biospecimens collected as part of the CLSA are valuable and finite resources. The CLSA SMT has the authority and the duty to responsibly manage biospecimens and to make sure the best possible scientific value is derived from these biospecimens. To achieve this objective, CLSA SMT and the DSAC will ensure that approved applications to use this resource will be of the highest scientific quality that will result in reliable, valid, informative and novel sets of biomarkers to advance the health and well-being of Canadians.

The CLSA is a longitudinal platform and the proposed use of the biospecimens should maximize the strength of this type of platform. The CLSA also requires the Users to return all the derived biomarker variables to the CLSA platform for use by other researchers. The intake of applications to access biospecimen will be once a year. The release of biospecimens to the user will require confirmation of funding to access and analyze the biospecimens. The CLSA's Biospecimen Access Guidelines can be found on the CLSA website at: https://www.clsa-elcv.ca.

2.5. Intellectual Property

The CLSA and its Lead Institution do not claim any ownership of, or exploitation rights to, any intellectual property resulting from the Users' research conducted with CLSA data/biospecimens.[2] Indeed, given the public nature of the CLSA research platform, it aims to promote a wide and accessible distribution of knowledge developed using this resource and achieves maximum public benefit. Thus, CLSA data and biospecimen Users are strongly encouraged to make their results (including research tools) rapidly and widely available to the scientific community.

[1]Alphanumeric data is available to all public sector investigators nationally and internationally. However, currently there is no provision to transfer biospecimens to applicants outside of Canada.
[2]Note that where the Applicant in question is an investigator from McMaster University, he/she will still be bound by the university's intellectual property policies. This is independent of the CLSA intellectual property policy.

Regarding genetic inventions, CLSA Users are strongly encouraged to follow the "Guidelines for the Licensing of Genetic Inventions" developed by the Organization for Economic Co-operation and Development (OECD) when licensing their intellectual property (presently found at: http://www.oecd.org/dataoecd/39/38/36198812.pdf).

2.6. Financial Considerations

The CLSA is a publicly funded research project and platform; access fees will be based on a cost recovery model and will be determined by the SMT.

2.7. Access Requests

Data and Biospecimen Access Application processes and procedures can be found on the CLSA website at https://www.clsa-elcv.ca.

2.8. Dissemination of Access Requests

To ensure transparency, and to ensure that participants are able to provide informed consent and withdraw if so desired, and to promote public awareness, the CLSA will provide information to study participants, to Applicants/Users and to the public on the general nature of research projects using CLSA data and/or biospecimens. Summary results from completed studies that use CLSA data and/or biospecimens will also be available in lay language. These will be provided by the researchers and will be posted on the CLSA website and in participant newsletters.

2.9. Obligations of Approved CLSA Data and Biospecimen Users

1.1. Research Quality

Users have a responsibility to enhance the value of the CLSA data by conducting high quality ethical research and sharing their findings in a timely manner to support dissemination and uptake. Formal scientific peer and ethical review of research proposals are important aspects of assuring quality and feasibility.

Safeguards will be maintained to ensure the anonymity and confidentiality of participants' data and biospecimens. Data and/or biospecimens provided to researchers from the CLSA will not contain any information that identifies any particular participant (i.e. they will be "de-identified" and coded). It is the obligation of the Users not to attempt to identify participants, and to use the data provided in a secure location to protect the privacy and confidentiality of the CLSA participants as per the CLSA Access Agreement as well as the CLSA consent form and Tri Council policies.

Return of Derived Variables

Data

As part of the conditions of the CLSA Access Agreement (as noted in Section 2) Users may be required to return to the CLSA derived variables for inclusion in the CLSA database for use by other researchers. In addition Users may be asked to return derived variables if such variables are identified in annual progress reports or manuscripts emanating from use of the CLSA data/biospecimens. In either case, Users will be asked to provide the code/syntax along with explanatory documentation to allow other researchers to understand the derivation and potential use of these derived variables. Users returning derived variables to the CLSA will work closely with the CLSA Statistical Analysis Centre.

