

The requirement for signed informed consent was **WAIVED** by our ethics and institutional review board for this purely **RETROSPECTIVE** study for which the participant study data was **ANONYMIZED**



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EDMONTON ZONE ADMINISTRATIVE APPROVAL FOR CLINICAL RESEARCH

All clinical research being conducted within the Edmonton Zone requires operational approval to access AHS areas and ethics approval by a recognized Alberta Research Ethics Board.
Other related documents may be required depending on the scope of the study.
Research in the Edmonton Zone cannot begin until Administrative Approval has been issued.

PROJECT: PRJ38670

Protocol Title: Comparison of two-point Dixon and six-point Dixon MR techniques in the detection, quantification and grading of hepatic steatosis using magnetic resonance spectroscopy as the reference standard

Principal Investigator:

Gavin Low
Medicine & Dentistry
Radiology & Diagnostic Imaging

Funding Agency:

Funding Type:

Overhead Rate:

No Funding Agency
Investigator-Initiated/No Funding
0%

Related Documents:

Research Ethics:
HSA Data Disclosure Agreement:

ID#

Pro00115324
RR10161

Status

Approved
Reviewed/Accepted

Effective

Mar 09, 2022
Mar 30, 2022

Edmonton Zone Administrative Approval

Approved:

Mar 30, 2022

Approved By:

Simon Wong
Director of Operations, NACTRC

between

Alberta Health Services ("AHS")
and

Gavin Low (the "Researcher")

regarding

REB ID : Pro00115324 Approved on 09-Mar-2022

Comparison of two-point Dixon and six-point Dixon MR techniques in the detection,
quantification and grading of hepatic steatosis using magnetic resonance spectroscopy as
the reference standard

WHEREAS:

- A. AHS and the University Of Alberta (the "University") are parties to the Data Cooperation Agreement (the "Cooperation Agreement") for the provision of certain health data and
- B. Pursuant to the Cooperation Agreement, the Researcher has requested from AHS access to the Data for the Permitted Purpose (as defined below), and AHS wishes to provide the Data to the Researcher, subject to the terms and conditions of this Agreement.

The parties hereby agree as follows:

1 Definitions

The following defined terms have the following meaning in this Agreement:

- (a) "**AHS Policies**" means AHS' policies, standards, procedures and guidelines applicable to the Data provided pursuant to this Agreement, including the AHS Research Information Management Policy (available at <http://www.albertahealthservices.ca/research/Page8601.aspx>), as may be amended by AHS
- (b) "**Applicable Laws**" means the HIA and any applicable federal legislation governing privacy, confidentiality and protection of Health Information;
- (c) "**Confidentiality Agreement**" means the AHS Confidentiality and User Agreement required to be executed for access to Data;
- (d) "**Confidential Information**" means the Data and all associated information (whether oral, visual, written, electronic, or other form) of a proprietary or confidential nature which is furnished or disclosed, indirectly or directly, by AHS to the Research Personnel in connection with this Agreement.
- (e) "**Data**" means the Health Information (as defined in the HIA) and other health records contained in the paper records or the Health Systems that are accessed, collected or used by the Research Personnel for the Permitted Purpose;
- (f) "**Health Systems**" means the Netcare and electronic health information systems and data repositories owned and operated by AHS;
- (g) "**HIA**" means the Alberta Health Information Act and the associated regulations;
- (h) "**Netcare**" means the Alberta Netcare Electronic Health Record;
- (i) "**Study Participant**" means an individual whose Health Information is part of the Data accessed by the Research Personnel through the Health Systems for the purposes of the Study;
- (j) "**Permitted Purpose**" is the purpose of the research activities conducted by the Research Personnel within the scope of the Study in accordance with the Applicable Laws;

