

Data Deposit Agreement

SECONDARY ANALYSIS TO GENERATE EVIDENCE (“SAGE”), a research and data facility operating under the authority of POLICYWISE FOR CHILDREN & FAMILIES (“POLICYWISE”), a corporation organized and existing in the province of Alberta, with its principle office located on the 6th floor, 9925 – 109 Street, Edmonton, Alberta, T5K 2J8;

AND

[Data Producer/Data Producer’s Institution Name], [Address] (the “Data Producer’s Institution” or “Data Producer”);

Both SAGE and [Data Producer/Data Producer’s Institution] wish to enter into this Data Deposit Agreement effective as of the Effective Date specified on the final page hereof.

PRELIMINARY STATEMENT

The Data Producer has collected Data from individuals pursuant to the Health Information Act (HIA) and/or pursuant to the Tri-Council Policy Statement 2 (TCPS2) (the “Data”).

The [Data Producer/Data Producer’s Institution] wishes to transfer the Data in its control and possession, from the Data Producer from the study approved by the Research Ethics Board on [Date], Ethics ID # [Number], entitled: [Title of Study] (the “Study”), to SAGE for storage and management of data for secondary data usage. Data related to this primary study may be routinely added to SAGE as it becomes cleaned, coded and available for transfer, at the discretion of the Data Producer.

NOW THEREFORE THIS AGREEMENT WITNESSETH that in consideration of the premises and of the mutual covenants herein set forth, the parties hereto have covenanted and agreed as follows:

I. DEFINITIONS

For purposes of this Agreement:

- A. “Agreement” refers to this Data Deposit Agreement.
- B. “Data” refers to the information included in Exhibit A, which has been collected and recorded from participants through methods described in Exhibit B.
- C. “FOIP” means the *Freedom of Information and Protection of Privacy Act*, R.S.A. 2000, c. F-25, as amended from time to time.
- D. “Study” refers to the project as described in Exhibit B.
- E. “Metadata” refers to all underlying data about the Data, without identifiers.
- F. “Data Producer” is the principal investigator, along with his or her research team, as listed on the Study outlined in Exhibit B. For the purposes of this agreement, the Data Producer will represent their research team and other co-investigators as the key contact and signatory.

- G. “Data Producer’s Institution” [Add definition. For example “a post-secondary institution, incorporate until the laws of....”]

II. AGREED TERMS AND CONDITIONS

1. **Research Work:** SAGE requests access to the Data at their sole risk and at no expense to the Data Producer solely for the non-commercial purpose outlined in Exhibit D.
2. **Non-transferability.** This Agreement is not transferable.
3. **Provision of Data.** The Data being transferred between the parties will be transferred via a secured method to SAGE server(s) such as secured file transfer protocol or a virtual private network. Upload access is limited to the Data Producer through secured authentication.
4. **Control and Ownership of Data.** The Data Producer is the owner of the Data as defined in Exhibit A.
 - A. The Data Producer shall be responsible for providing applicable Ethics certification associated with the data to be deposited.
 - B. The Data Producer shall provide a full copy of all the Data, defined in Exhibit A, to SAGE to allow it to perform the repository services defined in Exhibit D.
 - C. SAGE shall acknowledge the Data Producer’s ownership of the Data in any access agreements, public statement or communications.
 - D. This transfer of Data does not constitute a transfer to SAGE of any ownership rights or title to the Data. Except as provided in this Agreement, no express or implied licenses or other rights are provided to SAGE under any proprietary rights of the Choose an item to the Data.
5. **Use of Data**
 - 5.1. Responsibilities of the Data Producer
 - A. Initial Data Assessment
 - (i) The Data Producer will warrant that the Data is original and does not infringe copyright of a third party.
 - (ii) The Data Producer will warrant that it has the right to transfer and share data with SAGE.
 - (iii) The Data Producer will ensure that the appropriate Research Ethics Board (REB) approvals and any participant notification have been obtained, or that the REB has waived the consent and notification requirements for subsequent uses of the Data.
 - (iv) The Data Producer shall ensure the quality and integrity of the Data being transferred to SAGE but does not warrant absolute accuracy.
 - B. Metadata Preparation
 - (i) The Data Producer will provide the information and materials needed to prepare Metadata in consultation with SAGE personnel including items listed in Exhibit A.
 - (ii) The Data Producer will allow SAGE to publicly post/circulate Metadata on the Study to potential users and the public.
 - C. Role in Access Processes

