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.

"Other User" means an individual member of a research team that will receive access to CLSA data and/or biospecimens through the Approved User for the Project.

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

"Transferred Materials," means the CLSA data, Metabolon 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.

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 Other Users, 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 Institution, through Approved User, shall retain control of the Transferred Material at all times. It is the responsibility of the Approved User and Institution to inform all Other Users entering into contact with the Transferred Materials of the obligations contained in the CLSA Data and Biospecimen Access Policy and Guiding Principles as well as the restrictions and obligations contained in Schedule C and this Agreement and to ensure their compliance therewith. Other Users must sign Schedule F, as 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 use by the Approved User and Other Users solely in the Approved Project, which must be non-commercial in nature, 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.

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, if applicable. Fees must be paid in full prior to the release of any Transferred Materials. McMaster shall have no obligation to provide access to the Transferred Materials until such payment has been received

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 via the Magnolia Portal 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 and the publication is in line with the approved application objectives. The Approved User and all Other 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 12.1, the Approved User's and any Other User's right to publish shall end upon termination of this Agreement.

9. **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.

10. **Undertakings and Liability**

10.1 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 Institution shall ensure that 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.

10.2 The Institution assumes all liability or damages arising from the Approved User and Other User's use, storage or disposal of the Transferred Material 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, any Other User, the Institution or its employees. The Institution shall maintain at its own expense insurance policies with limits of liability sufficient to cover its potential liabilities under this Agreement arising from its performance or non-performance of its obligations under this Agreement.

11. **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 12.2, 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.

12. **Termination**

12.1 This Agreement will terminate two years after the end date of the Project unless (a) the parties agree in writing to renew it or (b) the Approved User notifies McMaster that the Approved Project and all associated publications have been completed. In the event that the Approved User notifies McMaster that the Project is complete, this Agreement will terminate effective as of the date of the Approved User's notice. Upon termination of the Agreement, the Institution shall ensure that the Approved User complies with the data destruction, media sanitization, and Magnolia attestation requirements set forth in Schedule C. Following termination of the Agreement, Approved User's and any Other User's right to publish pursuant to Section 8 hereunder shall end.

12.2 McMaster may terminate this Agreement if the Institution is 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 12.2, the Institution shall ensure that the Approved User immediately complies with the data destruction, media sanitization, and Magnolia attestation requirements set forth in 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 12.2, the Approved User will not be entitled to publish the results of

any Project except with the written agreement of McMaster.

13. 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.

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

For McMaster: CLSA Management Contact: 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. 22123 Email: praina@mcmaster.ca	**For Legal Matters:** 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
If for Approved User:	If for Institution:

15. General Provisions

15.1 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.

15.2 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.

15.3 The following provisions will survive termination of this Agreement: 2, 3, 5, 9, 10, 12, 13 and 14.

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

15.5 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.

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

15.7 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.

15.8 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	Signature
Name: Gay Yuyitung, PhD	Name: Parminder Raina, PhD
Title: Executive Director, MILO	Title: Lead Investigator, CLSA
Date:	Date:

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

INSTITUTION	APPROVED USER
Signature	Signature
Name:	Name:
Title:	Title:
Date:	Date:

Schedule A:

Canadian Longitudinal Study on Aging (CLSA)

Data and Biospecimen Access Policy and Guiding Principles

1. DEFINITIONS

1.1. **Access Agreement:** An agreement between McMaster University as custodian of CLSA data and biospecimens and the Applicant's institution which contractually binds the parties involved in accessing CLSA data. An executed Access Agreement, or Master Access Agreement and Project Agreement, is necessary to obtain access to data and/or biospecimens from the CLSA.

1.2. **Approved User:** A Primary Applicant who has received the necessary approvals to access CLSA data and/or biospecimens for their project ("Approved Project").

1.3. **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.

1.4. **Custodian:** The legal custodian of CLSA data and biospecimens, regardless of where the data and biospecimens were collected. The Custodian of CLSA data and biospecimens is McMaster University.

1.5. **Data Curation Centre (DCC):** The centre where data verification and preparation are carried out. The DCC also prepares alphanumeric datasets for Approved Users.

1.6. **Data and Sample Access Committee (DSAC):** The body under the governance of the CLSA responsible for the review of applications for access to and use of data and/or biological samples collected as part of the CLSA.

