DEFINITIONS

Glen Sather Sports Medicine Clinic (GSSMC) Research Office: Inclusive of the Research Director and designated staff (e.g., clinical research scientist, clinical research coordinator, research assistant).

GSSMC Research Advisory Committee: A committee that acts in an advisory capacity, providing strategic direction to the GSSMC Research Director and Research Committee with respect to the full range of GSSMC research, and evidence-based clinical practice and educational activities.

GSSMC Research Committee: A committee tasked with assisting the Research Office with implementing research activities within the clinic. This includes such things as approving research projects, operationalizing participant recruitment and data collection.

GSSMC Health Information Governance Committee: A committee tasked with approving all requests to use GSSMC patient health information for research purposes.

Principal Investigator (PI): To be consistent with 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
- Is autonomous (has the freedom to act independently as opposed to represent the views and stance of some organization) regarding their research activities
- Has an academic or research appointment which must commence by the effective date of funding, allows the individual to pursue the proposed research project, to engage in independent research activities for the entire duration of the funding, to supervise trainees and to publish the research results and obliges the individual to conform to institutional regulations concerning the conduct of research, the supervision of trainees, and the employment conditions of staff paid with GSSMC funding.

Authorship: To be consistent with the International Committee of Medical Journal Editors an author is an individual who meets all of the following:

- Made a substantial contribution to the conception or design of the work, or the acquisition, analysis or interpretation of data.
- Contributed to drafting the work or revising it critically for important intellectual content.
- Gave final approval of the version published.
- Agrees to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

All authors should be able to identify which co-authors are responsible for specific other parts of the work. In addition, authors should have confidence in the integrity of the contributions of their co-authors. Participation solely in the acquisition of funding, the collection of data or general supervision of the research group does not justify authorship.
GSSMC RESEARCH POLICIES

Purpose

1. To define the requirements for conducting research within the GSSMC in terms of:
   - Participant recruitment
   - Data collection
   - Use of the clinics facilities [inclusive of any other facilities associated with the clinic such as the Prevention and Return to Activity Centre (PRAC) at Foote Field].
   - Data storage
   - Data management
   - Use and disclosure of patient health information
   - Role of research office support staff [inclusive of the GSSMC Clinician Scientist and Clinical Research Coordinator and Clinical Research Assistants].
   - Acknowledgement of GSSMC in dissemination activities.

2. To set out the regulations for use of the GSSMC patient health information in terms of:
   - Health Information Act requirements
   - Custodianship
   - Access to patient health information
   - Approvals

3. To define the role of the GSSMC research office [inclusive of the Clinician Scientist and Clinical Research Coordinator and Clinical Research Assistants].

Policy statement

The GSSMC is a clinical academic unit of the Faculty of Rehabilitation Medicine, University of Alberta. Under the direction of the Faculties of Medicine and Dentistry, Physical Education and Recreation and Rehabilitation Medicine, the GSSMC has a mandate to provide patient care, educate students (inclusive of clinical and research training at the undergraduate, graduate, resident, fellow and specialist level), and to participate in clinical sports medicine and musculoskeletal outcomes research.

The GSSMC (University of Alberta) is the administrator of all health information collected at the clinic, thus, it has a duty to protect the privacy and confidentiality of the aforementioned health information. The GSSMC is committed to use health information for quality improvement and research purposes provided it is in accordance to this policy, the Alberta Health Information Act (HIA), the University of Alberta Policies and Human Ethics Research Board, and in accordance with the GSSMC strategic research plan. Information shall only be used and disclosed by the GSSMC for research purposes for which these considerations have been made and for which University of Alberta ethics approval has been obtained.

Applicability

Compliance with this policy is required by all GSSMC staff, contract staff, consultants (inclusive of health professionals) and external researchers (both from within the University of Alberta and beyond). This policy is subject to all applicable laws.

Policy Elements

1. GSSMC Responsibilities

   1.1 The GSSMC Research Director in consultation with the Executive Director and the Academic Clinic Director, shall grant the use of the GSSMC facility, staff, and consultants, access to 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) and the Alberta Freedom of Information and Protection of Privacy Act (FOIPP); and
1.1.2 Conditions set by the GSSMC Research Committee and the University of Alberta Research Ethics Board.

1.2 The GSSMC Research Committee (through the Research Director in consultation with the Executive Director and the Academic Clinic Director) may authorize, in accordance with section 1.1, access to its facility, staff, consultants and patient populations to a PI for the purpose of research.

1.3 The GSSMC Health Information Governance Committee (through the office of the Research Director) 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 principal investigator (PI) for the purpose of research.