- (i) The Data Producer is eligible for membership on the Access Review Roster as defined in SAGE's Terms of Reference (included as Exhibit E).
- (ii) The Data Producer shall follow the de-identification recommendations proposed by SAGE and work with SAGE to ensure that they meet current technical standards/best practices.
- (iii) The Data Producer shall provide SAGE with permissions for handling and modifying the Dataset for the purposes of preservation and the right to delete or remove the Data from the repository.

5.2. Responsibilities of SAGE

SAGE shall be responsible for Data management/user support processes.

A. Initial Dataset Assessment, De-identification and Confidentiality

- (i) SAGE personnel shall treat all information received pursuant to this Agreement in a confidential manner in conformity with this Agreement, applicable privacy legislation and policy.
- (ii) SAGE personnel shall administer an assessment of the initial Dataset and make recommendations to the Data Producer on any necessary changes to prepare it for use in relation to proper de-identification procedures.
- (iii) SAGE will embargo or otherwise limit the use of Data as guided by the Data Producer.

B. Metadata and Marketing

- (i) SAGE personnel will aid in preparation of metadata in alignment with a standard format (consulting the Data Producer as needed).
- (ii) SAGE personnel shall ensure that the metadata is reviewed and approved by the Data Producer before circulation to potential users and the public.
- (iii) SAGE personnel, in consultation with the Data Producer, will provide promotional services in relation to the Data, including but not limited to: making the research community aware of the availability of the Data through public posting of Metadata on websites, brochures, presentations, etc.
- (iv) SAGE shall respond to queries from potential users about the Dataset, the access process, and support services. SAGE shall consult the Data Producer as needed to provide timely and accurate responses.

C. Access Processes

- (i) SAGE shall provide a governance structure and administrative processes for formal access requests, approvals and release; including administering Data Access Agreements between SAGE and secondary users.
- (ii) SAGE personnel or the Data Producer may assist with secondary use proposals.
- (iii) SAGE shall provide assistance to approved secondary users for data management related services.
- (iv) SAGE shall provide reports back to the Data Producer on any active queries or processes that it is administering in relation to the Data Producer releasable Data upon request.

- (v) SAGE shall keep an inventory of findings (such as published papers, abstracts, presentations from original and new uses of the Data and publish these on a public website with appropriate links or citations).
 - (vi) SAGE shall ensure that records are removed for participants who have requested withdrawal for all subsequent uses when the Data Producer notifies SAGE of these situations.
 - D. De-identified Data
 - (i) SAGE shall administer Data Access Agreements with secondary users.
 - (ii) SAGE shall monitor secondary use for released Data and access compliance.
 - (iii) SAGE shall implement processes and policies for access and secondary use of data that mitigate the risk of infringement on copyright or intellectual property of the Data Producer and its institution and help ensure the use is in compliance with the HIA and other applicable Federal and Provincial legislative acts governing the use of the Data.
 - (iv) SAGE shall provide appropriate security infrastructure, processes and policies for storage and protection of the Data, and access for secondary uses.
 - (v) SAGE shall ensure compliance of policies and procedures of secondary use through Data Access Agreement with Data users.
 - (vi) SAGE will support or broker the development of research collaborations.
- 6. **Non-Identification.** SAGE agrees that Data will not be used, either alone or in conjunction with any other information, in any effort whatsoever to establish the individual identities of any of the participants from whom Data were obtained.
- 7. **Compliance Monitoring and Investigations,** SAGE shall record and monitor access to the Data in its custody, in order to establish a chain of responsibility, as follows:
 - A. SAGE will investigate all reported cases of:
 - (i) Unauthorized access to or modification of the Data in its custody;
 - (ii) Unauthorized use of the Data in its custody;
 - (iii) Unauthorized disclosure of the Data in its custody;
 - (iv) Unauthorized research on the Data provided to secondary users
 - (v) Breaches of privacy or security with respect to the Data in its custody or with respect to any computer system in its custody that is used to access the Data.
 - B. If requested, SAGE shall report to the Data Producer the results of any such investigations and the steps taken to address any remaining issues or concerns about the security of the Data or computer systems, or the privacy of individuals to whom the Data relates.
- 8. **Notice of Breach.** SAGE shall advise the Data Producer immediately of any circumstances, incidents or events which to its knowledge have jeopardized or may in future jeopardize; (i) the privacy of individuals, (ii) the security of any computer system in its custody that is used to access the shared Data, and/or (iii) any suspected or apparent risk of a breach, or actual breach, of any term of this Agreement.
- 9. **Termination for Unremedied Breach.** The Data Producer may give SAGE notice of breach of this Agreement and, if the breach has not been addressed to the Data