1.7. **Derived variable:** A derived variable is a new data-field constructed by the Approved User or Other User whilst undertaking a specific research project using CLSA raw alphanumeric data, biomarker data or a combination of both.

1.8. **Ethical, Legal, and Social Issues (ELSI) Committee:** The body under the governance of the CLSA with a mandate to provide independent advice to the CLSA Executive Committee (EC) on actions and best practices to address ethical, legal and social issues that arise or are foreseen in the planning and conduct of CLSA activities, and contribute to the advancement of ELSI knowledge related to the implementation and conduct of large-scale research platforms.

1.9. **Executive Committee (EC):** The body under the governance of the CLSA that advises the lead Principal Investigator (PI) and contributes to strategic direction, oversight, and leadership for the successful ongoing implementation and promotion of the CLSA platform.

1.10. **Biomarker and multi-omics Centres:** The centres where specified analyses for biomarkers and/or multi-omics are carried out on CLSA biospecimens to ensure standardized results.

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

1.12. **Master Access Agreement:** An agreement between the CLSA and the Applicant's institution which contractually binds the institution involved in accessing CLSA data and/or biospecimens. An executed Master Agreement is necessary to obtain access to data and/or biospecimens from the CLSA under a Project Agreement.

1.13. **Other User**: An individual member of a research team that will receive access to CLSA data and/or biospecimens through the "Approved User" for the "Approved Project". These Other Users must agree in writing to privacy and security conditions as required in the CLSA Access Agreement or CLSA Master Agreement and Project Agreement.

1.14. **Primary Applicant:** An investigator affiliated with a public research organization or privately owned university or college, based in Canada or elsewhere, who is applying to access data and/or biospecimens collected as part of the CLSA for use in a specific project that they are leading.

1.15. **Project Agreement:** An agreement under a Master Access Agreement that describes an "Approved Project" to be undertaken by an Approved User.

1.16. **Research:** For the purpose of this policy, any systematic inquiry into the dimensions of adult development, health and aging using CLSA data and/or biospecimens.

1.17. **Service Provider:** An organization or entity contracted by McMaster University on behalf of the Canadian Longitudinal Study on Aging (CLSA) to provide specific services that support, enhance, or enrich the CLSA holdings and platform. These services may include, but are not limited to, data management, data analysis, technical support, infrastructure maintenance, and other related services necessary for the operation, expansion, and improvement of the CLSA research capabilities.

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

2. DATA AND BIOSPECIMEN ACCESS POLICY AND GUIDING 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, such as the CLSA, is complex and must balance the interests of the study participants, CLSA, the Custodian, Approved User and Other Users.

Several principles establish the CLSA's approach to data access and the use of the CLSA data and biospecimens and these are described in this document. These principles are the foundation of CLSA policies that aim to create fair and transparent processes for accessing CLSA data and biospecimens.

The CLSA Data and Biospecimen Access Guiding Principles and Policy applies to the access of all CLSA data and biospecimens for research purposes. All Applicants, including CLSA investigators, who are requesting access to data and/or biospecimens for research are required to follow the CLSA Data and Biospecimen Access Policy 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 Canadian and international research community in addition to the CLSA Data Access Officer, a CIHR observer and an ex-officio CLSA investigator. The Committee functions in accordance with the CLSA policies, guidelines and procedures for data and biospecimen access.

2.2 Guiding Principles for data and biospecimen access

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

- The rights, privacy and consent of participants must be protected and always respected (see CLSA Privacy Policy on the CLSA website: www.clsa-elcv.ca).
- The confidentiality and security of CLSA data and biospecimens must be always safeguarded.
- CLSA data and biospecimens are resources that must used responsibly and in accordance with best practices to support research to benefit all Canadians.
- CLSA data and biospecimens will be made available to an Approved User for use in a responsible manner considering the need to assure data validity and biospecimen integrity.
- CLSA biospecimens constitute a finite resource that must be used responsibly and in accordance with best practices, aligned with the long-term research goals of CLSA, and in keeping with the participants' informed consent.
- CLSA data and biospecimens will only be released to Approved Users once ethics approval for their research project has been obtained from the appropriate Research Ethics Board (REB) and the Access, or Master Access, Agreement and Project Agreement between the Custodian and the Applicant's institution has been executed.
- To meet data quality standards set by the CLSA documentation pertaining to biospecimen handling and analysis will be required. This includes standard operating procedures (SOPs), 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.
- Data access procedures will aim to support timely access to data and/or biospecimens. All Applicants will be required to follow the access procedures that are listed on the CLSA website.
- Approved Users may be required to return derived variables and/or results to the CLSA within a timeframe specified in the Access Agreement noted above.
- The CLSA EC 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 EC is the decision-making body for such operational activities and the CLSA reports on these activities to CIHR annually.

