

Operating Guidelines Manual  SSCY Centre <small>Specialized Services for Children & Youth</small>	Guideline Name: Research and Program Evaluation Access	Number: 10.30.20	Page 1 of 7
	Section: Quality and Research	Approval Level: SSCY IWG	
	Date: June 20, 2016	Supercedes: New	

PREAMBLE

Applied research shares many features with good clinical practice, because both activities involve systematic attempts to discover principles or relationships or to examine the effects of known principles or relationships, in order to improve the condition of patients, clients or participants. Applied research differs from clinical practice in that research participants experience procedures which go beyond the participant's need for prevention, diagnosis or treatment, or which may invade their privacy. For these reasons, while the Specialized Services for Children and Youth (SSCY) Network and Centre support and encourage applied research, all proposed research is reviewed in order to ensure that the welfare, rights and dignity of participants are safeguarded.

Researchers retain full responsibility for obtaining consent from and protecting the welfare, rights and dignity of participants, at all times, by adhering to the exact conditions of the approved research proposal, all other guidelines of SSCY Centre and impacted partners, ethical standards of their professions concerning the conduct of research and by obtaining approval for the research from an appropriate university-based Research Ethics Board (REB) in accordance with the Tri-Council Policy Statement on *Ethical Conduct for Research Involving Humans*.

The SSCY Network is an alliance of government departments, the Winnipeg Regional Health Authority (WRHA) and various service provider agencies, and consists of both co-locating and non co-locating partners. SSCY Centre, located in Winnipeg at 1155 Notre Dame Ave., houses the co-locating partners. **The SSCY Research and Evaluation Committee is responsible for reviewing and approving proposals for all research that is conducted at SSCY Centre (including recruitment and data collection), involves electronic medical records covered by the SSCY Data Sharing Agreement, or that is about the SSCY Network.** For research conducted at a SSCY Network partner facility that is not SSCY Centre, the PI is responsible for obtaining all required approvals. The PI may consult with the SSCY Research and Evaluation Committee for clarification or guidance regarding which approvals are required and how to obtain them.

Knowledge translation and exchange is an important component of research at SSCY Centre; therefore researchers will be expected to share results appropriately with a variety of stakeholders. Stakeholder audiences can include SSCY Centre clients, families or therapists, members of the SSCY Network, policy makers, other researchers and interested community members. Knowledge translation and exchange activities at SSCY Centre should be tailored to the audience, be framed in the context of other research in the field, and explore the implications for SSCY Centre and /or stakeholders when appropriate. In this way, SSCY Centre will help foster an atmosphere of communication and collaboration between stakeholders and researchers to maximize the impact of relevant research. Information regarding past, ongoing and future research projects may be shared at SSCY Centre and on the SSCY Network website.

PURPOSE

1. To ensure that research conducted at SSCY Centre (including recruitment or data collection), with electronic medical records covered by the SSCY Data Sharing Agreement, or about the SSCY Network is consistent with SSCY Network's mission and values, and maintains the highest ethical and academic standards. Gaining new knowledge through research is considered an integral and valued component of the clinical activities at SSCY Centre.
2. To affirm and support research intended to create new generalizable knowledge that supports evaluation and enhancement of health care, while respecting academic freedom and the right to publish without interference.
3. To promote partnerships between qualified researchers and SSCY Centre in order to conduct research that supports children and youth with disabilities and/ or special needs.
4. To ensure that Research, Quality Improvement and Program Evaluation projects are conducted at SSCY Centre in accordance with accepted ethical and regulatory standards. This guideline shall apply to all potential researchers both internal and external to the SSCY Network.
5. To provide guidance to individuals in determining what approvals are required in order to conduct Research, Quality Improvement and Program Evaluation projects at SSCY Centre, and to provide assistance as required throughout the project lifespan.

DEFINITIONS

SSCY Network: Specialized Services for Children and Youth (SSCY) is an initiative focused on the integration and, where possible, co-location, of services for Manitoba children and youth with disabilities and special needs. The SSCY Network is an alliance of government departments, the Winnipeg Regional Health Authority (WRHA) and various service provider agencies, and consists of both co-locating and non co-locating partners.

SSCY Centre: The SSCY Centre is a building that houses the co-locating partners of the SSCY Network. Children and youth can receive a variety of specialized services at the SSCY Centre. The SSCY Centre is located at 1155 Notre Dame Ave, Winnipeg, Manitoba.

SSCY Data Sharing Agreement: All co-locating partners in the SSCY Network are bound by a Data Sharing Agreement which governs the protection and sharing of client personal information and personal health information. All research conducted at SSCY Centre must be conducted according to this Data Sharing Agreement.

