AGREEMENT BY RESEARCHER IN FAVOR OF CUSTODIAN

Pursuant to Section 54(1)
Health Information Act

Re: Study# _____; HREB# _____;

Study Name: _____

_____

I, _____, am conducting research approved by the University of Alberta Health Research Ethics Board (the "Board"), an ethics committee as defined in the Health Information Act and its Regulations (collectively the "Act") a copy of which Board Approval is attached hereto as Schedule A (the "Board Approval"). I will be using or will have disclosed to me by Covenant Health ("CH") health information as this term is defined in the Act. In accordance with Section 54(1) of the Act, I hereby agree as follows:

1) To comply with:
   i. the Act;
   ii. any conditions imposed by CH or the Board relating to the use, protection, disclosure, return or disposal of the health information as set forth in Schedule B or as established from time to time; and
   iii. any requirement imposed by CH or the Board to provide safeguards against the identification, direct or indirect, of an individual who is the subject of the health information.

2) To use the health information only for the purpose of conducting the proposed research as approved by the Board.

3) Not to publish the health information in a form that could reasonably enable the identity of an individual who is the subject of the information to be readily ascertained.

4) Not to make any attempt to contact an individual who is the subject of the health information to obtain additional health information other than that contemplated in the Board approved project, unless the individual has provided CH with consent.

5) To allow representatives from CH to access or to inspect my research premises to confirm that I am complying with the enactments, conditions, and requirements referred to in paragraph 1.

6) To pay to CH costs incurred for the purposes of my research in the preparation of information for disclosure, making copies of health information or in obtaining requisite consents. In accordance with the Act, these costs shall not exceed the actual cost of providing each service.

7) To be liable for my actions and the actions of my employees, agents, consultants or other persons for whom I am in law responsible respecting the collection, use or disclosure of the health information and for ensuring compliance with the Act by these persons.

8) If I contravene or fail to meet the terms and conditions of this agreement, this agreement shall be terminated.

_____ _____

Signature Date

Schedule B

Addendum to AGREEMENT BY RESEARCHER IN FAVOR OF CUSTODIAN
Pursuant to Section 54(1) Health Information Act (HIA)

CONDITIONS IMPOSED BY COVENANT HEALTH (COV)

As a researcher who is asking Covenant Health (check as many as apply)

- ☐ to disclose health information for the purpose of a research study (electronic data or paper records), or
- ☐ to access to health information in COV systems or records, or
- ☐ to perform data matching, or
- ☐ to perform other services to facilitate my research study

Upon receipt of operational/administrative approval from COV, I agree to implement the following conditions[i] if the condition is relevant to my proposed research study. I understand that it is my responsibility to review the following table to identify the conditions that apply.

Study # _____ Principle Investigator's Signature _____

Item	Conditions
Recruitment of Study Participants	1. Prior to any potential study participant being approached by a researcher, a COV employee should inform the patient of the study and obtain the patient's consent to provide the patient's contact information to the researcher. 2. When there is an established care relationship between a physician and patient, the physician in his/her role as a researcher must have an intermediary approach the patient regarding participation in a research study. 3. A researcher must not use existing information systems credentials provided for the purpose of delivering health services to query COV systems or databases to identify potential study participants. This work may be undertaken by authorized COV employees, other than the researcher. 4. Following COV operational/administrative approval, a researcher may post information regarding their study within COV facilities to enable potential study participants to self-identify and volunteer to participate Following COV operational/administrative approval, a researcher may approach COV unit managers or physicians regarding recruitment of patients or staff as study participants.
Informing Study Participants about Collection of their Health Information	A researcher must provide information in writing to the study participants to inform them about the collection of their health information. The written materials must describe • the detailed health information that will be collected from COV by the researcher, e.g. name, age, date of birth, diagnosis • how the information will be collected, e.g. from the patient directly, from paper health records, from a computer system • how long the information will be retained • the safeguards the researcher will implement to protect the information being collected in the study
Consent Required by Health Research Ethics Board (HREB) (HIA Condition)	A researcher, who is required by HREB to obtain consent from study participants that authorizes COV to disclose the health information requested for use in the research, • must ensure the consent form meets the requirements of section 34(2) of the HIA[ii]. See endnote below. • must collect the required consents before the information will be disclosed by COV[iii] • when asked by the department disclosing the information, must be able to verify that the consents have been collected or provide copies
Collecting Additional information (HIA Condition)	A researcher must submit an amendment to the HREB for review and re-approval, and provide corresponding notice to COV if he/she wishes to collect information not identified in the original study approved by the HREB (so that COV may obtain consent as required by the HIA[iv])