1.4 The GSSMC Research Office will ensure that in situations in which information held by the GSSMC is to be disclosed for research purposes a Research Agreement (see section 3) is in place between the GSSMC and the PI in accordance with the Alberta HIA and FOIPP.

1.5 The GSSMC research office will 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 its facility.

1.6 The GSSMC Research Committee (through the Office of the Research Director) must consider for approval all study posters, pamphlets and information sheets that will be posted or distributed within the clinic.

1.7 Upon receipt of proof of University of Alberta Research Ethics approval, appoint a representative of the GSSMC Research Office as decided upon by the GSSMC Research Director in consultation with the Executive Director, to contact and obtain consent from a current or past patient to be contacted about potential participation in the research study in question. Further, ensure that no independent PI, nor representative of a PI (e.g., trainees, co-investigator, collaborator, research coordinator or research assistant) contacts current or past patients without this consent to being approached having first been obtained.

2. Principal Investigator (PI) Responsibilities

2.1 Contact the GSSMC Research Office during the research planning stage on any research project (PI or trainee driven) in which the GSSMC facility, staff, consultant, patients or health records will be accessed.

2.2 Work with the GSSMC Research Office and Research Committee to outline mutually acceptable recruitment and data collection procedures, and address any budgetary considerations, as they apply to the GSSMC.

2.3 Complete all necessary data request forms and provide a copy of the most recent research proposal and its approval by the University of Alberta Research Ethics Board so that any request(s) can be adequately considered by the GSSMC Research Committee and Health Information Governance Committee.

2.4 Inform the GSSMC Research Committee (through the Office of the Research Director) of any changes to a study operating procedures as they pertain to the GSSMC within 7 business days.

2.5 Access GSSMC facilities, staff, consultants and patients in a respectful manner in accordance with the procedures outlined by the Research Committee (through the Research Office), this document, and keeping in mind that one of the mandates of the GSSMC is to provide patient care and thus no other mandate (education or research) will supersede it.

2.6 Enter into a Research Agreement (see section three) with the GSSMC in situations in which information held by the GSSMC is to be disclosed for research purposes in accordance with the HIA and FOIPP (Alberta).
2.7 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.

2.8 When appropriately requested and approved, anonymized health information will be disclosed through the GSSMC Research Office directly to the PI. The disclosed information will only contain the specific data elements delineated in the research proposal approved by the University of Alberta Research Ethics Board. Any additional information will only be released after submission of an updated research proposal and proof of ethics amendment approval(s) by the Research Ethics Board.

2.9 Researchers shall ensure that any health information disclosed by the GSSMC is held securely and then returned, disposed of, or retained in accordance with applicable legislation and the University of Alberta Policies.

2.10 Ensure that the ‘GSSMC Research Office’ has a current copy of the University of Alberta Research Ethics Board Approval (inclusive of renewals and amendments), 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 by the PI to the GSSMC Research Director within 7 business days of the update or amendment.

2.11 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.

2.12 Provide the GSSMC Research Committee (through the GSSMC Research Office) with a copy of the termination of ethics within 7 business days of receiving it.

2.13 Acknowledge the contribution of the GSSMC facilities, staff, consultants, patients in all funding, ethics and dissemination activities (e.g., publications, presentations, reports).

2.14 Provide the GSSMC Research Office with monthly updates (due by email on the 25th of each month) on the progress of the research project including information about successful funding, community engagement and/or dissemination activities (e.g., publications, abstracts, presentations).

3. Research Agreement

3.1 A research agreement between the GSSMC and PI is required in accordance with the HIA and FOIPP (Alberta), where information is to be disclosed by the GSSMC for research purposes.

3.2 Research agreements are not required for activities related to quality improvement, program evaluation, or education of health services providers.

3.3 Research agreements shall include:

   3.3.1 The name of PI and all PI affiliates (e.g. co-PI, coinvestigators, co-applicants, collaborators, research staff) who will have access to the requested information

   3.3.2 The name of a GSSMC designate (Executive Director, Clinical Academic Lead and/or Research Director).

   3.3.3 A copy of the research proposal

   3.3.4 The University of Alberta Research Ethics Board application and approval letter

   3.3.5 A list of specific data elements being included in the proposal

   3.3.6 A list of additional information that will be collected from research participants

   3.3.7 A statement about whether data matching will occur or not.

3.4 By signing a research agreement with the GSSMC, researchers authorized to collect, use or receive information for research purposes agree to:
3.4.1 Comply with applicable legislation and all conditions imposed by The GSSMC and obtain the approval and comply with imposed conditions of the University of Alberta Human Ethics Research Board.