- (k) **"Research Associates"** means the authorized research team members employed by the University or enrolled in the University study programs (including research coordinators, associates, assistants, students and postdoctoral fellows) who are designated as the Study staff on their applications to the REB;
- (l) **"Research Personnel"** means the Researcher and the Research Associates;
- (m) **"Research Disclosure"** means an application submitted by the Researcher to AHS for permission to access, collect and use the Data in the Health Systems for the Permitted Purpose in accordance with this Agreement and the Applicable Laws;
- (n) **"Study"** means a research proposal titled
 Comparison of two-point Dixon and six-point Dixon MR techniques in the detection, quantification and grading of hepatic steatosis using magnetic resonance spectroscopy as the
 approved by the REB for which the Data is accessed, collected and used by the Research Personnel in accordance with the Applicable Laws.
- (o) **"System Access Requirements"** means the rules and applicable procedures governing access to the Health Systems and collection, use and disclosure of the Data contained in the Health Systems, including the Netcare Information Exchange Protocol and the applicable Privacy Impact Assessment, as may be revised or amended from time to time.

2 Health System Access

- (2.1) **Access Request.** The Researcher may submit to AHS a Request for Disclosure, and AHS may, upon review and approval, grant access to the Health Systems to the Research Personnel. The collection and use of the Data shall at all times be subject to the System Access Requirements.
- (2.2) **Scope of Access.** The Researcher shall ensure that the Research Personnel access the Health Systems solely for the Permitted Purpose and in accordance with the System Access Requirements, AHS Policies, the Applicable Laws and any other conditions that may be imposed by AHS or the REB relating to the use, security, disclosure, disposal or return of the Data.
- (2.3) **System Credentials.** The Researcher shall not use the existing Health System credentials used by the Researcher in his or her capacity as a physician or other clinical service provider, for the purpose of delivering health services to access the Health Systems in order to (i) identify potential Study Participants, or (ii) collect contact information for the eligible Study Participants, or those who have agreed to be contacted for future studies, without AHS' prior written approval.
- (2.4) **Research Personnel Requirements.** If access to Health Information and/or Health Systems is required, the Researcher shall ensure that the Research Personnel complete the required privacy and security training and Health Systems training, as applicable, and execute the Confidentiality Agreement that shall be renewed annually for each year the access to the Health Systems or Health Information is required.
- 2.5 **Cost.** The Researcher shall be solely responsible for all costs associated with file retrieval, obtaining consents, data matching and any other services provided by AHS to the Researcher in connection with the Request for Disclosure.

3 Use of Data

- 3.1 **Use of Data.** The Researcher shall ensure that the Research Personnel use the Data solely for the Permitted Purpose and in accordance with the AHS Policies and the Applicable Laws and no other purpose, unless approved by AHS in writing in advance.
- 3.2 **Consent.** If required by AHS or the REB, the Researcher shall obtain the consent of the Study Participant prior to any use of the Data. The Researcher agrees that if consent to disclose the Health Information is sought from an individual other than the Study Participant, the Researcher shall ensure that any such individual is legally authorized to provide consent on the Study Participant's behalf, in accordance with the Applicable Laws.

- 3.3 **Restrictions on Use.** Unless specifically as part of the Permitted Purpose, the Researcher shall not:
- (a) use the Data outside of the Permitted Purpose without the express consent of AHS;
 - (b) use the Data for research activities using the Data for a commercial purpose; or
 - (c) provide or make available the Data for any purpose to a third party without the prior written consent of AHS.
- 3.4 **Subject Identification.** The Researcher further acknowledges that the Data has the potential to generate information that could potentially be used to identify an individual. The Researcher shall not:
- (a) use or disclose the Data in a form that may identify the Study Participant;
 - (b) attempt to re-engineer the identity of the Study Participant;
 - (c) perform data matching beyond the Permitted Purpose without the prior written consent approval of AHS;
 - (d) attempt to contact the Study Participant to obtain additional Health Information without the Participant's properly documented consent; or
 - (e) publish the Data in a form that could reasonably enable the identity of the Study Participant to be readily ascertained.
- 3.5 **Secondary Use of Data.** If the Researcher wishes to use the Data for a new research purpose, or make any modifications to the Study that affect the scope of access to the Health Systems, the Researcher shall submit an amended Protocol to the REB for approval and notify AHS of any such change. If required by AHS, the parties will cooperate with respect to the implementation of any required amendments to this Agreement.
- 3.6 **Third Party Disclosure.** In the event the Researcher is requested by AHS to disclose the Data to a third party for research purposes, the Researcher shall ensure that the Data has been de-identified in accordance with the AHS Non-Identifying Health Information Standard.
- 3.7 **Data Retention and Disposal.** At the request of AHS or upon completion of the Study, expiry or termination of this Agreement, the Researcher shall, at the option of AHS, (a) return all the remaining Data to AHS, as directed; or (b) securely destroy all remaining Data in its possession or control. The Researcher shall comply with the applicable data retention and data destruction policies of AHS and the University, and shall ensure compliance by the Research Associates.