Research: A class of activities designed to contribute to generalizable knowledge, including testing the application of new knowledge that is to be performed at SSCY Centre or using electronic medical records covered by the SSCY Data Sharing Agreement, or that is about the SSCY Network. Generalizable knowledge consists of theories, principles or relationships, or the

accumulation of information on which these are based that can be corroborated by acceptable scientific methods of observation, inference and/or equipment.

Quality Improvement: A range of activities conducted to assess, analyze, critique and improve current processes of health care delivery and services performed at SSCY Centre. Quality Improvement is also referred to as quality assurance/ assessment, audit or performance measurement.

Program Evaluation: The systematic collection and analysis of information about programs at SSCY Centre, focused on a broad range of topics including accessibility, comprehensiveness, integration, cost, efficiency and effectiveness, and designed for uses such as management, accountability and planning.

If a Quality Improvement or Program Evaluation project at SSCY Centre involves human participants and meets any of the following criteria, it shall require approval through the SSCY Research and Evaluation Committee following this guideline:

- presents a risk or burden to participants which is above minimal risk or an increase over accepted standard of care
- requires participants to take medication, undergo invasive procedures, protocols, psychometric testing or provide biological samples or give sensitive information, that is not routine to the program, service or care provided
- is intended to be published in peer-review literature
- is not an approved SSCY Network quality improvement plan
- has the potential to infringe on the privacy rights or professional reputation of participants

A Quality Improvement or Program Evaluation project that does not fall within the above parameters shall be approved through internal processes such as standards committees, quality councils or management committees. Publication or presentation of Quality Improvement or Program Evaluation results outside of SSCY Centre shall require the approval of the Department Head and the SSCY Research and Evaluation Committee.

Tri-Council Statement on Minimal Risk: “If potential subjects can reasonably be expected to regard the probability and magnitude of possible harms implied by participation in the research to be no greater than those encountered by the subject in those aspects of his or her everyday life that relate to the research then the research can be regarded as within the range of minimal risk.”

Principal Investigator: The person who directs a research project or program. The principal investigator (PI) usually writes and submits the grant application, oversees the scientific and technical aspects of the grant, and has responsibility for the management of the research.

Researcher: The term researcher applies to all members of the team conducting the research, including students and volunteers. The PI is responsible for ensuring adherence to this guideline.

GUIDELINE

The SSCY Research and Evaluation Committee will be responsible for reviewing and approving proposals for all research conducted at SSCY Centre (including recruitment and data collection), involving electronic medical records covered by the SSCY Data Sharing Agreement, or that are about the SSCY Network. For research conducted at a SSCY Network partner facility that is not SSCY Centre, the PI is responsible for obtaining all required approvals. The PI may consult with the SSCY Research and Evaluation Committee for clarification or guidance regarding which approvals are required and how to obtain them.

Performing research at SSCY Centre requires the following:

- Research proposals shall be submitted for and have received approval from one of the Research Ethics Boards at the University of Manitoba, and current approval must be maintained throughout the duration of the project. In limited circumstances, approval from a Research Ethics Board at another recognized institution may be accepted, if the research meets the Tri-Council Statement on Minimal Risk, at the discretion of the SSCY Research and Evaluation Committee.
- Compliance with *The Personal Health Information Act* (Manitoba) and *The Freedom of Information and Protection of Privacy Act* (Manitoba) for each facility or program in which the Research is to be conducted is required.
- Note: Receiving approval from a Research Ethics Board is a requirement, but it does not guarantee approval from the SSCY Research and Evaluation Committee.

At an early stage in a research project development, the PI(s) should include program and site management as stakeholders, to improve the overall quality and dissemination of research results. The PI(s) should consult with the SSCY Research and Evaluation Committee to ensure that SSCY Network partners are appropriately consulted regarding their involvement with the proposed project.

Researchers must be able to document the authenticity of data generated in research while ensuring protection of confidentiality for participating subjects. Secure storage of confidential data must be maintained. If a research project will require direct contact with individuals, a trustee shall not disclose personal health information about those individuals without first obtaining their consent.

The PI should give the SSCY Centre Research Coordinator a minimum of two weeks written notice prior to research or media publication or presentation. The PI must submit a copy of any report or publication that arises out of research conducted at SSCY Centre, with electronic medical records covered by the SSCY Data Sharing Agreement, or that is about the SSCY Network.

Authorship will include each person who contributed intellectually or substantially to the research. Researchers will respect the contributions of the SSCY Network partners, and acknowledgments will include all SSCY Network partners that contributed to the subject of the research project, as applicable. The PI(s) should consult with the SSCY Research and Evaluation

Committee for guidance on which SSCY Network partners should be acknowledged in what manner.