- As a publicly funded research platform, the CLSA aims to support wide and accessible distribution of knowledge developed using this resource and achieve maximum public benefit.

2.3 Limits on the Use of CLSA Data and Biospecimens

CLSA data and biospecimens will only be released by the CLSA to an Approved User for use in an Approved Project. Approved Users must be affiliated with either a public sector research organization or a privately owned university or college. The Approved User will, subject to the terms and conditions of an Access Agreement or Master Agreement and Project Agreement, control who else from the research team receives access to the data and/or biospecimens.

While only investigators affiliated with a public research organization or privately owned university or college may serve as Approved Users and receive data and biospecimens directly from the CLSA, Other Users may include investigators from private companies who are members of a research team and may receive access to CLSA data or biospecimens from the Approved Users where such access is required to execute the Approved Project and where such researchers agree in writing to certain privacy and security conditions as required in the Access Agreement or Master Agreement and Project Agreement. In all cases, Approved Projects must have received REB approval prior to the release of CLSA data and/or biospecimens.

Notwithstanding the preceding, the CLSA may provide data directly to a Service Provider, subject to a service agreement that the CLSA will establish with the Service Provider.

In circumstances where CLSA participant data and biospecimens are to be linked to third-party data holdings (e.g., provincial healthcare databases, The Canadian Urban Environmental Health Research Consortium (CANUE), Health Canada data, etc.) 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.

If an Approved User wishes to use CLSA data and/or biospecimens already received for a purpose other than the original purpose, they must submit a new application to the DSAC. Any other change to the original Approved Project will require an amendment to the application and the Access Agreement or the Project Agreement (as appropriate). Approved Users are not permitted to share the data or biospecimens provided to them with others, apart from the Other Users who have been identified in the Access Agreement or Project Agreement.

2.4 Intellectual Property

The CLSA and its Lead Institution do not claim any ownership of, or exploitation rights to, any intellectual property resulting from the Approved Users' research conducted with CLSA data and/or biospecimens.[1] CLSA data and biospecimen Approved Users are strongly encouraged to make their results (including research tools) rapidly and widely available to the scientific community.

Regarding genetic inventions, CLSA Approved 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.

[1] Where the Approved User in question is an investigator from the Lead Institution (McMaster University), they will be bound by the university's intellectual property policies independent of the CLSA intellectual property policy.

2.5 Financial Considerations

The CLSA is a publicly funded research project and platform. Access fees will be based on a partial cost recovery model and will be determined by the EC.

2.6 Access Requests

Data and Biospecimen Access Application procedures can be found on the CLSA website.

2.7 Dissemination of Access Requests

To ensure transparency, promote public awareness and ensure that participants can provide ongoing informed consent and withdraw if so desired, the CLSA will make information available about Approved Projects through dissemination channels including the CLSA website, newsletter and webinars.

2.8 Obligations of Approved Users:

- ***Research Quality***

Approved Users have a responsibility to enhance the value of the CLSA research platform in accordance with the best practices of research integrity and excellence, projects making use of CLSA data and/or biospecimens are expected to be overseen by an institutional ethics review board and published in a timely manner in a peer reviewed journal, preferably open access.

The CLSA has put in place safeguards to ensure the confidentiality of participants' data and biospecimens. CLSA data and/or biospecimens provided to Approved Users will not contain any information that identifies any participant (i.e., they will be "de-identified"). It is the obligation of the Approved Users not to attempt to identify participants, and to use the data provided in a secure location to protect the confidentiality of the data as per the Access Agreement or Master Agreement as well as the CLSA consent form and Tri-Council policies.