4 Confidentiality and Security

- 4.1 **Confidentiality.** The Researcher undertakes to keep confidential and not disclose to any third parties the Confidential Information provided to the Researcher pursuant to this Agreement. The Researcher shall use the same degree of care to prevent the use or disclosure of the Confidential Information as it exercises in protecting its own information of similar nature, and use appropriate safeguards to prevent any unauthorized use or disclosure of the Confidential Information.
- 4.2 **Access to Data.** The Researcher shall limit access to the Confidential Information only to the Research Personnel who need access for the Permitted Purpose and who are bound by the terms and conditions of this Agreement. The Researcher shall ensure that all Research Personnel complete the necessary training regarding the security standards applicable to the Data. The Researcher shall not permit the Data processing or analysis to be subcontracted or otherwise performed by anyone other than the Research Personnel without AHS's prior written approval.
- 4.3 **Safeguards.** The Researcher shall implement and maintain appropriate administrative, technical and physical safeguards to ensure the security, protection and integrity of the Data, and to prevent unauthorized access to it. Such safeguards shall include, without limitation, replacing identifiers with study numbers and storing the master key that links this information separately from the data set, hard disk encryption technology implemented on any electronic devices containing the Data.

- 4.4 **Reporting.** The Researcher shall report to AHS any unauthorized access to, modification of, use, or unauthorized disclosure of the Data contrary to the Applicable Laws or AHS Policies, or breach of confidentiality or the security standards by the Research Personnel (the "Breach") of which the Researcher becomes aware. The Researcher agrees to investigate all Breaches and to cooperate with AHS in their respective mitigation, investigation, and remedial and disciplinary measures.
- 4.5 **Monitoring and Audit.** The Researcher acknowledges and agrees that the Research Personnel's Health System access, activity, user permissions and the use of the Data may be tracked, monitored and reviewed by AHS at its sole discretion. AHS may conduct audits of the Researcher's premises to ensure the Researcher's compliance with the privacy and security requirements and other terms of this Agreement.

5 Data Ownership

- 5.1 **Ownership.** The Researcher acknowledges and agrees that AHS shall remain the sole owner of all right, title or interest in or to the Data. The transfer of the Data does not constitute a transfer to Recipient of any right, title or interest in and to the Data, except the right to use the Data for the Permitted Purpose in accordance with this Agreement and the Applicable Laws.
- 5.2 **Publications.** The Researcher shall have the right to use the de-identified information and results arising out of analysis of the Data as part of a publication or presentation of the results of the Study, provided that such publication or presentation shall not disclose the Confidential Information without AHS's written approval. Any publication made pursuant to this Agreement shall acknowledge the contribution of AHS in accordance with the AHS Policies.

6 Limitation of Liability

- 6.1 **No Warranties.** The Researcher acknowledges and agrees that the Data is provided to the Researcher on an "as-is" basis. AHS makes no representation or warranty, whether expressed or implied, with respect to the Data, including any representation or warranty as to the suitability of the Data for the purposes of the Study or the non-infringement of the Data on the proprietary rights of a third party. Any use of the Data by the Researcher will be at the sole risk and liability of the Researcher, whether or not the Researcher has consented to such use.
- 6.2 **Limitation of Liability.** AHS shall not be liable or responsible for any any and all liability, losses, damages, claims, expenses, demands or judgments (the "Claims") that may arise from the Research Personnel's access to the Health Systems and the acceptance, use, handling, storage or disposal of the Data. The Researcher shall indemnify, defend and hold AHS and its employees, directors and officers harmless from any and all Claims which may arise in connection with the any breach by the Researcher of any term or condition of this Agreement.

