Team Name: Quality, Patient Safety & Risk Team Lead: Regional Director Quality, Patient Safety & Risk Approved by: VP - Planning, Innovation, Quality, Safety & Risk	Reference Number: ORG.1810.PL.004 Program Area: Quality, Patient Safety & Risk and Ethics Policy Section: General
Issue Date: March 4, 2015 Review Date: Revision Date: February 15, 2017	Subject: Research Application and Approval Process

POLICY SUBJECT:
Research Application and Approval Process

PURPOSE:
To outline the Research Application and Approval Process in Southern Health-Santé Sud.

BOARD POLICY REFERENCE:
Executive Limitation (EL-2) Treatment of Clients Executive Limitation (EL-3) Treatment of Staff
Executive Limitation (EL-7) Asset Protection & Risk Management

POLICY:
Southern Health-Santé Sud promotes research with the goal of contributing to enlarging the body of knowledge related to the delivery of health care.

Research involving human subjects (including staff) is to receive approval from the Human Research Ethics Board at the University of Manitoba or the local National Research Council Ethics Board and is to conform to the standards of the *Tri-Council Policy Statement for Ethical Conduct for Research Involving Humans* and in accordance with the requirements of the *Personal Health Information Act of Manitoba* (PHIA), *The Freedom of Information and Protection of Privacy Act* (Manitoba) and, as applicable, the *Mental Health Act*.

Any research requests that require access to Southern Health-Santé Sud clients, client information, facilities, staff, technologies, or volunteers must be reviewed and approved in accordance to the following procedure.

Activities related to Quality Improvement or Program Evaluation shall be approved through internal processes such as standards committees, regional program teams or management teams.

Any project that involves human subjects and meets any of the following criteria is considered research:

- is part of a Master, PhD, medical student, undergraduate resident or fellow Research project; or
- presents a risk or burden to participants; or
- 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; or
- is intended to be published in peer-review literature; or
- has the potential to infringe on the privacy rights or professional reputation of participants.

Record retrieval and data preparation for funded research projects are subject to Southern Health-Santé Sud's fee schedule.

DEFINITIONS:

Research: an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation consisting 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 experiment.

Quality Improvement: a range of activities conducted to assess, analyze, critique and improve current internal processes of health care delivery and services performed at Southern Health-Santé Sud facilities or Southern Health-Santé Sud-funded facilities.

Program Evaluation: the systematic collection and analysis of information about programs at Southern Health-Santé Sud facilities or Southern Health-Santé Sud funded facilities, 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.

Tri-Council Statement on Minimal Risk: research in which the probability and magnitude of possible harm implied by participation in the research is no greater than those encountered by participants in the aspects of their everyday life that relate to the research.

Researcher: the term researcher applies to all members of the team conducting the research. The principal investigator is responsible for ensuring adherence to this policy.

Resources may include space, staff, equipment, client population, time, etc.

PROCEDURE:

Research Application Process:

1. The Researcher(s) complete the Application to Conduct Research ORG.1810.PL.004.FORM.01.
2. The Researcher(s) submit the completed Application to Conduct Research to Southern Health-Santé Sud Quality, Patient Safety, and Risk Management's Administrative Support.

   The Chair of the Regional Ethics Team reviews the Application to Conduct Research in collaboration with the appropriate directors and other stakeholders. Approval is based on compliance with the Disclosure of Personal Health Information for Health Research ORG.1411.PL.506.
3. Additional information from the Researcher(s) may be requested as deemed necessary.
4. The Chair of the Regional Ethics Team advises the Researcher(s) of approval/denial of the research Application in writing using within 4 (four) weeks of the initial receipt of the Application.
   - 4.1. If the Researcher(s) is (are) granted approval, he/she/they will be provided with the appropriate Southern Health-Santé Sud contact information.
   - 4.2. If the Researcher(s) is (are) denied approval, the reason for denial will be provided in writing.
5. Southern Health-Santé Sud Quality, Patient Safety, and Risk Management's Administrative Support uploads a list of approved research applications on the internal portal.
6. Upon completion of the Research, the Researcher(s) provides a copy of the research findings to Southern Health-Santé Sud Quality, Patient Safety, and Risk and to applicable site(s) and program(s).
7. Researchers are to provide the site(s), program(s) and Southern Health-Santé Sud's Quality, Patient Safety, and Risk a minimum of five (5) business days' notice prior to research publication or presentation.

SUPPORTING DOCUMENTS:

ORG.1810.PL.004.FORM.01 Application to Conduct Research
ORG.1810.PL.004.FORM.01.FR Demande d'autorisation de recherche

REFERENCES:

Brandon Regional Health Authority (2009). *Research Approval process Policy R.GEN.050.* Manitoba, Canada.

Canadian Institute on Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada (2010). *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* www.pre.ethics.gc.ca/pdf/eng/tcps2/TCPS_2_FINAL_Web.pdf. Manitoba, Canada.

Winnipeg Regional Health Authority Research and Quality Improvement (2006). *Ethical Conduct Policy 10.50.080.* Manitoba, Canada.

Regional Health Authority – Central Manitoba Inc. (2011). *Use and Disclosure of Personal Health Information AD-705.000*. Manitoba, Canada.