3.4.2 Ensure the safety and confidentiality of all information in their possession

3.4.3 Only use information for the purpose of their approved research project

3.4.4 Cooperate with any GSSMC or University of Alberta investigation and audits

3.4.5 Disclose all unauthorized access to information and all privacy breaches to the GSSMC and University of Alberta as soon as the breach is identified

3.4.6 Not publish or disclose any information that could reasonably identify an individual for whom that information applies.

3.4.7 Be respectful of patients, clinic administration and support staff, clinicians, educators, and other researchers.

4. Fees

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.

GSSMC RESEARCH PROCEDURES

1. GSSMC Research Office: It is a responsibility of the Research Office to ensure that the policies outlined in this document are upheld. Specifically;
   1.1 Develop an administrative structure that will facilitate the research needs of the GSSMC. Including the initiation and administration of the GSSMC Research Advisory, Research and Data Governance committees (see below).
   1.2 Develop and implement a GSSMC Strategic Research Strategy, in consultation with the Research Advisory Board, which outlines the vision, mandate, goals (priorities), 5-year deliverables and description of priority areas of strength and leadership in sport and exercise-based musculoskeletal and sports medicine care research.
   1.3 Ensure that all research undertaken at the clinic addresses a gap in knowledge and therefore has potential to be impactful and falls within the scope of the GSSMC research strategy (e.g., fits the research needs of the GSSMC).
   1.4 Facilitate interdisciplinary collaboration in key priority areas of strength, and emerging strength, across clinic disciplines, faculties as well as research, academic and healthcare institutes (provincially / nationally)
   1.5 Put in place infrastructure support to facilitate the development of clinician researchers and inter-professional clinical research teams at the GSSMC.
      1.5.1 Coordinate with PI’s early and often throughout their proposed research projects to ensure maximal success of all research undertaken at the clinic. This may include seeking input from the GSSMC Operations Advisory Committee, Executive Director, Academic Clinic Director.
      1.5.2 Guide and reinforce to researchers the necessary requirements for health research including Human Ethics Research Board approval, service providers Administrative approvals (e.g. AHS, Covenant Health) and Operational Approval (e.g NACTRAC, AHS, Covenant Health).
1.5.3 Guide and facilitate the identification and application processes of potential funding agencies

1.6 Work with the GSSMC Research Committee to coordinate research with clinic workflow (e.g. will the research impact the number of participants that clinicians can see in their typical schedule, and how will this be accomodated)..

1.7 Guide and facilitate knowledge dissemination of research studies

1.8 Provide monthly updates to the GSSMC Operations Management Committee on the status of ongoing, upcoming and recently completed research projects.

1.9 To promote research activities and findings of GSC research to the general public, community based providers, policy and decision makers at the local and provincial level.

2. GSSMC Research Committees: Three research committees will ensure that all levels of this policy are achieved.

2.1 GSSMC Research Advisory Committee (RAB): This committee will act in an advisory capacity to the GSSMC Research Director and Research Committee, with respect to the full range of GSSMC Research and educational (e.g. research trainees, public engagement) activities.

2.1.1 The RAB will give specific attention to:

2.1.1.1 Assisting the Research Director and Research Committee with the development and implementation of the GSSMC’s Strategic Research Plan and the establishment of research priorities and knowledge translation strategies for the GSSMC.

2.1.1.2 Assisting the Research Director and Research Committee with the development and implementation of the GSSMC’s Research Impact Assessment Strategy.

2.1.1.3 Encouragement of interdisciplinary, integrative musculoskeletal and sport medicine health research, including partnerships, community links, engagement of other relevant stakeholders, and development and implementation of knowledge translation strategies to accelerate beneficial applications of research findings.

2.1.1.4 Communication of the GSSMC’s activities to the research community and to the public.

2.1.1.5 Annual evaluation of GSSMC’s research performance and reporting to the GSSMC Clinical Management Committee (made up of Deans or representatives) on success in meeting the research objectives set out for the GSSMC, Faculties of Physical Education and Recreation, Rehabilitation Medicine, and Medicine and Dentistry, and the University of Alberta. In particular, the GSSMC’s progress in the development of strength across the full breadth of the areas of research strength outlined in the research strategy and in the creation of an integrated clinical MSK and sport medicine research agenda in the areas of the GSSMC’s mandate.