Producer's reasonable satisfaction (including by retrieving research information that has been used or disclosed contrary to this Agreement) within thirty (30) days after the notice is given, the Data Producer may give notice of termination of this Agreement, which becomes effective fifteen (15) days after it is given. Within thirty (30) days after termination of this Agreement SAGE must return all copies of Data in any medium or must securely destroy all copies to the Data Producer's reasonable satisfaction, as the Data Producer directs in a notice given to SAGE. SAGE's obligations under this Agreement respecting use, disclosure and security of Data remain in force despite termination of the rest of this Agreement.

10. Non-Data. Notwithstanding the definition of "Data" or the agreed Terms and Conditions of this Agreement, if the Data Producer transfers written confidential information concerning the Data along with the Data, then to the extent permitted by law, SAGE agrees to treat in confidence, any of Data Producer's said confidential information. SAGE's obligations of confidentiality under this Agreement shall not extend to any information:

- A. that can be demonstrated to have been publicly known at the time of disclosure; or
- B. that can be demonstrated to have been in the possession of or that can be demonstrated to have been readily available to SAGE from another source prior to the disclosure; or
- C. that becomes part of the public domain or publicly known by publication or otherwise, not due to any unauthorized act by SAGE; or
- D. that can be demonstrated as independently developed or acquired by SAGE without reference to or reliance upon Data provided under this Agreement; or
- E. that is required to be disclosed by law, provided SAGE takes responsible and lawful actions to avoid and/or minimize such disclosure.

11. Intellectual Property. Existing intellectual property, inventions, and technology (collectively "IP") that formulate and constitute SAGE are the sole property of SAGE. No other Party shall have any claims to rights in such existing IP. IP rights to the Data generated through the course of the Study and collected under this Agreement are the property of the Data Producer.

12. Acknowledgments. SAGE agrees to require secondary users to acknowledge the contribution of the Data Producer in any and all oral and written presentations, disclosures, and publications resulting from any and all analyses of Data.

13. Limitation of Liability and Indemnity. SAGE assumes all liability for loss or damages arising from the use, storage or disposal of the Data and further agrees to indemnify, defend and hold harmless the Data Producer and Data Producer Institutions from all claims, actions and damages whatsoever, including legal fees, resulting from or in connection with the use, storage or disposal of the Data. The Data Producer shall in no event be liable for any loss of profits, be they direct, consequential, incidental, or special or other similar or like damages arising from any defect, error or failure to perform with respect to the Data, even if the Data Producer has been advised of the possibility of such damages.

14. Any notice, direction or waiver which may be or is required to be given under this Agreement must be in writing to be effective and must be delivered or sent by fax transmission or e-mail using the address information set out below. Any notice,

direction or waiver that is delivered is considered to have been given on the next business day after it is dispatched for delivery. Any notice, direction or waiver that is sent by fax transmission or e-mail is considered to have been given on the day it is sent if that day is a business day, but if that day is not a business day, it is considered to have been given on the next business day after the date it is sent. If a party changes its address, fax number, e-mail address or all of them, it must immediately give notice of the new address, fax number or e-mail address to the other party as provided in this section.