1.2. Biospecimens

All data arising from research using CLSA biospecimens will be returned to the CLSA with exclusive use by the researcher who obtained funding for and produced the analyses lasting for a period of one year after which the data will be made available to all researchers.

2.10. Return of participants personal results from analyses conducted by Users

As a general policy, the CLSA will not return to participants their personal results from analyses conducted by Users. Nevertheless, given the duration of CLSA and the impossibility of foreseeing the nature of research projects that will be conducted using the CLSA data and biospecimens, Users shall be aware of the possibility that the CLSA may return validated results back to CLSA participants where such information is determined to be critical for the care of the participant. The decision regarding this return, whether and what to return will be taken by the SMT in consultation with the CIHR ELSI Advisory Committee and the relevant research ethics boards. Any situation in which personal results of analyses are returned to CLSA participants will be managed by the CLSA.

2.11. Public Disclosure and Proprietary Interests

The need to protect proprietary interests (e.g. patents) or pre-publication results may result in corresponding constraints on public disclosure of research results. In such situations, and where the time period during which results must be returned to CLSA is not sufficient, the User may request an extension.

2.12. Publications arising from Data and Biospecimen Access

Copies of all proposed publications using CLSA data and/or biospecimens must be submitted to the National Coordinating Centre at McMaster University for review by the CLSA Publication Review Committee at least 15 working days prior to submission. This review will be limited to ensuring that participants cannot be identified in such publications, appropriate acknowledgement has been given (see below), and that results are presented in accordance with the objectives stated in the CLSA Access Agreement. Users should review the CLSA publication policy prior to preparing manuscripts (The CLSA publication policy can be found on the CLSA Website: https://www.clsa-elcv.ca).

2.13. CLSA Acknowledgement in Publications

Full acknowledgement of the source of CLSA data and biospecimens must be included in any publications that arise from access to, and use of, the CLSA data and biospecimens. This acknowledgement must reference the sources of funding for the CLSA and its data platform and the core CLSA team responsible for the creation and implementation of the platform. Additional acknowledgements may apply if linked data have been used. All publications must include at a minimum the following acknowledgment for sources of funding:

“This research was made possible using the data/biospecimens collected by the Canadian Longitudinal Study on Aging (CLSA) [Data set version #]. Funding for the Canadian Longitudinal Study on Aging (CLSA) is provided by the Government of Canada through the Canadian Institutes of Health Research (CIHR) under grant reference: LSA 94473 and the Canada Foundation for Innovation”. The specific wording of the acknowledgements will be operationalized in the CLSA Access Agreement.

Revision and Approval History

New Version #	**Revision Date**	**CIHR Approval Date**	**Summary of revisions**
2.0	March 2018	N/A	Editorial changes
Version #	**Date**	**CIHR Approval Date**	**Summary of revisions**
1.3	February 2017	December 2017	Modification
Version #	**Date**	**CIHR Approval Date**	**Summary of revisions**
1.2	September 2014	December 2017	Minor editorial changes
Version #	**Date**	**CIHR Approval Date**	**Summary of revisions**
1.1	January 2014	March 2014	Minor modification
Version #	**Date**	**CIHR Approval Date**	**Summary of revisions**
1.0	June 2012	July 2012	Document development

Schedule B – Approved CLSA Data Request Application

Schedule C – Specific security measures

Definitions

Information:

- Any CLSA data and samples obtained from the CLSA pursuant to this Agreement, with or without name or other identifying information, and any aggregation of responses that could directly or indirectly identify an individual person, business, or organization.

Authorized Person:

- Person who is the PI(s) on the approved project.

Identified Person:

- Authorized Person and all others listed as Co-investigators/Collaborators or staff on the approved project.

Transportable media:

- All types of transportable storage media on which data can be saved, including laptops, CD-ROMs, flash memory sticks, and removable hard disk.

