clsa élcv
Canadian Longitudinal Study on Aging
Étude longitudinale canadienne sur le vieillissement

Guidance Document
Consent for CLSA Data Linkage

1.0 BACKGROUND

The Canadian Longitudinal Study on Aging (CLSA) is a large, national, long-term study and research platform of more than 50,000 individuals who were between the ages of 45 and 85 at recruitment. CLSA participants will be followed until 2033 or death.

The CLSA was designed to examine health transitions and trajectories with the goal of identifying modifiable factors with the potential to develop interventions to improve the health of populations as they age. Its overall aim is to provide the most accurate picture of the dynamic process of adult development and healthy aging.

When the CLSA was first conceived the intention was to form alliances and collaborations with provincial agencies and federal partners with plans to link data to provincial and national databases. CLSA data is available for linkage with health administrative databases at several provincial Data Centres, as has been anticipated in all approved protocols, with additional data centres expected to have linked data available in the near future. The purpose of these linkages is to collect complementary information on medical use and health services resources utilization, as well as to ascertain deaths and causes of death.

Some examples of the uses of linked data include:

- CLSA information linked with physician billing information and seniors' medication insurance program information to understand diagnoses and medications prescribed for certain conditions.
- CLSA self-identified diagnosis information linked with health services use information to confirm diagnosis.

As per the study protocol, data linkage processes were negotiated between the CLSA and each province.

2.0 CONSENT FOR LINKAGE

Original information packages and consent forms describing consent for linkage:

- CLSA tracking cohort consent form
- CLSA tracking cohort study information package
- CLSA comprehensive cohort consent form
- CLSA comprehensive cohort study information package

The information packages and consent forms included the following text related to the linkage of CLSA data to administrative health data:

- "Why am I being asked to give the CLSA my Health Card Number?
    - Your provincial healthcare records will be linked to data collected by the CLSA to study patterns of health and health care over time. For example, Ministries of

Health in each province keep records about your visits to doctors and hospitals, medicines you fill a prescription for, and what people die from.
    - Linking will occur from the date you agree to participate in the CLSA onward."
- "I give permission to the Provincial Government to provide the CLSA team with information about me held in provincial health databases.
    - I understand that this will allow researchers to link my provincial health information to information collected from me by the CLSA.
    - I also understand that, should I withdraw my consent, data about me that has already been linked will remain part of the CLSA database."

At the point of consent, all 51,338 participants were asked to provide their health insurance numbers to permit linkage with Medicare claims data held in provincial healthcare databases (e.g., drug plans [for those aged 65 years and over or those who are on social assistance], physician visits, medical service plans, hospitalizations, homecare, and mortality).

- 92% (N=~47,230) of CLSA participants consented to linkage and provided their health information number (HIN, i.e., health card number) at enrollment.

Hamilton Integrated Research Ethics Board (HiREB) issued a letter attesting to the generality of the original consent (see HIREB Letter to ICES and CLSA [Appendix A]) for linkage of CLSA data with provincial data holdings.

The original consent to linkage specified that linkage was prospective only, and excluded linkage to information held in provincial and national administrative databases before the date of original consent to participate in the CLSA

In 2021, the CLSA went through an extensive reconsent pilot to allow for extended linkage that demonstrated that reconsent was not possible or feasible and would render the linked data unusable given a high degree of conditions resulting from loss to follow-up and non-response.

- From baseline to follow-up 1, there was a 13.6% and 26% loss to follow-up for any reason in the comprehensive and tracking cohorts, respectively.
- Reconsent of the comprehensive cohort was attempted either by mail or by the Data Collection Site staff
    - Note: reconsent was not attempted with the Tracking cohort
- Of 5,569 reconsent packages sent by mail, there was 32.1% non-response.
    - 8% of consent forms returned were not completed correctly and required follow-up from the CLSA Participant Management Team.
- However, 98.3% of those who responded consented to extended linkage, particularly those who were informed by phone call.

The CLSA reconsent pilot demonstrated that the vast majority of participants consent to extended linkage. This supports HiREB's prior ruling on the generality of the original consent and lack of substantial alteration. The attempted reconsent process (and all reconsent approaches identified) was impractical from both a scientific and operational perspective.

The CLSA and Data Centres have complied with any known preferences previously expressed by individuals about any use of their information:

- Participants who did not give permission for the CLSA to link their health information to information collected from them by the CLSA upon original consent do not have their data linked.

- Participants who did not give their permission to link their data during the reconsent pilot process in 2021 have their preferences respected and their data is not linked.