2.1.1.6 Application of an ethical framework to all GSSMC activities and research

2.1.1.7 Any other matter, which may be referred to the RAB by the Research Director and Research Committee.

2.1.2 Membership and Terms

2.1.2.1 The RAB will consist of no more than 10 members including the Chair and the Vice-Chair.
2.1.2.2 The Chair will be appointed by the Dean of Rehabilitation Medicine with the advice from the Deans of Physical Education and Recreation, and Medicine and Dentistry.

2.1.2.3 The Vice-Chair is elected by the RAB.

2.1.2.4 All RAB members shall serve in a personal capacity and not represent a particular constituency.

2.1.2.5 Membership will reflect, to the greatest extent possible, the diversity of Alberta and Canada's health research community and society.

2.1.2.6 Membership will include researchers reflective of the highest standards of excellence across the fields of clinically based musculoskeletal and sports medicine outcomes-based research including the priority field of knowledge translation.

2.1.2.7 The GSSMC Research Director is a non-voting, ex-officio member of the RAB, and not eligible to serve as its Chair or Vice-Chair. GSSMC Research Committee members, while not eligible to serve as RAB members, may attend any meeting of an RAB.

2.1.2.8 Members shall be invited to serve an initial term of up to three years and may be re-appointed for a second term of up to three years, for a maximum of six consecutive years of service on the RAB. In order to maintain continuity, after the first three years appointments will be staggered so that one-third of members will be considered for replacement or re-appointment each year.

2.1.2.9 Meetings will be held three times annually at the call of the Chair, following consultation with the GSSMC Research Director.

2.2 GSSMC Research Committee: Members of this committee will be tasked with assisting the Research Office with implementing research activities within the clinic. This includes; approving research projects, operationalizing participant recruitment and data collection etc.

2.2.1 The Research Committee will evaluate research projects proposed by internal and external investigators in order to assess the;

2.2.1.1 Suitability of the proposed research with respect to

- the GSSMC strategic research plan
- the ongoing research and clinical populations available at the GSSMC
- the clinical expertise of the staff and clinical consultants at the GSSMC

2.2.1.2 Impact, barriers and enablers of the research related to;

- administrative or clinical staff
- clinical space
- conflicts of interest
- affect on the Clinic’s revenue generation
- clinical practice patient care

2.2.1.3 Address issues that may arise from research projects

2.2.2 Membership and Terms

2.2.2.1 Members will include: the GSSMC Research Director, Executive Director, Academic Clinic Director, GSSMC Clinical Research Scientist; one nominated representative from each clinical department (e.g.
Orthopedic Surgery, Physical Therapy, Primary Care Sport Medicine and Exercise, Varsity Health).

2.2.2.2 The Research Committee will meet at the discretion of the Research Director, but at least once every 3 months (quarterly) and minutes of all meetings will be kept.

2.3 **GSSMC Health Information Governance Committee**: Members of this committee will be tasked with approving all requests for patient health information held by the GSSMC.

2.3.1 Responsibilities of the GSSMC Health Information Governance Committee will include;

2.3.1.1 Developing policies, procedures on the use and sharing of patient health information held by the GSSMC for research purposes

2.3.1.2 Evaluating research projects proposed by internal and external investigators in order to identify projects to which patient information can be shared based on the relevance of the work, feasibility, risk impact assessment and overlap of research studies.

2.3.2 Membership and Terms

2.3.2.1 Members will include: GSSMC Research Director, Executive Director, University of Alberta Health Information Privacy Advisor (or designate), a clinician from one of the service units.

2.3.2.2 Participation in this committee percludes participation in the GSSMC Research Committee with the exception of the GSSMC Research Director.

2.3.2.3 The Committee will meet as needed (once proposals have been presented or issues have arised) but not more than once per month at the discretion of the Research Director.

3. **Procedures for conducting research at the GSSMC**: These procedures apply to all research activities within the GSSMC including but not limited to patient recruitment, poster displays, data collection, access to patient information held by the GSSMC.

3.1 Prior to initiating any research activities at the GSSMC, all internal and external PI’s are required to submit their research for approval by the Research Office and Research Committee. The approval process has five steps.

3.1.1 **Step 1** - complete a GSSMC Research Summary Form *(Appendix 1)* and submit it along with the principal investigators Canadian Common CV to the GSSMC Research Office (through the office of the Research Director) for consideration. This form provides basic information about the proposed research.

3.1.1.1 To minimize the time required to acquire GSSMC Research Committee approval and the need for changes to data collection procedures and associated ethics amendments, PI’s are highly encouraged to present this form for consideration in the study design phase.

3.1.1.2 The GSSMC Research Office will make decisions on the complexity, feasibility and impact of the study on clinic operations based upon the GSSMC Research Summary Form and will either decide to accept, reject, or request revisions or further information.