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Item	Conditions
Collecting Information by Audio/Video Recording Equipment	A researcher who wishes to collect information by way of audio, video or other electronic method must • inform each study participant in writing of the method to be used • describe the information to be collected, how long the recordings will be retained and the safeguards to be used to protect the information • obtain each participant's written consent
Using Netcare for Research	Section 4.4 of the Alberta Health Netcare Information Exchange Protocol[v] sets out the rules for use of Netcare for research. • A researcher who wishes to use Netcare shall inform COV so that an existing Netcare Research Agreement can be confirmed or a Netcare Research Agreement can be executed • A researcher must obtain explicit consent from each study participant for the use of the Netcare for the proposed study
Data Identifiers	When data identifiers are removed from information to protect the confidentiality of the study participants, the master list or data table must be • securely retained in a location separate from the de-identified study materials or database, e.g. locked file cabinet, encrypted computer, secure network computer drive • only accessible to authorized study team members
Data Matching or Linkage	When data matching or linkage is being performed, reasonable safeguards must be in place to protect the source data files and the new data being created
Data Storage in Paper Format / Transportation of Records	Health information collected in paper format must be appropriately secured. • Data collection forms, other records or media must be stored in locked filing cabinets in locked rooms with key access limited to those on the study team • Briefcases or other secure record containers are to be used when paper records are carried by team members or transported between collection areas and storage locations
Data Storage in Electronic Format / Electronic Transmission	Electronic data collected on computers or other devices, or transmitted outside of the COV or AHS network, must be appropriately secured. • Data storage on secure network drives, with access limited to study team members only, is preferable to data storage on computer hard drives • Laptops or other external hard drives must be password protected and have encryption enabled software. USB memory devices must be protected using AES-256 bit encryption. Password protection alone is not sufficient to protect information if a device is lost or stolen. • Knowledge of passwords/encryption keys must be limited to study personnel. If the information is to be recorded, it should be kept in location separate from the study records or equipment. • Data transmitted electronically must utilize a secure communication method, e.g. encrypted email, VPN/virtual private network or be entered directly to a secured server
Commitment to Confidentiality by Study Personnel	A principle investigator is responsible to ensure that all members of the research team understand their obligation to maintain the confidentiality of the study participants' information and to safeguard records collected and databases created. This may be accomplished by • Confirming team members have appropriate ethical, privacy and security, or other relevant training • Obtaining signed confidentiality agreements from each team member • Informing all team members of the specific safeguards to be implemented in relation to the proposed study
Data Retention and Secure Disposal	Compliance with the applicable data retention requirement and eventual secure destruction of the study records (paper and/or electronic) rests solely with the principle investigator.

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Questions regarding any of the conditions listed above may be directed to Information and Privacy at 1-866-254-8181 or privacy@covenanthealth.ca.

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[i] As per section 54(1)(a)(ii) of the Health Information Act

[ii] As per section 34(1) and 34(2) of the Health Information Act

(1) Subject to sections 35 to 40, a custodian may disclose individually identifying health information to a person other than the individual who is the subject of the information if the individual has consented to the disclosure.

(2) A consent referred to in subsection (1) must be provided in writing or electronically and must include

(a) an authorization for the custodian to disclose the health information specified in the consent,

(b) the purpose for which the health information may be disclosed,

(c) the identity of the person to whom the health information may be disclosed,

(d) an acknowledgment that the individual providing the consent has been made aware of the reasons why the health information is needed and the risks and benefits to the individual of consenting or refusing to consent,

(e) the date the consent is effective and the date, if any, on which the consent expires, and

(f) a statement that the consent may be revoked at any time by the individual providing it.

[iii] As per section 53(2)(b)

[iv] As per section 55 of the Health Information Act

[v] As per section 4.4 Alberta Netcare Electronic Health Record Information Exchange Protocol (Alberta Health)