3.0 RESEARCHER REQUIREMENTS FOR EXTENDED RETROSPECTIVE LINKAGE: EXEMPTION TO CONSENT

3.1 Retrospective linkage

Researchers requesting extended retrospective linkage of CLSA data to administrative health data prior to enrollment in the CLSA must seek REB approval from their own institutions for an exemption to the requirement to seek (new) consent for the extended retrospective linkage of CLSA data to healthcare records. They will have to argue that the retrospective linkage is necessary, and it is impossible or impracticable to seek consent from individuals to whom the information relates.

- Note: The data sharing agreements between CLSA and the provincial data centres prohibit researchers requesting access to linked data from contacting CLSA participants.
- Note: The use of identifiable information is limited to the linking process. The data are subsequently de-identified before use for approved research purposes.
- Note: Extended linkage does not include indices of diagnoses and health services (e.g., Charlson Comorbidity Index, dementia ascertainment algorithm) that rely on a look-back period for calculation purposes to understand an individual's present state (i.e., index date at the time of enrollment).

3.2 Justification for the exemption to consent: As per the TCPS 2 (2022). Chapter 5, Sections D and E: (1)

Identifiable information is essential to the data linkage: without identifiable information, it would not be possible to link CLSA data to health services use data in provincial or national data holdings.

The use of identifiable information without the participants' consent is unlikely to adversely affect the welfare of individuals to whom the information relates: participant information will continue to be managed and kept safe according to the processes described in the participant information package, in addition to the very stringent policies and regulations followed by the provincial Data Centres. The risk is expected to be minimal, and this assessment is based on the commonplace nature of this linkage and very high privacy and security standards and rigorous privacy and security reviews.

The researchers will take appropriate measures to protect the privacy of individuals and to safeguard the identifiable information: CLSA data is transferred to provincial Data Centres using secure file transfer processes as described in data sharing agreements, reviewed by relevant privacy and legal experts at McMaster University and the Data Centres. Identifiable information is used to link CLSA data to health services use data. Only a restricted number of individuals within the Data Centres perform the function of linking the data, independent of the researcher requesting access to the linked data. Once linked, a coded copy of the data is created, and any direct personal identifiers are removed. Data Centres comply with relevant legislation and regulations. Data Centres ensure that all researchers requesting access to the coded data meet CLSA researcher eligibility requirements, and have received all necessary authorizations, including research ethics approval and local safeguard measures as required. The policies and procedures of provincial and national Data Centres are designed and monitored by appointed privacy commissioners. Researchers requesting access to the linked data do not have access

to identifiable information and will not be able to identify any individual, as enforced by the Data Centres throughout the data access process.

The CLSA and Data Centres have complied with any known preferences previously expressed by individuals about any use of their information: Participants who did not give permission for the CLSA to link their health information to information collected from them by the CLSA upon original consent do not have their data linked. Participants who did not give their permission to link their data during the reconsent pilot process in 2021 have their preferences respected and their data is not linked. Based on the high reconsent rate in the pilot, the CLSA has strong evidence for preferences on this matter.

It is impossible or impracticable to seek consent from individuals to whom the information relates: The CLSA conducted a reconsent pilot in 2021 to obtain consent specifically for extending existing provincial data linkage consent to start dating back 10 years. The results indicated that the vast majority of participants consent to extended linkage. However, participants had trouble understanding how this new consent was different from the previous, and there was high non-response to letters. The reconsent process was found to be impractical from both a scientific and operational perspective.

- **Scientific**: It is clear that a large longitudinal cohort cannot obtain opt-in reconsent without compromising the integrity/utility of the cohort. Response rates are low, differential response introduces significant bias, and those lost to the study (dead, etc.) are potentially excluded if their original consent cannot be interpreted by an ethics board (also introducing significant bias).
- **Operational**: A reconsent process is very costly due to the need for follow-up and ineffective means to contact ‘non-responders’. The cost-benefit scenario is impractical.

The researchers have obtained any other necessary permission for secondary use of information for research purposes: To enable the linkage of CLSA data with provincial data holdings, we have executed data sharing agreements with each of the provincial Data Centres. Throughout this process, the agreements were reviewed and approved by appropriate data stewards and privacy commissioners, and respect relevant privacy legislation, regulations and institutional policies. As part of the data access agreements, researcher requests for access to linked data must be reviewed and approved by the Data Centres and the CLSA to ensure requests comply with their policies and procedures, as well as all relevant legislation. Data Centres will confirm that the project has received all necessary authorizations, including research ethics approval for the full duration of the proposed projects and other local safeguard measures as required (e.g., data privacy and security training, and criminal record checks). Researchers will not have access to identifiable information and will have no opportunity to contact individuals to whom the information relates. Strict procedures restrict the possibility of indirect identification and disclosure.