Visitor:

- Person, other than an Authorized Person, who has been invited into the secure area by an Authorized Person, as permitted by the Institution's access policies.

Security Requirements

The Institution must ensure that adequate protection is in place to provide for the security of the Information.

The security requirements described below are the minimum requirements that must be met by the Institution.

Physical Access

1. The Information must be accessed only from within a secure location that allows access only to Authorized and Identified Persons. The secure location can be within a series of buildings, one entire building, an entire floor within a building, or a single room. Once the perimeter of the secure location is defined, the procedures apply to all areas within the perimeter. Where a series of buildings are involved, a secure perimeter must be defined for each building.

2. Access to the Information is limited to Authorized and Identified Persons. The manager responsible for ensuring that the Institution's requirements are met must maintain an auditable trail, listing the Identified Persons, the specific Information to be accessed, the period for which this access is granted, the purpose for the access, and where applicable, that the Person meets any special requirements for access.

3. Visitors may have access to the secure area. However, under no circumstances may visitors be provided access to the Information.

IT Storage and Transmission

4. All computers with access to the Information must employ logical access controls (passwords) at the device and network level.

5. Where the Information is held on laptops, CD-ROMs, flash memory sticks or other transportable media of any type, passwords and full encryption must be used. This applies equally to backups of the Information stored on transportable media.

6. The Information cannot be electronically transmitted, except as described in points 7 and 8. This includes the transmittal of the Information by facsimile or by e-mail.

7. Servers storing and transmitting unencrypted data, where used, must be located in a secure, controlled-access area, preferably in the same area where the Information is accessed. If located in a separate area, controls must be in place to ensure that only Identified Persons can access the server. Unless the Information is encrypted continuously while outside the secure area, conduit must be used for all cabling and all cross-connect areas must be physically secured.

8. Network firewalls and access rules must be in place to prevent access to the Information, other than to Identified Persons. Information may be stored on and transmitted over networks not meeting these requirements, provided that it is encrypted, except when in use by an Identified Person. Alternatively, the Information may be stored on a stand-alone computer with no external connections, or on a closed network. When a network transmits information that leaves a secure area (for example, when a series of buildings house employees within a single organization), the data must be encrypted whenever it is outside the secure area.

Physical Storage

9. When not in use, transportable media containing the Information must be stored in secure containers. This applies equally to backups of the Information.

10. The Information shall not be removed from the secure area (as described in point 1, above) in any format (e.g., laptops, printouts, flash memory sticks, transportable media of any type, etc.), except as described in points 7 and 8 above.

11. When not in use, printed documents containing the Information must always be stored in secure containers.

Information Copying and Retention & Record Management

12. Copies and extracts of the Information may only be made for the purposes of carrying out work as covered by this Agreement. When no longer needed, any such copies or extracts must be destroyed in a secure manner (as per points 13 and 14 below).

13. Paper documents containing the Information must be destroyed (shredded) in a secure manner before disposal. Destruction must occur within the secure area.

14. All electronic storage media used in the processing of the Information, including all back-up and transportable media must be sanitized or destroyed on completion of their use. Destruction must occur within the secure area.

15. These security requirements must be communicated regularly to all Identified Persons and be available for reference, as required.

Data Destruction Certificate

CLSA Application ID and Title:

_____

Date destroyed:

_____

Authorized by:

_____

Signature:

_____

Box #	File title/record series	date range

Schedule D - Return of Derived Variables

Canadian Longitudinal Study on Aging (CLSA)
Policy on the Return of Derived Variables

In accordance with the Canadian Longitudinal Study on Aging's Data and Sample Access Policy and Guiding Principles and your signed CLSA Access Agreement, you may be asked to return to the CLSA Derived Variables that you created as part of your research.

What are Derived Variables?
Derived Variables (DVs) include new data-fields (apart from simple recoding) constructed by you whilst undertaking your research project using CLSA raw alphanumeric data, biomarker data, or a combination of both. A separate policy governs the return of biomarker data obtained from biospecimens to the CLSA.

