

GLEN SATHER SPORTS MEDICINE CLINIC RESEARCH POLICIES AND PROCEDURES

All research and quality assurance projects being conducted in full, or partially, through the Glen Sather Sports Medicine Clinic (GSSMC), including studies in which the GSSMC is a recruitment site must obtain approval from the GSSMC Research Committee, sign a research agreement, and adhere to the following policies and procedures.

Please send all questions and study documents/materials to the GSSMC Research Office (gssmcresearch@ualberta.ca).

The GSSMC Research Proposal Summary form must be submitted to the Research Office at least one week in advance of the Research Committee's meeting or it will not be considered until the next research meeting.

1. DEFINITIONS (Apply to all research being performed at the GSSMC)

Glen Sather Sports Medicine Clinic Research Office: Inclusive of the Clinical Research Faciliator and designated staff.

GSSMC Research Committee: A committee tasked with assisting the Research Office in an advisory and operational capacity, with respect to the full range of GSSMC research, quality assurance and research-related knowledge translation activities. This includes approval of specific projects based on their fit with the capacity and strategic priorities of the GSSMC.

Principal Investigator (PI): To be consistent with on guidelines set out by tri-council funding policies a PI is an individual who will:

- Be responsible for the direction of the proposed research activities
- Assumes the administrative and financial responsibility for the grant or award
- Receive all related correspondence from GSSMC or indicate appropriate designate
- Is autonomous (has the freedom to act independently as opposed to represent the views and stance of some organization) regarding their research activities
- Has adequate time/experience to lead the proposed research project for the entire duration of the proposed research (including supervision of research staff &/or trainees) and will conform to institutional regulations concerning the conduct of research, the supervision of trainees, and the employment conditions of staff paid with GSSMC funding, if applicable.

Authorship: Authorship for all research projects undertaken with support of the GSSMC Research Office will follow the International Committee of Medical Journal Editors guidelines (<http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html>)

2. GSSMC RESEARCH OFFICE & COMMITTEE RESPONSIBILITIES

- 1.1 Shall only grant access to the GSSMC facility, staff, consultants patient populations and/or use and disclosure of health information held by the GSSMC for the purpose of research in accordance with:
 - 1.1.1 The **Alberta Health Information Act (HIA)**,
 - 1.1.2 The **Alberta Freedom of Information and Protection of Privacy Act (FOIPP)**,
 - 1.1.3 The **Universtiy of Alberta Research Ethics Board**, and
 - 1.1.4 Conditions set by the **GSSMC Research Committee**
- 1.2 May authorize, in accordance with section 1.1, access to the GSSMC facility, staff, consultants and patient populations to a PI for the purpose of research.
- 1.3 May authorize, in accordance with section 1.1, the disclosure of patient information held by the GSSMC on behalf of the custodians of the data (e.g., physicians) to a PI for the purpose of research.
- 1.4 Securely hold a copy of the current University of Alberta Ethics Board Approval (inclusive of renewals and amendments), ethics research proposal (inclusive of amendments and study information and consent forms) for all studies conducting research within the GSSMC.
- 1.5 Consider for approval all study posters, pamphlets and information sheets that will be posted or distributed within the clinic. This includes approval of the processes and manner in which these materials are posted and/or distributed.
- 1.6 Provide monthly updates to the GSSMC Operations Management Committee on the status of ongoing, upcoming and recently completed reseach projects.

3. PRINCIPAL INVESTIGATOR RESPONSIBILITIES

- 3.1 Be respectful of patients, clinic administration and support staff, clinicians, educators, and other researchers
- 3.2 Comply with the Alberta Health Information Act and all regulations made under it as well as any applicable federal legislation governing privacy, confidentiality and protection of patient information.
- 3.3 Comply with any specific conditions imposed by the University of Alberta Human Ethics Research Board and/or the GSSMC Research Committee.
- 3.4 Ensure that the GSSMC Research Office has a current copy of the University of Alberta Research Ethics Board Approval (inclusive of annual renewals detailing amendments and termination), ethics research proposal (inclusive of amendments to study operating procedures, recruitment materials and consent forms) for any studies involving research within the GSSMC (inclusive of PRAC). This information will be provided to the GSSMC Research Office within 7 business days of the update or amendment.
- 3.5 Ensure that any health information disclosed by the GSSMC or its patients is held securely and then returned, disposed of, or retained in accordance with applicable legislation and the Univesity of Alberta Policies.
- 3.6 Ensure that any health information disclosed by the GSSMC or its patients is only used for the purpose of their approved research project.
- 3.7 Ensure that materials for distribution to clinicians, adiminstrative staff or the public (inclusive of patients and their representatives) such as posters, pamphlets or information sheets are only shared after they, and the process by which they are to be disseminated, are approved by the Research Committee.
- 3.8 Ensure that the posting and/ or distribution of approved study posters, pamphlets or information sheets is coordinated through the GSSMC Clinical Research Facilitator and

