SAGE: Helpful Wording for Ethics Applications

1. Study Objectives and Design

Briefly describe the methods:

This study will access data from SAGE (Secondary Analysis to Generate Evidence), a secure data repository developed by PolicyWise for Children & Families – a small Alberta based non-profit organization…

2. Risk Assessment

Provide details of the risks and discomforts associated with the research, in addition to standard care:

This is not applicable as this research uses existing data.

If your study has the potential to identify individuals who are upset, distressed, or disturbed, or warranting medical attention, describe the arrangements made to try to assist these individuals. If no arrangements have been made, please explain why:

This is not applicable as this research uses existing data.

3. Informed Consent Determination

What type of consent will you be seeking?

Waiver of consent requested

Provide justification for requesting a Waiver of Consent (minimal risk only):

This research uses secondary data which will be anonymized/de-identified by the data custodian prior to the study team access this data.

4. Registries and Databases

Where will the database servers be located? Specify if the database server will be under Canadian jurisdiction or elsewhere:

The database servers will be located in the office of PolicyWise for Children and Families. These servers are located in a secure server room within PolicyWise' office in Edmonton (601 – 9925 109 Street). The Director of Data Initiatives at the PolicyWise along with the Secondary Analysis to Generate Evidence (SAGE) team will provide support to access the data. The database server will be under Canadian Jurisdiction.

Who will have access to the database? How is that access determined?

The study team will have access to the database. The study team will make a formal data access request, along with the research proposal, to the Secondary Analysis to Generate Evidence (SAGE). Once the

research ethics is approved, the formal data access request is reviewed by the SAGE team, and the access to the database will be determined. The access to the de-identified data by study team will occur through a remote, password-protected virtual desktop system.

Will identifying information be stored within the database or will it be coded?

We will only have access to the database that is de-identified.

Will identifying information be shared?
No

If the database is to be maintained locally, what steps have been taken to ensure the privacy and security of the database are upheld?

The database will not be maintained locally. It will be maintained by the office of PolicyWise for Children & Families through their secure server.

The SAGE team from PolicyWise facilitates access to the data while protecting the participant confidentiality and privacy through a number of security measures such as 1) A Data Access Agreement that outlines terms and conditions of secondary use such as an agreement not to use the data in any way to re-establish the identity of individuals, 2) Data will be de-identified by SAGE staff prior to sharing with secondary users 3) Access to de-identified data by secondary users will occur through a remote, password-protected virtual desktop system. As a function of this virtual desktop system, confidentiality and privacy are protected because data can never leave the SAGE servers (i.e. it cannot be saved to a local desktop).

Who is responsible for the database?

PolicyWise for Children & Families will be responsible for the database. Data will be housed on servers provided by the PolicyWise. The Director of Data Initiatives at the PolicyWise along with the Secondary Analysis to Generate Evidence (SAGE) team will provide support to the secondary data users.

Are there standard operating procedures for the database management, use and access?

Yes

5. **Data Confidentiality and Privacy**

How will confidentiality of the data be maintained? Describe how the identity of participants will be protected both during and after the research:

The data will be housed on servers located in a secure server room within PolicyWise' office in Edmonton. Access to the de-identified data will occur through a remote, password-protected virtual desktop system. As a function of this virtual desktop system, the system requires two-factor authentication for user access, and does not have internet connectivity. Hence, data can not be removed from the virtual research environment located in the PolicyWise' servers. This maintains the confidentiality of the data.

How will the Principal Investigator ensure that all study personnel are aware of their responsibilities concerning participants' privacy and the confidentiality of their information?

…In addition, Secondary Analysis to Generate Evidence (SAGE) facilitates secondary data users to protect participant's confidentiality and privacy through providing a virtual research environment and a Data Access Agreement that outlines terms and conditions of secondary data use, such as an agreement not to use the data in any way to re-establish the identity of individuals.

6. Data Storage, Retention and Disposal

Describe the electronic security provisions and the physical security provisions:

The data will be housed on servers provided by PolicyWise for Children and Families. These servers are located in a secure server room within PolicyWise' office in Edmonton (601 – 9925 109 Street). Access to de-identified data by secondary users will occur through a remote, password-protected virtual desktop system. As a function of this virtual desktop system, the system requires two-factor authentication for user access, and does not have internet connectivity. Hence, data can not be removed from the virtual research environment located in the PolicyWise' servers, that means it cannot be saved to a local desktop. This provides both electronic and physical security of the data.

If you plan to destroy your data, describe when and how that will be done and who will have access. Indicate your plans for the destruction of the identifiers at the earliest opportunity consistent with the conduct of the research and/or clinical needs:

This is not applicable as this research will access de-identified secondary data through a remote, password-protected virtual desktop system provided by the PolicyWise for Children and Families. We will have access to the de-identified data until our research is completed.