3.1.1.3 At this stage, research projects may be rejected if outside the scope of the GSSMC strategic plan, overlap with other ongoing research projects in terms of patient populations and/or clinician availability or are incomplete.
3.1.1.4 If accepted, the research will be presented to the GSSMC Research Committee for consideration.

3.1.1.5 The GSSMC Research Committee with review the GSSMC Research Summary Form and decide to accept the research as proposed, reject or request revisions or further information based on the impact of the study on clinic operations.

3.1.1.6 Studies may be rejected based on scope, clinic impact, rationale, concept, data collection, recruitment procedures or timeline.

3.1.1.7 A full research proposal may be requested at this stage before studies that require a larger commitment from the GSSMC such as clinicians involvement, use of the facilities for data collection, involvement of administrative staff or that require modification of such (e.g. randomized controlled trials, interventions studies) may be considered.

3.1.1.8 A written decision of the GSSMC Research Committee review will be communicated to the PI in a timely fashion.

3.1.1.9 GSSMC’s Operations Advisory Committee will be informed about all studies that receive approval by the GSSMC Research Committee.

3.1.2 **Step 2** – Upon approval by the Research Committee, PI’s will complete and submit a full Research Proposal Form (Appendix 2) to the GSSMC Research Office (through the office of the Research Director) for consideration.

3.1.3 **Step 3** – A meeting between the PI (including research designates) and GSSMC Research Office will be arranged to discuss the proposal and in particular how the study will be operationalized within the GSSMC.

3.1.3.1 PI’s should be prepared to answer questions on the operationalization of the study within the clinic. The goal of this meeting will be to ensure that all aspects of how the study will be operationalized within the clinic are addressed in a mutually beneficial manner such that the PI can submit for ethics approval.

3.1.4 **Step 4** – Complete and submit an ethics proposal to the University of Alberta Research Ethics Board and sight a research agreement with the GSSMC.

3.1.4.1 Once ethics approval has been acquired, a copy of the approval and full ethics application outlining the processes that have been approved must be provided to the GSSMC Research Office.

3.1.4.2 Once ethics is in place the PI will be asked to sign a research agreement with the GSSMC (Appendix 3)

3.1.4.3 The GSSMC’s Operations Advisory Committee will be informed of all studies that have been approved including timeline and how the study will be operationalized within the clinic.

3.1.5 **Step 5** – Conduct and complete research.

3.1.5.1 All PI’s conducting research within the GSSMC must provide the GSSMC Research Director with monthly updates (due by email on the 25th of each month) on the progress of the research project including information about successful funding, community engagement and dissemination activities (e.g., publications, abstracts, presentations). This information will be shared with the GSSMC Operations Advisory Committee on a monthly basis.

3.1.5.2 Materials for distribution to clinicians, administrative staff or the public (inclusive of patients and their representatives) such as posters and flyers may only be shared after approval by the Research Office and the
GSSMC Executive Director. Prior to sharing or posting, an email should be sent to all staff of the Clinic (through the office of the Research Director) explaining the study and what is needed from the Clinic staff.

4. Health Information Collection and Sharing

4.1 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 may sign a data sharing agreement (Appendix 4) 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.

4.2 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.

4.3 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 5).
APPENDICIES

Appendix 1: GSSMC Research Summary Form
Appendix 2: GSSMC Research Proposal Form
Appendix 3: Research Agreement (adapted from AHS)
Appendix 4: Data Sharing Agreement (adapted from AHS)
Appendix 5: Health Information Poster (adapted from AHS)
APPENDIX 1: GSSMC RESEARCH SUMMARY FORM

THIS FORM MUST BE COMPLETED AND RETURNED TO THE GSSMC RESEARCH OFFICE.

THIS FORM WILL BE REVIEWED BY THE RESEARCH OFFICE AND THE RESEARCH COMMITTEE.

THE FOLLOWING IS A LIST OF ITEMS THAT THE RESEARCH OFFICE AND RESEARCH COMMITTEE WILL CONSIDER WHILE MAKING THEIR DECISION.