GSSMC Research Office. As part of this process the PI will provide the GSSMC Clinical Research Facilitator with a brief email that can be sent to the staff and consultants of the clinic (through the Research Office) explaining the study.

- 3.9 Inform the GSSMC Research Committee (through the GSSMC Research Office) if the relationship with the GSSMC is to be terminated (e.g., such as removing the clinic as a recruitment site), regardless of whether the particular research project continues.
- 3.10 Provide the GSSMC Clinical Research Facilitator with monthly email updates (due on the 1st day of each month) on the progress of the research project including information about funding applications, project status (i.e., percent of recruitment completion), community engagement and/or dissemination activities (e.g., full citations of all publications, abstracts, presentations).
- 3.11 Acknowledge the contribution of the GSSMC facilities, staff, consultants, patients in all funding, ethics and dissemination activities (e.g., publications, presentations, reports).
- 3.12 Not publish or disclose any information that could reasonably identify an individual for whom that information applies.
- 3.13 Disclose all unauthorized access to information and all privacy breaches related to the GSSMC and University of Alberta as soon as the breach is identified.
- 3.14 Cooperate with any GSSMC or University of Alberta investigation and audits.
- 3.15 In situations in which the research project involves data linking, a PI shall have in place, and will provide the GSSMC Research Office with a copy of, a privacy assessment that sets out administrative practices, technical and physical controls, and departmental procedures for managing research requests and requested patient information.

4. FEES (Fee schedule to be created)

- 4.1 The GSSMC may charge a fee for:
 - 4.1.1 Preparing information for disclosure
 - 4.1.2 Obtaining the consents required as per the HIA, the University of Alberta and the University of Alberta Human Ethics and Research Committee
 - 4.1.3 Operationalizing agreed upon components of a research project including but not limited to scheduling, filing, scanning, and data collection.

5. HEALTH INFORMATION COLLECTION AND SHARING

- 5.1 The GSSMC is an interdisciplinary clinic with mandates for quality improvement, risk surveillance, preventive care, medication recall, observational research, performance monitoring and other forms of clinical inquiry. Thus, Primary Care Providers, Encounter Providers, and/or Supervising Providers have signed data sharing agreements to facilitate patient care and to allow an authorized designate of the GSSMC to conduct searches within the GSSMC EMR and generate reports of aggregate patient data.
- 5.2 Primary Care Providers, Encounter Providers, and/or Supervising Providers will be contacted by a designate of the GSSMC about any GSSMC EMR searches that include aggregate information about a patient for whom they have provided care. At that time the Primary Care Providers, Encounter Providers, and/or Supervising Providers will be able to revoke their consent to share patient data if they decide to do so.
- 5.3 A poster informing GSSMC patients about the use of their health information for quality assurance and research purposes will be displayed at the front desk and at all clinical work stations to ensure transparency. (**Appendix 1**).

APPENDIX 1: HEALTH INFORMATION POSTER

Your health information is collected and protected under the Alberta's Health Information Act



The Glen Sather Sports Medicine Clinic respects your confidentiality and privacy. Your information is collected, used, disclosed and protected according to the provisions of provincial and federal legislation.

Your health information is collected by the Glen Sather Sports Medicine Clinic in accordance with section 27(1) of the Health Information Act (HIA) (Alberta). The purpose of this collection is primary for:

- providing health services
- determining eligibility for health services
- processing payment for health services
- conducting research
- providing for health services provider education
- internal management purposes.

Information will be collected directly from you, except in the limited circumstances where we are authorized by the HIA to indirectly collect such information.

Questions related to the collection and privacy of your information should be directed to:

Gordana Brouillette
Office Administrator
780-407-5194