Why might I be asked to return Derived Variables to the CLSA?
The objectives in asking for the DVs and documentation are that, in keeping with the CLSA as a research platform, CLSA can:

(i) expand and enhance the utility of the CLSA platform;
(ii) make your DVs available for use by other approved users;
(iii) make your methods for constructing DVs available to other researchers so that analyses can be replicated.

How do I report on Derived Variables?
In accordance with the CLSA's Data and Sample Access Policy and Guiding Principles and your signed CLSA Access Agreement, you will be asked to submit a Final Report at the end of your project. In this Report, you will be asked to describe any DVs you have created.

When do I return Derived Variables?
Once the CLSA has reviewed the Final Report and determined that the DVs would be of utility to the CLSA platform, the Statistical Analysis Centre (SAC) will send you a document with guidelines on the Return of Derived Variables to the CLSA by Approved Users, including details on what needs to be returned and how to transfer files to the CLSA. Researchers will be asked to return DVs within 6 months of the date of the first publication using the DV.

How will my Derived Variables be used by CLSA?
The DVs will be made available with acknowledgement of the provenance. The CLSA will not audit your DVs and is not responsible for its accuracy or validity. The CLSA will review the documentation and algorithms you provide to ensure that sufficient explanatory documentation has been provided. Derived variable fields and accompanying documentation may be made available for use by other approved users, and may be included in our DataPreview Portal (http://clsa-elcv.ca/).

Researchers who have any questions concerning the process or content for the return of DVs should contact the CLSA Statistical Analysis Centre via access@clsa-elcv.ca.

Schedule E – Fees

All fees in CDN dollars

Fees in accordance with this project and article 4 have been set at $3,000 and must be paid 30-45 days after receipt of an invoice that will be sent to the primary user.

Schedule F: Project Team

All Co-Applicants and Other Personnel listed below are indicated in the application Schedule B, as well as any changes to co-applicants/other personnel required since the initial submission of Schedule B and requiring direct access to the CLSA Data. Each of these Co-Applicants must sign Schedule F to agree to comply with the conditions outlined in Articles 2.1 and 2.3 (excerpts below) of this CLSA Access Agreement also located at (https://clsa-elcv.ca/doc/1042). All others should be listed but will not require a signature if they will not have direct access to the data.

Sample and Data Security.

Security measures specified in Schedule C attached hereto will apply to all Transferred Materials. The Approved User and institution undertakes to respect these security measures during the Project and afterwards, during storage of Transferred Materials where necessary.

Transferred Materials, including any copies thereof, may only be used for the Project described in Schedule B and may not be disclosed, transmitted or shipped to anyone except employees working directly with the Approved User or co-investigators including co-applicants or other personnel from other not-for-profit institution(s), indicated in the Project who will require direct access to the CLSA Data and who agree to be bound by the terms of this Agreement or to persons expressly designated in writing by McMaster. The Approved User shall retain control of the Transferred Material at all times. It is the responsibility of the Approved User's Institution to inform the staff and co-investigators, including co-applicants and other personnel at other third-party institution(s) entering into contact with the Transferred Materials of the obligations contained in the Data and Biospecimen Access Policy and Guiding Principles and this Agreement. As such, co-applicants and other personnel at other third-party institution(s) must submit a signed Schedule F attached hereto. The transfer of any CLSA Data to any for-profit entities is strictly prohibited.. Transfer of any CLSA biospecimens outside Canada is strictly prohibited. Data access will only be provided to institutional email addresses.

Co-Applicants and Other Personnel
Please list all co-applicants including students and any other personnel who will be involved in the project (eg: advisor, statistician, research assistant, etc.).

Name	Affiliation & institutional email address	Academic Position and Role on Project	Signature

Name	Affiliation & institutional email address	Academic Position and Role on Project	Signature