1. The primary mandate of the GSSMC is patient care and this needs to be kept in mind when approving any research involvement at the clinic. Does the proposed research impact this mandate in a negative manner?
2. Does the proposed research align with the research strategy of the GSSMC?
3. Does the proposed research address a knowledge gap and therefore have the potential to be impactful.
4. Does the proposed research involve multiple sites?
5. Does the proposed research involve trainees?
6. How does the proposed research impact the administrative or clinical staff (e.g. will administrative or clinical staff have to perform any tasks; if so, when, frequency, duration; who will perform them; who will pay for them to perform them)?
7. How does the proposed research impact the use of the clinic space (any recruitment and or intervention will need to be coordinated with existing clinics, classes etc.)?
8. How might the proposed research impact the revenue generation of the clinic?
9. How will the proposed research impact the current clinic workflow (e.g. will the study impact the number of participants that a clinician can see in their typical schedule, if so how will we accommodate for this)?
10. How will the proposed research coordinate with clinicians to ensure that they understand their role in the research etc?
11. How will the proposed research impact current research underway in the GSSMC?
12. Does the proposed research follow procedures consistent with ethics approval from the University of Alberta?

*It is important that all potential barriers are identified and a plan to address them is in place at the proposal stage (prior to ethics or funding application) of the research. The reason for this is that these barriers, and the proposed solutions, will have implications on methodology (particularly, recruitment, data collection and intervention) and budget.

*These considerations are relevant to any research being conducted at the GSSMC inclusive of the Prevention and Return to Sport Centre (PRAC).
GSSMC RESEARCH SUMMARY FORM

Date:

Research Proposal Title:

Name(s) of Principal Investigator (note this cannot be a trainee):

Name(s) of co-investigators, trainees, research staff:

Please provide a summary of your research by answering the questions below. Use size 12 font and limit your summary to 2 pages.

1. Why is this study relevant to GSSMC? (e.g. How will the study improve the care or clinical outcomes of patients with ambulatory MSK/sports medicine and exercise disorders? Consider how it fits with the GSSMC Research Strategy).

2. In a few words explain the gap in the literature that this research will address.

3. What is the study design?

4. What patient population does the study involve?

5. What will be the role of GSSMC administrative (inclusive of the research office) and clinicians in the study?

6. Describe why this project is feasible to conduct at the GSSMC. What resources are required to complete this project (e.g. data sources, access to participants, etc.)?

7. What is your recruitment plan?

8. What is the timeline of the project?

9. Is funding being applied for and if so what is the agency and amount requested?

10. Outline how the study will alter normal patient management (e.g., whether patients will be asked to do anything beyond routine care) and clinic workflow.

* Evidence of ethical approval from the University of Alberta Health Research Ethics Board will be required of any study conducted at the GSSMC.

☐ I acknowledge that I have read, understood and will abide by the GSSMC Research Policies and Procedures Document.

Signature of the Principal Investigator

PLEASE EMAIL A SIGNED COPY OF THIS FORM TO THE GSSMC RESEARCH DIRECTOR

(Dr. Jackie Whittaker, jwhittak@ualberta.ca)
APPENDIX 2: GSSMC RESEARCH PROPOSAL FORM

GSSMC RESEARCH PROPOSAL FORM

1. RESEARCH TEAM DETAIL

A. Principal Investigator(s)
Name, post held, institution, address, telephone, email

B. Research Team
Name, post held, institution, address, telephone, email

2. PROJECT TITLE


3. SPECIFIC RESEARCH QUESTION

Should be well defined, important, relevant, and answerable by the proposed methodology
PICO: Patient population, interventions (if applicable), comparison, outcome.


4. RELEVANCE TO GSSMC

How do you think your research will impact clinical care or outcomes at the GSSMC or the management of ambulatory patients with musculoskeletal or sports medicine and exercise conditions?


5. LITERATURE REVIEW

What is known about this subject? What is the gap in the literature? Provide a brief summary (200 words) of findings with key references (references not included in word count).


6. METHODS

A. Study Design
Summarize the design and describe if the project is quantitative, qualitative or mixed.
B. Population/ Sample
Describe the target population and sample. Will the project require recruitment of participants at GSSMC? If so, who do you wish to recruit and how do you propose this will be done? How many participants are needed? Inclusion/exclusion criteria? Please include a sample size calculation.

C. Measures and Data Collection
Describe the specific information you will need to complete the study, why you require this data, and how you plan to gather it. Will you require access to patients or patient files? If so, what specific data elements are needed? Specify variable names.

D. Analysis Plan
Briefly describe the statistical strategy or qualitative analysis to be used. Will you require input from a statistical consultant?

7. ETHICAL CONSIDERATIONS
Any study that involves altering normal patient management or asking patient to do anything beyond routine care (even completing a questionnaire) needs Ethics Committee approval.

8. PROJECT PLAN
Include timelines, required Clinic resources and deliverables. Is any funding being sought for this research? How will the materials required (e.g. data collection sheets, computers, databases) be funded? Have travel costs been considered? Note: Any involvement of clinic administrative staff and/or clinicians may have a cost involved.