If to the Data Producer: [Data Producer's Name] [Institution] [Address] [Phone Number] [Fax] [E-mail]	Technical Notices: [Name] [Institution] [Address] [Phone Number] [Fax] [E-mail]
If to SAGE: [Institution] [Address] [Phone Number] [Fax] [E-mail]	

- 15. Designated Representatives.** The parties agree the individuals signing this Agreement are their designated representatives for all purposes of this Agreement. A party may give notice to the other designating a new representative, and must do so promptly after its representative changes.
- 16. Binding on Successors.** This Agreement ensures to the benefit of and is binding upon the parties and their respective successors, contractors, trustees, administrators and receivers, despite any rule of law or equity to the contrary. If SAGE ceases to exist, the Data Producer reassumes total responsibility for the Data and further use of the Data must be approved by the Data Producer.
- 17. Whole Agreement.** This Agreement and its exhibits, is the entire Agreement between the parties and it terminates and supersedes all previous communications, representations, warranties, covenants and Agreements, whether verbal or written, between the parties with respect to the subject matter of this Agreement.
- 18. Waiver.** Waiver of any breach of this Agreement must be expressed and in writing to be effective and a waiver of a particular default does not waive any other default.
- 19. Counterparts.** This Agreement may be executed in counterparts and when each of the parties to this Agreement has executed a counterpart, each of those counterparts is considered to be an original and all of those counterparts when taken together constitute one and the same Agreement.
- 20. Severance.** If any portion of this Agreement is held invalid by a court of competent jurisdiction, the invalid portion must be severed and neither the decision that it is invalid nor the severance affects the validity of the remainder of this Agreement.
- 21. Amendments.** This Agreement may only be amended by a document signed by the authorized representatives of the parties and no other purported amendment is effective.

As evidence of their Agreement to be bound by the above terms, the authorized signatories of the parties have executed and delivered this Data Deposit Agreement, to be effective as of [Date] (“Effective Date”)

Signed for and on behalf of [Data Producer’s Institution Name] by its duly authorized officer:

Name:

Title:

Date:

Read and Acknowledged by:

Name: [Data Producer’s Name]

Title:

Date:

Signed for and on behalf of SAGE Executive by its duly authorized officer:

Name:

Title:

Date:

Exhibit A -

Data to be Deposited in SAGE from Institution

TEMPLATE

Exhibit B –

Study

TEMPLATE

Exhibit C-

Research Ethics Board Approval Certificates

Attach REB Approval Here.

TEMPLATE

Exhibit D-

SAGE Overview of Repository Services

What is Secondary Analysis to Generate Evidence?

SAGE is a data and research platform where research data, service delivery data, and administrative data related to child and youth development, health and well-being are stored, cleaned, catalogued and managed for secondary research and policy uses. SAGE will have highly secured computing systems and staff at PolicyWise for Children & Families (PolicyWise) in Edmonton and Calgary. PolicyWise will provide state-of-the-art technical infrastructure and governance processes for secondary use of data while ensuring privacy.

Outcomes for Alberta's children, youth, families and communities will be improved through using and combining data in *new ways* to inform social, educational and health policy, practice and service planning. PolicyWise will build and leverage research capacity, (including infrastructure and both data-related and child health and development-related content expertise) in an unprecedented way.

What are its Vision and Mission?

The VISION of SAGE is to *'maximize the potential of Alberta's children and youth'*. The MISSION of SAGE is *'to enable evidence-informed policy and practice through collaborative, optimal use of data'*.

Why is it important?

There are many benefits of sharing research data, including that it:

- Encourages quicker generation of new knowledge for greater impact;
- reduces costs because similar data don't have to be collected repeatedly;
- enables richer answers to complex policy and research questions by combining data from multiple sources and of multiple types;
- promotes collaboration and cooperation across diverse disciplines;
- allows new research questions on existing datasets and new dataset combinations;
- facilitates independent verification of findings;
- encourages quality data management practices;
- reduces unnecessary/duplicate participation of research volunteers;

and perhaps most importantly; it -

- uses "to best effect the gift of data made by study participants"

Recently, the Social Sciences and Humanities Research Council of Canada (SSHRC) set a policy encouraging data sharing and allowing associated costs in research budgets.