7 Term and Termination

- 7.1 **Termination.** Either Party may terminate this Agreement for any reason following delivery of written notice sixty (60) days in advance of the proposed date of termination. In addition, AHS may terminate this Agreement without notice in the event of a Breach pursuant to Section 6 of this Agreement. Upon termination of this Agreement, the Researcher will discontinue the use of the Data and will, upon AHS's discretion, return or destroy any remaining Data.

8 General

- 8.1 **Amendments.** The Agreement and may be amended or varied in writing by a mutual agreement of the parties.
- 8.2 **Governing Law.** This Agreement shall be governed by the laws of the province of Alberta, excluding laws dealing with conflicts of laws. The parties irrevocably attorn to the exclusive jurisdiction of the courts of the province of Alberta.

- 8.3 **Survival.** The provisions of the Agreement which by their terms or intent survive the expiry of this Agreement, including the confidentiality obligations contain herein, will remain in effect and be enforceable following expiry of the Agreement.
- 8.4 **No Assignment.** The Researcher shall not assign any or all of its rights and obligations under this Agreement without AHS's prior written consent, which consent may be reasonably withheld.
- 8.5 **Entire Assignment.** This Agreement constitutes the entire agreement between the parties with respect to the subject matter and supersedes all prior negotiations and discussions.
- 8.6 **Counterparts.** The parties may execute this Agreement in counterparts, each of which will be deemed to be an original. The counterparts together will constitute one and the same instrument, notwithstanding that all of the parties are not signatories to the original or the same counterpart.
- 8.7 **Notices.** All notices, reports and formal communications will be in writing and may be delivered personally or sent by registered mail, email or fax to the following addresses (or such other address as the relevant party may notify from time to time):
For AHS:
Alberta Health Services - Systems Innovation & Programs
Email: Research.Administration@ahs.ca

Concurrent copy to: Alberta Health Services
Attention: Legal and Privacy
10301 Southport Lane SW
Calgary, AB T2W1S7
Facsimile: (403) 943-0907

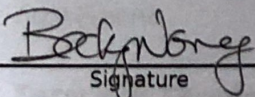
For the Researcher:
Email: low1@ualberta.ca
- 8.8 **Effective Date.** Notwithstanding the date on which this Agreement has been signed, the parties agree that the terms and conditions of this Agreement have been effective as of the Effective Date.

The parties have executed this Agreement on the date stated below.

ALBERTA HEALTH SERVICES

Becky Wong
Director, Health Systems Access

Name and Title



Signature

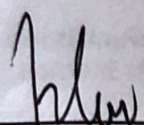
29-Mar-2022

Date

RESEARCHER (PRINCIPAL INVESTIGATOR)

Gavin Low

Name



Signature

29 MARCH 2022

Date

SCHEDULE A
AHS DATA REPOSITORIES

Name of Data Repository	Method Of Access
PACS-IMPAX	Direct
ConnectCare	Direct
Comments or Additional Considerations:	
No comment.	

SCHEDULE "B"

Additional Conditions

Where applicable, the Researcher shall ensure compliance by the Researcher and the Research Associates with the following conditions.