Failure to comply with these Guidelines may result in research access being revoked or may negatively impact future research access applications.

PROCEDURE

1. Any PI who wishes to conduct research at SSCY Centre, with electronic medical records covered by the SSCY Data Sharing Agreement, or about the SSCY Network must submit their proposal in writing to the SSCY Centre Research Coordinator who will then initiate review by the SSCY Research and Evaluation Committee. The submission may be forwarded to the Department Head(s) of the area(s) involved for review and feedback. The submission will include:
 - SSCY Centre Research Access Application Form
 - signed and dated signature page, accepting the conditions set out in this Guideline (last page of this Guideline)
 - research protocol
 - informed consent and assent forms
 - questionnaires or other materials to be given to participants
 - advertisements to be posted at SSCY Centre or on the SSCY Network website
 - budget
 - current PI CV
 - completed Research Ethics Board submission form
 - Research Ethics Board Certificate of Final Approval
 - Health Canada Letter of No Objection (if applicable)
 - Clinical Trial Registry number (if applicable)
2. The SSCY Research and Evaluation Committee will review all proposals with an emphasis on issues such as merit of the proposal, alignment with SSCY Network's mission, vision and values, benefits and risks to the participants, research design, credentials of the researchers, presence of ethical approval, impact on the organization's resources, and involvement of appropriate SSCY Network partners. This review must be completed before initiating any research activity. The PI will be notified in writing regarding the outcome of this review.
3. Approved projects will receive a SSCY Centre Research Access Number, which should be referenced on all SSCY Research and Evaluation Committee correspondences. A file containing all documents and correspondences will be maintained for each research project conducted at SSCY Centre, with electronic medical records covered by the SSCY Data Sharing Agreement, or about the SSCY Network.
4. Upon approval of the research proposal, the PI and all staff, students and volunteers involved in the research will be required to complete and sign a Personal Health

Information pledge of confidentiality and the PI will be required to sign the Agreement for Health Information for Research Purposes prior to initiating the research project.

5. The PI and all staff, students and volunteers involved in the research are required to abide by the conditions set out in the Data Sharing Agreement that governs the SSCY Network co-locating partners.
6. Requests for space or equipment contributions and staff participation must occur through the SSCY Centre Research Coordinator and agreement documented in writing before any research activity occurs.
7. The PI will submit, to the SSCY Centre Research Coordinator, a copy of all REB correspondence that results from a major protocol or informed consent/assent change or update to the approval status of the project (including the updated protocol, informed consent form or assent form), all Adverse Event reporting forms, all protocol deviation reporting (minor and major), the REB Annual Study Status Reports and Certificates of Annual Approval, and the Final Study Status Report.
8. In order to post research recruitment advertisements at SSCY Centre or on the SSCY Network website for research projects that do not require research access approval from the SSCY Research and Evaluation Committee, the PI must submit the protocol, REB submission form, REB Certificate of Final Approval and advertisement to the SSCY Centre Research Coordinator for approval.
9. PI(s) may be asked to participate in a variety of KT activities at SSCY Centre (including but not limited to: posters, presentations, pamphlets, etc). Researchers will be expected to share results appropriately with a variety of stakeholders, which can include SSCY Centre clients, families or therapists, members of the SSCY Network, policy makers, other researchers and interested community members. Information regarding past, ongoing and future research projects may be shared at SSCY Centre and on the SSCY Network website.
10. The PI must submit a copy of any report or publication that arises out of research conducted at SSCY Centre or with electronic medical records covered by the SSCY Data Sharing Agreement, or that is about the SSCY Network.
11. The SSCY Research and Evaluation Committee will have a list maintained about the numbers and types of research projects that are occurring at SSCY Centre. In this way the internal impact of research can be anticipated and plans made.

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REFERENCES

1. Tri-Council Policy Statement: Ethical Conduct for Research Involvement Humans (2003). Accessed from: www.pre.ethics.gc.ca/english/pdf/TCPS%June2003_E.pdf
2. WRHA Research and Quality Improvement Policy – Ethical Conduct – 10.50.080
3. RCC Research and Program Evaluation Policy – ADM 1.110
4. RCC Credentialing Researchers Policy – ADM 1.115
5. St Amant Research Access Policy – 80:10:01

CONSULTATION

1. RCC Board Policy Committee
2. SSCY Research and Evaluation Committee

I, the undersigned, agree to abide by these SSCY Research and Program Evaluation Access Guidelines in their entirety. I understand that failure to abide by these Guidelines may result in my current research access being revoked or may negatively affect any future research access requests at SSCY Centre.

Principal Investigator: Name

Principal Investigator: Signature

Date