4.0 DEFINITIONS

4.1 Personal health information (PHI)

The same meaning as defined in Section 4(1) of the Personal Health Information Protection Act (PHIPA) (2)

- Identifying information about an individual in oral or recorded form, if the information,
    - Relates to the physical or mental health of the individual, including information that consists of the health history of the individual’s family

- Relates to the providing of health care to the individual, including the identification of a person as a provider of health care to the individual
- Is a plan that sets out the home and community care services for the individual to be provided by a health service provider or Ontario Health Team
- Relates to payment or eligibility for health care, or eligibility for coverage for health care, in respect of the individual
- Relates to the donation by the individual or any body part or bodily substance of the individual or is derived from the testing or examination of any such body part of bodily substance
- Is the individual's health number, or
- Identifies an individual's substitute decision-maker

4.2 Identifiable information

The same meaning as defined in the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2; 2022) (1)

- Directly identifying information – the information identifies a specific individual through direct identifiers (e.g., name, social insurance numbers, personal health number)
- Indirectly identifying information – the information can reasonably be expected to identify an individual through a combination of indirect identifiers (e.g., date of birth, place of residence or unique personal characteristic)

4.3 Coded information

The same meaning as defined in TCPS2 (2022) (1)

- Direct identifiers are removed from the information and replaced with a code. Depending on access to the code, it may be possible to re-identify specific participants (e.g., the PI retains a list that links the participants' code names with their actual names so data can be re-linked if necessary).

4.4 Parties involved

Canadian Longitudinal Study on Aging, hereinafter referred to as "CLSA": A large, national, long-term study and research platform that collects the personal health information of more than 50,000 individuals who were between the ages of 45 and 85 at recruitment. The CLSA participants will be followed until 2033 or death. The aim of the CLSA is to find ways to help us live long and live well and understand why some people age in a healthy fashion while others do not.

Health Data Research Network Canada (HDRN) Data Access Support Hub (DASH), hereinafter referred to as "DASH": Multi-centre coordination team from various provincial/territorial Data Centres (as defined below) and pan-Canadian organizations. They provide data access support for researchers and aim to harmonize, streamline, and automate the multi-jurisdictional data access process in Canada where possible.

Provincial and national Data Centres, hereinafter referred to as "Data Centres": Programs located within public universities, organizations, not-for-profit corporations in Canada to support population health, health services and related research that provide researchers with access to cross-sectoral, linked, population-wide data in order to support the advances in understanding the complex interplay of influences on human health and development. Provincial Governments

provide permission to Data Centres through legislation to facilitate access to health datasets for approved researchers. May be funded by Ministries of Health but are largely independent.

- Examples of Data Centres:
  - ICES (Ontario)
  - Population Data (PopData) BC (British Columbia)
  - Newfoundland and Labrador Centre for Health Information (Newfoundland and Labrador)
  - Canadian Institute for Health Information (CIHI; national)

Researchers: approved Canadian public sector researchers, including graduate students and postdoctoral or clinical fellows who wish to use the CLSA data linked to health system usage databases for their thesis or fellowship research.

5.0 REFERENCES

1. Canadian Institutes of Health Research, Natural Sciences and Engineering Research, Council of Canada, and Social Sciences and Humanities Research Council of Canada. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans. Ottawa, Ontario: Secretariat on Responsible Conduct of Research; 2022.
2. Personal Health Information Protection Act [Internet]. 2004, S.O. 2004, c. 3, Sched. A. Available from: https://www.ontario.ca/laws/statute/04p03

6.0 APPENDICES

Appendix A: HiREB Letter to ICES and CLSA

HiREB
Hamilton Integrated Research Ethics Board

June 29, 2020

Re: Linkage of the CLSA to databases under provincial jurisdictions through provincial governments, provincial data centres (often prescribed entities), as well as federal data centres (often prescribed entities) who hold provincial data

Dear Institute for Clinical Evaluative Sciences (IC/ES), Drs. Parminder Raina (Lead Principal Investigator, CLSA) and Andrew Costa (Associated Scientific Director,CLSA),

As the lead REB for the Canadian Longitudinal Study on Aging (CLSA), the Hamilton Integrated Research Ethics Board (HiREB) issues final approval on behalf of the listed REBs below:

- University of British Columbia (H10-02143)
- VIHA Clinical Research Ethics Board (C2010-08)
- Dalhousie University (2010-2336)
- University of Manitoba (H2010:330)
- McGill University (A10-E59-10A)
- Memorial University (11.003)
- Universite de Sherbrooke (2009-)18
- University of Victoria (11-320)
- Simon Fraser University (2010s0527)
- University of Ottawa (M16-10-023)

The Hamilton Integrated Research Ethics Board's confirms that the CLSA protocol contemplates linkage with the Institute for Clinical Evaluative Sciences (IC/ES) and the consent provided by participants expresses their assent for such linkage.