9. KNOWLEDGE TRANSFER
Identify key user groups or potential audiences that would be interested in these research findings. Identify how you will increase the usability and transferability of your findings.

PLEASE EMAIL A SIGNED COPY OF THIS FORM TO THE GSSMC RESEARCH DIRECTOR
(Dr. Jackie Whittaker, jwhittak@ualberta.ca)
APPENDIX 3: RESEARCH AGREEMENT

Research Agreement

between

The Glen Sather Sports Medicine Clinic (GSSMC)

and

Insert Name of Principal Investigator

(Referred to as “the Researcher”)

Regarding

Insert Title of the Research Proposal

INTRODUCTION

1. Names of the parties to this agreement

   Insert Name of Principal Investigator
   GSSMC Executive Director
   GSSMC Clinical Academic Lead
   GSSMC Research Director
   Identify the GSSMC Service Providers(s)
   Identify the GSSMC Service Providers(s)
   Identify the GSSMC Research staff (e.g., Clinical Research Scientist, Research Coordinator etc.)

2. The Researcher has applied to the Glen Sather Sports Medicine Clinic to access GSSMC patient(s), provider(s) or facilities and/or for the disclosure of health information for the research purposes described in the Researcher’s proposal.

RESPONSIBILITIES OF THE RESEARCHER

3. The Researcher agrees;

   a. To comply with the Health Information Act and all regulations made under it as well as any applicable federal legislation governing privacy, confidentiality and protection of patient information. HIA section 54(1)(a)(i)

   b. To comply with any conditions imposed by The GSSMC and University of Alberta as per their policies and regulations relating to the collection, use, protection, disclosure, return or disposal of the health information. HIA section 54(1)(a)(ii), GSSMC Research Policies and Procedures.
c. To comply with any requirements of The GSSMC to provide safeguards against the identification, direct or indirect, of an individual who is the subject of the health information. *HIA section 54(a)(a)(iii)*

d. Not to make any attempt to contact an individual who is a patient of the GSSMC and is the subject of the health information to obtain additional identifiable health information unless The University of Alberta Human Ethics Research Board has approved and the individual has provided the custodian with the consent required as part of section 55 of the Health Information Act. *HIA sections 54(1)(d) and 55*

e. No 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. *HIA section 54(1)(c)*

f. To allow The GSSMC to access or inspect the Researcher’s premises to confirm that the Researcher is complying with the *Health Information Act* and *Health Information Act Regulations*, any imposed conditions on use, protection, disclosure, return or disposal of the information and any requirements related to the provision of security safeguards. *HIA section 54(1)(e)*

g. To pay the costs associated with file retrieval, obtaining consents (*section 55 of the Health Information Act*), data matching, and any other services provided by The GSSMC to the Researcher in connection with the request for disclosure of health information described herein. *HIA sections 54(1_(2) and 55*

h. To report to the GSSMC any breaches of confidentiality and/or security respecting the information from the records at the facility immediately upon identification of such breaches, and to take steps to both remedy the breach and prevent similar occurrences in the future.

i. To securely disposed or return to the GSSMC any personally identifying information as set out in section 9 and 10 herein.

j. To use the research information only for purposes identified in the Researcher’s proposal as described in Schedule A. *HIA section 54(1)(b)*

k. Not to use or disclose the information for any subsequent or other purposes not identified in Schedule A without the prior written approval of the GSSMC, and, if required by the University of Alberta Human Research Ethics Board, the consent of the individual who is the subject of the information.

l. To notify all individuals on the research team that have access to the health information that they must comply with the *Health Information Act* and regulations and with any conditions imposed by the GSSMC as set out in this Agreement.

m. To acknowledge in the publication that the GSSMC was one of the sources of information for this study.

**RESPONSIBILITIES OF THE GLEN SATHER SPORTS MEDICINE CLINIC**

4. The GSSMC agrees to disclose the health information or data in the specific format as outlined in Schedule A and in compliance with any conditions required by the University of Alberta Human Ethics Research Board.
5. The GSSMC shall provide other services to facilitate the research allowed by the University of Alberta Human Ethics Research Board as itemized in Schedule D.

6. The GSSMC agrees to maintain the research proposal as confidential.

GENERAL PROVISIONS

7. This agreement may be amended or varied in writing with the mutual agreement of the parties

TERMINATION OR TRANSFER OF AGREEMENT

8. This agreement may be terminated by either party at any time subject to the following conditions:
   a. Written notification with up to two notice if appropriate
   b. All research data collected will be kept by the Researcher and subject to the conditions in this document regarding the safeguards and disposition of health information.