ITEM	CONDITION
Research Associates	The Researcher shall maintain an up-to-date list of the Research Associates for the Study approved by the REB.
Recruitment of Study Participants	<ol style="list-style-type: none"> 1) The Researcher shall not approach any potential Study Participant until an AHS employee has informed the patient of the Study and obtained the patient's consent to be approached by a member of the Research Personnel. 2) When there is an established care relationship between a physician and a patient, the physician in his/her role as a researcher must have an intermediary approach the patient regarding participation in a study. 3) With AHS's assistance through the AHS Operational Approval for Research Process, the Researcher will determine mechanisms/ intermediaries to: <ol style="list-style-type: none"> a) advertise the opportunity to participate in the Study; b) screen for/contact patients who may be eligible to participate in the Study; and c) obtain permission for the Researcher to discuss the Study with a patient.
Direct Access to Health Systems	<ol style="list-style-type: none"> 1) The Researcher shall not use Health Systems, including Netcare, SCM or eClinican, credentials for the purposes of the Study without AHS' prior written approval. 2) To obtain Data from Netcare for research purposes, the Researcher must ensure that explicit consent has been obtained from the Study Participant and the Researcher must comply with the Alberta Health Netcare Information Exchange Protocol, including the specific conditions pertaining to research (http://www.albertanetcare.ca/Research.htm).
Personal Identifiers	<ol style="list-style-type: none"> 1) The Researcher shall remove personal identifiers from the Health Information and replace them with a study code to protect the confidentiality of the Study Participant. 2) The Researcher will ensure that the master list linking the study code to the Study Participant is: <ol style="list-style-type: none"> a) 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; and b) Only accessible to the Research Associates. 3) The Researcher shall keep and/or securely transmit master lists linking personal identifiers of the Study Participant to study codes separately from the database or paper records containing de-identified information. 4) The Researcher shall use the AHS Non-Identifiable Health Information Standard to help determine if the information is potentially identifiable.
Data Matching	<p>If AHS or the Researcher are required to data match for research purposes, the following conditions apply:</p> <ol style="list-style-type: none"> 1) AHS or the Researcher shall data match the information from the sources in Schedule "A" in accordance with the REB approval letter. 2) AHS shall provide information in accordance with the following privacy principles: least amount of information, highest degree of anonymity and on a need-to-know basis. 3) AHS or the Researcher, as applicable, shall provide and store the Data in a secure manner and accordance with the AHS Policies and this Agreement.

ITEM	CONDITION
Data Storage, Transportation and Destruction of Paper Records	<ol style="list-style-type: none"> 1) The Researcher shall ensure that the Data collected in paper format is securely stored and destroyed in accordance with AHS Policies. 2) The Researcher shall ensure that data collection forms, other records or media are stored in locked filing cabinets in locked rooms with key access limited to the Research Personnel. 3) The Researcher shall ensure that briefcases or other secure record containers are used when paper records are carried by the Researcher or the Research Associates, or transported between collection areas and storage locations. 4) Should photocopying of paper records be required, the Researcher shall ensure: <ol style="list-style-type: none"> a) Only the relevant portion(s) of the chart are copied; b) Identifiable personal information is redacted and replaced with a study ID number; c) The photocopy is transitory and appropriately and securely destroyed once data collection is complete.
Data Storage in Electronic Format / Electronic Transmission	<ol style="list-style-type: none"> 1) The Researcher shall ensure that electronic data collected on computers or other devices, or transmitted outside of the AHS network are secured in accordance with the AHS Policies. 2) The Researcher shall store the Data on secure network drives, with access limited to the Research Personnel only, instead of on computer hard drives, whenever possible. 3) The Researcher shall ensure that laptops or other external hard drives are password protected and have encryption enabled software. The Researcher shall protect USB memory devices using AES-256 bit encryption, as password protection alone is not sufficient to protect information if a device is lost or stolen. 4) The Researcher shall ensure that knowledge of passwords/encryption keys is limited to research team members. If any passwords are to be recorded, the Researcher shall keep the passwords in a location separate from the study records or equipment. 5) The Researcher shall ensure that all data that is transmitted electronically utilizes a secure communication method, including but not limited to encrypted email, VPN/virtual private network or be entered directly to a secured server.
Transfer of the Data and/or Material	<p>If the Data and/or biological samples collected by the Researcher from AHS are required to be transferred to a third party for research purposes, and such Data has not been de-identified in accordance with the AHS Non-Identifying Health Information Standard, the Researcher shall contact AHS to request a Data Transfer Agreement and/or Material Transfer Agreement to be entered into by AHS and the third party.</p>
Alberta Health Data	<p>If Alberta Health data ("AH Data") is requested to be disclosed via AHS, Alberta Health approval is required for the disclosure of the AH Data. AH Data includes, but not limited to, PIN and Practitioner Claims data sets.</p> <p>Additional Alberta Health approval (facilitated by an AHS analyst) is required for updates to the Alberta Health dataset after initial disclosure.</p> <p>Details for AH Data disclosure will be documented in the Data Disclosure Schedule separately prepared by an AHS analyst and provided to Alberta</p>