



Canadian Longitudinal Study on Aging (CLSA)

Data and Biospecimen Access Policy and Guiding Principles

1.0. 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.

2.0. 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 organization¹. 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.

¹Alpha-numeric 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.

2.4. 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.

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

²Note 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.

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

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.

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