What Agreements are Required?

Most research projects conducted within a Shared Health facility, program and/or affiliated service requires an executed research agreement/contract with Shared Health prior to project initiation. The type of agreement required is based upon the type of research project being conducted and what data and Shared Health resources is being accessed for the project.

Below are some guidelines for the most common types of agreements and when they are necessary.

1. Clinical Trial Agreements (CTA) or Clinical Study Agreements (CSA)

Clinical Trial or Clinical Study Agreements are negotiated and legally binding between two or more parties to terms and obligations with respect to the conduct of a research project. Parties to these agreements are typically, at minimum, Shared Health, the University of Manitoba and a third party that typically sponsors the research. They may also be referred to as collaboration agreements, or sub-site agreements.

Agreements are required when any of the following conditions are met:

1.1. The study is being conducted within a Shared Health facility, program and/or affiliated service; and/or
1.2. The study is recruiting participants from within a Shared Health facility, program and/or affiliated service; and/or
1.3. Shared Health service(s) is are being utilized (e.g. diagnostic services, records retrieval by HIS etc.); and/or
1.4. If the Research is accessing data, including personal health information, which is to be shared with and/or disclosed to a third party, where Shared Health is a Trustee of that data.

2. Material Transfer Agreement (MTA)

A Material Transfer Agreement is an agreement that governs the transfer of tangible, research materials (physical, biological or otherwise) between the provider and the recipient of such material and legally binds two or more parties to terms and obligations with respect to that transfer of the material(s).

An MTA is required when any of the following conditions are met:

2.1. Materials which Shared Health is a Steward (e.g. biological specimens) are being used for research purposes and being transferred to another party external to Shared Health; or where
2.2. Materials which are being used for research purposes and being received by Shared Health from another party.

3. Data Sharing Agreements (DSA) / Data Transfer Agreements (DTA)

Data Sharing Agreements are agreements are negotiated between two or more parties that governs and legally binds the parties to terms and obligations with respect to accessing, collection, storage, retention, disclosure/sharing, exchange and transfer of and destruction of information where Shared Health is a Trustee of the information or data. The provision of obligations within the DSA/DTA are to ensure alignment and compliance with PHIA regulations within Manitoba.

A DSA/DTA is typically required when any of the following are required:

3.1. When information, including personal health information, which Shared Health is the Trustee, is being used for research purposes, either retrospectively or prospectively; and/or
3.2. When access to a Shared Health system containing information, including personal health information, where Shared Health is the Trustee of that information, is being requested.

Note: When information is being disclosed by Shared Health in aggregate or anonymized format and access to a Shared Health system is not required, a DSA may not required.

As different types of agreements are relevant to different situations for a single project, often a project may require multiple agreements (i.e. a CSA and a DSA).

Agreements are typically initiated by the study Sponsor and negotiations can begin upon initial acceptance of an institutional impact submission. DSAs are initiated by Shared Health following all conditions of the project being met.

We always strive to approach agreements in the most efficient manner possible.