We, the Hamilton Integrated Research Ethics Board (HiREB), warrant that the CLSA Design and Protocol (available at https://www.clsa-elcv.ca/wp-content/uploads/2023/06/combinedprotocol_v3_2013_for_web.pdf) clearly contemplates linkage to databases under provincial jurisdictions through provincial governments, provincial data centres (often prescribed entities), as well as federal data centres (often prescribed entities) who hold provincial data, as described in:

- **Section 3: Overview of the CLSA Design**: *"All 50,000 participants are asked to provide their health insurance numbers to permit linkage with Medicare claims data held in provincial healthcare databases."*

- **Section 4.8. Secondary Data Collection**: *"… the primary data of all CLSA participants who provide a health insurance number and signed consent for linkage will be linked to existing health care administrative databases (e.g., drug plans [for those aged 65 years and over or those who are on social assistance], physician visits, medical service plans, hospitalization, homecare, and mortality). The purpose of these linkages will be to collect complementary information on medication use and health services resource utilization, as well as to ascertain deaths and causes of death."*
- **Section 4.8. Secondary Data Collection: "***The sources of social cohesion, neighbourhood, and environmental quality data will include Statistics Canada, Environment Canada, police reports and provincial and municipal data."*
- **Section 8.3. Data Flow Post-collection**: *"All data linkages with provincial healthcare registration databases will be initiated and overseen by the NCC in collaboration with the Statistical Analysis Centre."*
- **Section 8.5. Linkage with Provincial Healthcare Registration Databases:** *"In cases where provincial healthcare registration database data are not permitted to leave the province of origin, the CLSA will develop data access protocols with the data stewards to facilitate data access for the study."*

As reported in recent annual renewal (2019), the CLSA already has data sharing agreements in place with 8/10 provincial governments to obtain vital status information.

We, the Hamilton Integrated Research Ethics Board (HiREB), further warrant that participants who have signed the CLSA consent are expressing their wish for the CLSA to use their Health Card Number to link their primary data collected in the CLSA to databases under provincial jurisdiction and held by either provincial governments, provincial data centres (often prescribed entities), as well as federal data centres (often prescribed entities) who hold provincial data. This wish is clearly described in:

- **CLSA Study Information Package:** *"Why am I being asked to give the CLSA my Health Card Number? Your provincial healthcare records will be linked to data collected by the CLSA to study patterns of health and health care over time. For example, Ministries of Health in each province keep records about your visits to doctors and hospitals, medicines you fill a prescription for, and what people die from."*
- **CLSA Consent Form:**
    - *"I understand that if I choose to give my Health Card Number, it will be used to link information about me in my public healthcare records held by the Provincial Government."*
    - *"I give permission to the Provincial Government to provide the CLSA team with information about me held in provincial health databases."*
        - *"I understand that this will allow researchers to link my provincial health information to information collected from me by the CLSA. "*
        - *"I also understand that, should I withdraw my consent, data about me that has already been linked will remain part of the CLSA database.*
        - *"I also understand that, should I withdraw my consent, data about me that has already been linked will remain part of the CLSA database."*

We do not interpret the CLSA participant consent to limit linkage to data shared (vs., held) directly by a Provincial Government given that:

HiREB
Hamilton Integrated Research Ethics Board

- The consent form statement reflects the most comprehensive lay language declaration that could be devised in 2011 to reflect the intention of the participant to allow the CLSA to link databases commonly held under provincial jurisdiction (by either the province or authorized prescribed entities or equivalent) as described in the CLSA Protocol Section 4.8 'Secondary Data Collection': *"There are many practical, methodological, and ethical issues involved in using provincial healthcare registration databases for research. Each province has a unique set of data liberation requirements that makes obtaining a common set of health indices across provinces challenging. Recognizing this issue, the CLSA investigators have done extensive preparatory work to learn about the province-specific regulations and engage provincial data stewards and privacy commissioners to help facilitate the data linkage process.(268) In addition a working group composed of the data stewards and CLSA researchers has been formed to support the process of sample selection and health care utilization data acquisition. Most recently, in September 2011, a workshop was held to bring together investigators from large Canadian cohort studies (CLSA and the Canadian Partnership for Tomorrow Project) and data custodians from each provincial ministry of health to address challenges and opportunities related to a pan-Canadian linkage program.(269)"*
- It remains unfeasible for the consent statement to specifically reflect the changing procedures for linkage to provincial healthcare data as well as the changing entities (e.g., data centres and prescribed entities) that facilitate research linkage with healthcare data under provincial jurisdiction.

Please feel free to contact me if you have any questions or concerns with our interpretations of these documents.

Sincerely,

Dr. Mark Inman MD PhD,
Professor, Dept of Medicine,
McMaster University
Co-Chair, Hamilton Integrated Research Ethics Board