9. In the event the agreement is breached by Researcher and/or health information is disclosed or used in contravention of the terms and conditions of the agreement or the Health Information Act or the regulations, the agreement may be immediately terminated by the GSSMC. HIA section 54(4). The GSSMC may withdraw the research privileges of the Researcher and will require that all individually identifying health information that has been disclosed for the research purpose be returned to the GSSMC.

10. Upon expiration of the time period for which the Researcher must retain the health information to comply with relevant legislation, policies and procedures, the Researcher must return or dispose of the health information provided by the GSSMC and any copies made thereof by the Researcher. Should the GSSMC agree to the disposition rather than its return, the researcher shall provide the GSSMC with a letter that confirms the date and the means of disposition.

11. The Researcher agrees to obtain authorization from the GSSMC prior to the transfer of the agreement to another person. Authorization may be withheld at the discretion of the GSSMC. Successors shall be bound by the terms and conditions of this Agreement.

By my signature hereunder, I AGREE to be bound by the terms and conditions herein.

Researcher (Principal Investigator) on behalf of co-PI, co-investigators, co-applicants, collaborators, and research staff who will have access to the requested information.

__________________________________________________
Name

__________________________________________________
Signature

__________________________________________________
Date
List of co-PI, co-investigators, co-applicants, collaborators and research staff that will have access to the requested information (please attach additional pages if needed).

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Glen Sather Sports Medicine Clinic

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ATTACHMENTS REQUIRED

**SCHEDULE A: A copy of the research proposal**
A copy of the research proposal along with the amendments.

**SCHEDULE B: A copy of the University of Alberta Human Ethics Research Board application**
Provide a copy of the latest full ethics application (including last amendments).

**SCHEDULE C: A copy of the University of Alberta Human Ethics Research Board approval**
Provide a copy of the original and amendment approval letter(s).

**SCHEDULE D: A list of required data elements**
A list of requirements from the GSSMC.
**SCHEDULE E: Additional conditions**

This is an optional schedule where The GSSMC can request additional detail for the research agreement. Examples include, statement of fees, additional information on security and privacy controls to protect health information including a signed Confidentiality Agreement if the Researchers is provided access to GSSMC network for this specific research proposal.
APPENDIX 4: DATA SHARING AGREEMENT

GLEN SATHER SPORTS MEDICINE CLINIC ELECTRONIC MEDICAL RECORDS (EMR)

GROUP DATA SHARING ACKNOWLEDGMENT

The Glen Sather Sports Medicine Clinic (GSSMC) is an interdisciplinary clinic where one individual patient may be cared for by a number of healthcare providers. The sharing of patient information through the GSSMC EMR (Health Quest) optimizes patient care within this interdisciplinary environment. In addition to facilitating patient care the sharing of health information facilitates quality improvement, risk surveillance, preventive care, medication recall, observational research, performance monitoring and other forms of clinical inquiry.

Without a data sharing agreement in place information about a patient cannot be shared beyond authorized provider(s) (e.g., Primary Care Provider, Encounter Provider, Supervising Provider and/or Patient Care Team) who have a health care relationship with an aforementioned patient.

The GSSMC Health Information Governance Committee (see GSSMC Research Policies and Procedures, Research Procedures, Section 2.3) is responsible for approving access and use of health information held by the GSSMC for any purpose other than patient care, inclusive of and not limited to; quality improvement, risk surveillance, preventive care, medication recall, observational research, performance monitoring and other forms of clinical inquiry.

By signing this document, you and your affiliates acknowledge for any designate of the GSSMC, upon authorization from the GSSMC Database Governance Committee, may conduct searches within the GSSMC EMR including your patient’s health files. All health information will be used in accordance with the Alberta Health Information Act and the Alberta Health Information Act Regulations.

By signing this document you acknowledge that:

- All present and future designates of the GSSMC, upon authorization from the GSSMC Database Governance Committee, will be able to conduct searches within the GSSMC EMR that aggregate patients including patient for whom you have been the Primary Care Provider, Encounter Provider, and/or Supervising Provider.
- You will be contacted by a designate of the GSSMC about any GSSMC EMR searches that include aggregate information about patient for whom you have been the Primary Care Provider, Encounter Provider, and/or Supervising Provider. At that time you will be able to revoke your consent to share patient data if you decide to do so.

Name of Health Care provider: ____________________________________________
(please print)

Signature: ________________________ Date: ____________________________
APPENDIX 5: 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:

Louisa Pothier
Executive Director
780-407-5189