HRDP-SK Project-Specific Data Integration

Research teams may request to include data in their research and analysis that:

- they have collected or obtained from individuals or organizations that are not one of the data trustees party to the Master Health Data Sharing Agreement (MHDSA) or
- data from a MHDSA trustee that is not currently in HRDP-SK's central repository.

This data is referred to as ***project-specific data***.

If a researcher seeks to integrate data into HRDP-SK using the Project-Specific Data Integration process they are required to provide information that demonstrates the legal authority under which this can occur. Below are three ways in which this can be demonstrated.

1. **The researcher is the data trustee.**

   Trustee Declaration - If a researcher is the data trustee they must provide documentation to demonstrate that their collection, use or disclosure of the project-specific data is in alignment with *The Health Information Protection Act* (HIPA) or other applicable legislation. For example, a clinician researcher using their electronic medical record to identify a patient level cohort. A sample Trustee Declaration is provided in Appendix 1.

2. **The researcher is the data trustee.**

   Consent - The researcher has collected data with the express consent of the individuals. For example, a patient level survey. If they have collected the data with consent of the individual; the legal authority would be demonstrated by providing a copy of the research project documentation, ethics approval, consent form and other subsequent documents that they used to receive approval to collect the data. Information on express consent is available in Appendix 2.

3. **The researcher has received permission from the data trustee.**

   Data Sharing Agreement - A data sharing agreement may be in place between the data trustee and the researcher. A data sharing agreement must include:

- Signature of both the researcher and the data trustee.
- Clear purpose that the data can be used for the project, and nothing else, and linked with data as aligned with and outlined in the HDRP-SK Stage 2 Request.
- Detailed identification of the data elements to be shared.
- Legal authority for the data to be shared (collected, used, disclosed).
- Obligations of each party for the securing and safeguarding the data including storage, retention, destruction, and appropriate methods of transmitting data to HRDP-SK.

Appendix 1:

Guideline for Trustee Declaration

The trustee declaration must include:

- Name
- Signature
- Location
- Applicable Legislation
- Applicable sections

The trustee is responsible for citing the appropriate legislation and sections within relative to their authority.

Example:

I, __(name)_____ as a _____(provider role)___ and owner of , ___(clinic name)_____ clinic, in _____(City/town)_____, Saskatchewan.

Under section 2(1)(t)_____ of *The Health Information Protection Act* (HIPA), I am the trustee of the _____ database/data set.

Under section 26(2)(a) and 29(2) and _____ of HIPA, I have the authority to use this data without consent of the individuals for the purpose(s) of _____.

Under section 29(2) and _____ of HIPA, I have the authority to disclose this data to HRDP-SK without consent of the individuals for the purpose(s) of _____.

Insert Signature

Insert Name

Insert Date

Appendix 2:

HRDP-SK Guideline for Obtaining Express Consent

The following information is provided as guidance and should be used to ensure consent forms are appropriate.

Consent

Consent is the informed, voluntary agreement with what is being done or proposed with respect to the collection, use or disclosure of personal health information. Section 6 of *The Health Information Protection Act* (HIPA) provides trustees with guidance. Express consent is the highest standard and must meet all the following conditions:

- Identify the specific personal health information (data elements) to be collected, used or disclosed.
- Identify the specific uses and/or disclosures, including whether the data will be linked with other data and identifying such.
- Identify to whom the personal health information will be disclosed.
- Provide the date the consent is effective and the date on which the consent expires.
- Identify any potential risks associated with the collection, use or disclosure.
- Provide a process for an individual to revoke their consent or opt out.

ELEMENTS OF A CONSENT FORM (usask.ca)

Specific considerations for consent forms that will be used for HRDP-SK Project-Specific Data Integration:

1. Ensure that the consent form includes language on linkage should be clearly specified without any ambiguity such that participants are aware that the collected data may be linked to other administrative and/or clinical data for research purpose.
2. In order to link data to HRDP-SK Health Services Number is required to be shared with eHealth as the Information Management Service Provider for the Health Research Data Platform- Saskatchewan.