- ***Return of Derived Variables***

The CLSA recognizes that derived variables may emerge from Approved Projects. As part of the conditions of the Access Agreement or Master Agreement, Approved Users may be required to return to the CLSA derived variables for inclusion in the CLSA database for use by other researchers. Approved Users may be asked to return derived variables if such variables are identified in 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. Approved Users returning derived variables to the CLSA will work closely with the CLSA Data Curation Centre (DCC).

2.9 Return of Individual-level Participant Personal Results from analyses conducted by Approved Users

The CLSA will not return any individual-level (i.e., personal) results from analyses conducted as part of an Approved Project to participants. However, given the duration of the CLSA and the impossibility of foreseeing the nature of research projects that will be conducted using CLSA data and biospecimens, Approved Users shall be aware of the possibility that the CLSA may be required to return validated results of the derived variables back to CLSA participants where such information is determined to be critical for the health of the participant. Any situation in which personal results

of analyses are required to be returned to CLSA participants will be managed by the CLSA EC in consultation with the ELSI Committee and relevant research ethics boards.

2.10 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 period during which results must be returned to CLSA is not sufficient, the Approved User may request an extension to the relevant access agreement.

2.11 Publications arising from Approved Projects

Approved Users agree to submit for CLSA review their final article draft at least 15 working days prior to peer-reviewed journal submission proposed publications will be reviewed to ensure that participants cannot be identified, appropriate acknowledgement, CLSA methods have been accurately described, and that results are presented in accordance with the objectives stated in the Access Agreement or Master Agreement. Approved Users should review the CLSA Promotion and Publication policy prior to preparing manuscripts.

2.12 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.

The approved user will be required to include an approved acknowledgement in the manuscript that will be prepared and approved during review of the manuscript as noted in the CLSA Publication Policy. The current CLSA Promotion and Publication policy can be found on the CLSA website.

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.

Approved User:

- Person who is the Primary Applicant (PA) on the approved project.

Other User:

- Approved User and all others listed as Co-investigators/Collaborators or staff on the approved project who require direct access to the Information and have signed the required schedule of this Agreement (the CLSA Access Agreement) and whom the Approved User's institution has approved.

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.

Non-Authorized or Non-Identified Person:

- Person, other than an Approved User or Other User, who has been invited to collaborate on the project by an Approved User, as permitted by the Institution's access policies but who has not signed the required Schedule of this Agreement (the CLSA Access Agreement) or has not been approved by the Approved User's institution.

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.

Data Access

1. Access to the Information is limited to Approved and Other Users who have a need to know for this project, have signed the required Schedule of this Agreement and have been approved for access by the Approved User's institution. The manager responsible for ensuring that the Institution's requirements are met must maintain an auditable trail, listing the persons who have accessed the Information, the period for which this access is granted, and the purpose for the access. Under no circumstances may anyone else (including Non-Approved or Non-Other Users) be provided access to the Information.

2. Where Information is transferred by the Approved User to Other Users affiliated with institutions other than the Approved User's institution **(not recommended)**, the Approved User's institution must accept responsibility for the use of the Information at the Other User's institution as per the CLSA Access Agreement and the specifications of this Schedule.

IT Storage and Transmission

3. The Information should be stored in electronic format, as made available to the Approved User by CLSA through the Magnolia Portal.

4. All computers with access to the Information must employ logical access controls (passwords) at the device level with screen locking enabled after idle time and at the network level.

5. Where the Information is stored in a controlled-access folder on a server or cloud platform managed by the Approved institution (strongly recommended) or Other User's institution (not recommended), with access to the folder restricted to Approved and Other Users.

    a. If stored on a server: The server will be physically located onsite at the Approved or Other User's institution. It is acknowledged that Approved and Other Users accessing the Information may not be physically proximate to the server on which the data are stored, but will access the Information via secure VPN from approved work areas, as designated by the Approved or Other User's institution and/or department (which may include research offices located on-campus or in affiliated buildings, a home office or other remote work location).

    b. If hosted on a cloud platform: the Information must be hosted on a commercial cloud platform that meets ISO/IEC 27001:2022 and SOC 2 Type II security standards and complies with applicable data protection laws and regulations (e.g., GDPR, CCPA). The cloud storage must use a single-tenant architecture, with the contract held by the institution of the authorized individual.

        i. All network communications with the cloud storage must use HTTPS/TLS (Hypertext Transfer Protocol Secure/Transport Layer Security) for encrypting network traffic between clients and its services.