Governance, Ethics and Privacy Protection

SAGE has a three-pronged approach to ethics and privacy protection – guided by CIHR best practices, Canada's Tri-Council Policy Statement 2 on the 'Ethical Conduct for Research Involving Humans' and the relevant literature placed in context of relevant legislation in Alberta. The first prong is ***governance***. There is a Strategic Advisory

Committee made up of representatives of key stakeholder groups that use an adaptive governance model to develop fair and accountable access, deposit, ethics review, privacy protection, and engagement processes. In addition, a second level Operations Advisory Committee oversees more operational and data management components of SAGE. Finally, an internal SAGE Team will oversee the management of a systematic and efficient access, release and follow-up process.

The second prong to the ethics and privacy protection approach is ***formalized connections*** to Research Ethics Board review processes and the Office of the Information and Privacy Commissioner of Alberta (OIPC) for advice and, when necessary, privacy impact assessments. Data requiring the greatest level of protection will be analyzed on-site only. Those at a second level may be released to qualified researcher/policy analyst teams or analyzed by remote access after completion of an approval process (including REB approval) under the terms of a formal Data Deposit Agreement. Data sets that can be completely anonymized will be more readily available. In all cases, only the minimum amount of data will be provided to the secondary user to meet the objectives of the research.

The third prong to the ethics and privacy protection approach is ***technology***. Staff will have special training, and state of the art identity protection and de-identification software will be used. The approach to physical data security will integrate learnings from the Child and Youth Data Laboratory (CYDL) model which follows a strict code of practice for information security.

Functions and Operations

SAGE operates according to the following principles:

- Best practices for research repository operations internationally
- Best practices for research ethics in Canada
- Principles for data stewardship (Research Data Canada)
- Best practices for governance for biobanks
- A commitment to consult with and involve all stakeholders e.g., Research Ethics Boards, OIPC of Alberta, research participants, and the public in implementation and governance.

The services SAGE provides include core supports for data users that are known best practices for research repositories such as access processes, dataset preparation and preservation, metadata development, as well as value added services such as rapid analyses in response to policy questions, training and knowledge mobilization. Researchers and policy analysts with specific interests will be able to search for information on-line about the data holdings (metadata).

Exhibit E-



Access Review Roster Terms of Reference

Role Statement: The Access Review Roster will include individuals who are responsible for scientific review of requests for data held within SAGE. Members are selected from the research community based on knowledge and expertise in both content and methodology.

Process: Applications for data will be evaluated by 3 reviewers, of which one may include the data depositors.

Reviews may be provided by research scientists from the Child and Youth Data Lab (CYDL), PolicyWise staff members, or other research affiliates of PolicyWise.

Reviews may also be provided by members of the Review Roster, particularly when the appropriate methodological and/or content expertise does not exist internally, or when the appropriate internal reviewers are in Conflict of Interest with the applicant or team members. External reviewers may be members of the national or international research community.

Designated data relevance reviewers are assigned based on the deposit agreement. A PI depositing data may delegate the option to the data manager.

Membership:

- Internal Reviewers (may include PolicyWise or CYDL staff)
- External Reviewers (identified and invited by the Grants Manager on behalf of the Scientific Director)
- Designated Data Depositors (primary custodians of the data, or their designate, and as outlined as per deposit agreement)

Member Qualifications:

1. Minimum of a PhD or relevant clinical, research, policy, or community experience.
2. In depth understanding of research methodologies, service provision and/or policy.
3. Interest and expertise in at least one PolicyWise' focus area:

- Early Childhood Development
 - Middle Childhood Development
 - Successful Transitions for Youth
 - Developmental Disabilities
 - Family Capacity Building
 - Community Capacity Building
 - Tracking Long-Term Outcomes
 - Aboriginal Focus
 - New Canadian Research
 - Quantitative Methodologies
 - Qualitative Methodologies
 - Policy Relevance
4. May be designated through a data transfer agreement.

Appointment: Revolving and ongoing.

Duties:

- i. Review Assignment: When an application is received, a minimum of 3 reviewers are assigned by SAGE Staff. Each reviewer evaluates the application according to specific criteria. Reviewers assign a numeric score to each criterion and provide written comments in each area. Reviewers may provide comments on things done well in the application, as well as areas where there is room for improvement.
- ii. Each Access Request will be given the opportunity of revision if the request is denied the first time.

Meeting Frequency: There are no meetings required of this roster.