6. All server and cloud storage must be encrypted at rest. Cloud storage backups and snapshots, if utilized, must be housed in the same project as the Information.

7. Where the Information is stored 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.

    a. If stored on transportable media of any type, when not in use, transportable media containing the Information must be stored in secure containers. This applies equally to backups of the Information.

8. A distinct group with governance responsibilities separate from research will be responsible for configuring project roles, permissions, networking, firewalls, and other services that influence access and security. Network firewalls and access rules must be in place to prevent access to the Information, other than to Approved and Other Users.

9. The Information cannot be electronically transmitted, except as described in points 10 and 11. This includes the transmittal of the Information by facsimile or by e-mail.

10. 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 Approved and Other Users 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.

11. Network firewalls and access rules must be in place to prevent access to the Information, other than to Approved or Other Users. Information may be stored on and transmitted over networks not meeting these requirements, provided that it is encrypted, except when in use by an Approved or Other User. Alternatively, the Information may be stored on a stand-alone computer with no external connections, or on a closed network. In this situation, 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.

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.

13. All electronic storage media used in the processing of the Information, including all back-ups must be expunged or destroyed on completion of their use.

14. These security requirements must be communicated at least annually to Other Users and be available for reference, as required.

15. Upon termination of the project Agreement, all Information, copies, backups and snapshots, will be deleted and expunged, as per this Agreement. The Approved User must complete data destruction via Magnolia one year following the termination of this Agreement. This includes any copies held by Other Users. All electronic storage media used in the processing of the Information, including all back-up must be sanitized or destroyed on completion of their use. Data destruction information is submitted through Magnolia. For each data version provided to the Approved User (including those disseminated to Other Users), they must provide the date and time of destruction. Once completed, this will be considered their attestation that the data has been properly destroyed as per this Agreement.

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 $4,000 and must be paid 30-45 days after receipt of an invoice that will be sent to the primary user. Fees must be paid before the approved data can be released.

Invoices shall be sent to the following Accounts Payable contact or delegate at the Sponsor:

(Insert details)

Schedule F: Project Team

Purpose:
This Schedule F identifies all co-applicants and other personnel (each an "Other User") who will be involved in the Project and who may require direct access to the Transferred Materials. The purpose of this Schedule is to: document the individuals involved in the Project, confirm which individuals will require direct access to the Transferred Materials, and record the Institution's review and approval of such access.

Institutional Acknowledgement and Approval:
By signing this Schedule F, the Institution confirms that (i) it has reviewed and approved the individuals listed below who require access to the Transferred Materials, (ii) it is aware of the identity, role and institutional affiliation of each Other User listed in this Schedule, (iii) it will ensure that access to the Transferred Materials by such Other Users is provided in a manner that is compliant with the terms of this Agreement, including the Data and Biospecimen Access Policy and Guiding Principles and the security requirements set out in Schedule C, and (iv) it may implement such measures, agreements or institutional controls as it deems appropriate to facilitate such access in a manner that is compliant with this Agreement.

Obligations of Other Users:
Each Other User that requires direct access to the Transferred Materials must sign below to confirm that they 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)). 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:

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.

2.3 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 Other Users, 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 Institution, through Approved User, shall retain control of the Transferred Material at all times. It is the responsibility of the Approved User and Institution to inform all Other Users entering into contact with the Transferred Materials of the obligations contained in the CLSA Data and Biospecimen Access Policy and Guiding Principles as well as the restrictions and obligations contained in Schedule C and this Agreement and to ensure their compliance therewith. Other Users must sign Schedule F, as attached hereto. 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 (Other User)
Please list all co-applicants including students and any other personnel who will be involved in the project (eg: advisor, statistician, research assistant, etc.). If the personnel listed do not require direct access to the data, you can indicate this under the signature section as they are not required to sign (example text: direct access to the transferred materials not required).

By signing in the table below, the Institution confirms its review and approval of each Other User listed.

Name	Affiliation & institutional email address	Academic Position and Role on Project	Signature of Other User	Approved Institutional Signature

Name	Affiliation & institutional email address	Academic Position and Role on Project	Signature of Other User	Approved Institutional Signature