Saskatoon Health Region	**POLICY** Number: 7311-100-001 Title: RESEARCH
Authorization [ ] President and CEO [X] Vice President, Finance and Corporate Services	Source: Vice President, Research and Innovation Cross Index: Date Approved: December 1, 2011 Date Revised: December 23, 2014 Date Effective: December 23, 2014 Date Reaffirmed: Scope: SHR & Affiliates

This policy applies to all Saskatoon Health Region (SHR) employees, practitioner staff, contractors, vendors, students and volunteers. It also extends to non-SHR personnel if they use SHR or affiliate facilities, resources, patients, long-term care residents or staff to conduct research.

DEFINITIONS

Affiliates: According to the *Regional Health Services Act, Chapter R-8.2 of The Statutes of Saskatchewan, 2002*[1], an affiliate means a person who is the operator of a hospital approved pursuant to *The Hospital Standards Act* or a not-for-profit special-care home licensed pursuant to *The Housing and Special-care Homes Act*, and includes any successor to that operator but does not include a regional health authority or a prescribed person.[2]

Clinical Trial means a research investigation involving human subjects that is designed to answer specific questions about the safety and efficacy of a biomedical intervention (e.g., drug or device) (Applied Clinical Trials 2009). Clinical trials also include studies intended to discover or verify the clinical, pharmacological or pharmacodynamic effects of a drug, or study the absorption, distribution, metabolism and excretion of a drug (Health Canada 2003).

Department Impact Assessment means a process to identify the SHR departments whose services or support will be needed for the research and to determine each department's ability to provide the needed services or support.

[1] Available at www.qp.gov.sk.ca/documents/english/statutes/statutes/r8-2.pdf.
[2] The special care homes owned and operated by SHR are listed in Appendix A. The SHR-affiliated special care homes are listed in Appendix B.

Good Clinical Practice (GCP) means a standard for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial subjects are protected (Applied Clinical Trials 2009).

Health Information Protection Act (HIPA) means Saskatchewan provincial legislation regarding the rights of individuals and obligations of the trustees (physicians, regional health authorities, health professionals, etc.) in the health system with respect to personal health information.

Human Participants means those individuals whose data, or responses to interventions, stimuli or questions by the researcher, are relevant to answering the research question (TCPS2).

Investigator-Initiated Research means research that is initiated and conducted by an investigator.

Patient means an inpatient, outpatient or client of a facility or program of SHR or an SHR affiliate.

Principal Investigator (PI) means the person who directs a research project or program using SHR facilities, resources, patients, long-term care residents or staff.

Quality Assurance (QA), Quality Improvement (QI) and Program Evaluation Studies mean assessments of the performance of SHR or its staff. These studies are generally of interest within SHR, and the results cannot usually be generalized outside of SHR.

Research means an undertaking designed to extend knowledge through a disciplined inquiry or systematic investigation (TCPS2). Research includes, but is not limited to, clinical research (the study of human disease, including its prevention, diagnosis and treatment, using human participants, human populations or materials of human origin).

Research Ethics Board (REB) means a body of researchers, community members and others with specific expertise (e.g. in ethics, in relevant research disciplines) established by an institution to review the ethical acceptability of all research involving humans conducted within the institution's jurisdiction or under its auspices (TCPS2).

Resident means a person living or residing in an SHR or SHR-affiliate long-term care facility.

Saskatoon Centre for Patient-Oriented Research (SCPOR) is an initiative of the Saskatoon Regional Health Authority, the University of Saskatchewan and the Saskatchewan Cancer Agency devoted to providing clinical, technical and administrative support to clinical researchers.

SHR Facilities means all facilities in the region, including urban and rural facilities, owned, operated or funded by SHR or SHR affiliates.[3]

[3] A directory of SHR facilities is available at https://www.saskatoonhealthregion.ca/locations_services/locations/Pages/Home.aspx.

SHR Operational Approval means approval of research that will be conducted in an SHR facility or will involve SHR resources, patients, long-term care residents or staff. Before approval of a proposed research study can be granted, the study must (1) undergo research ethics review and be granted ethics approval or a letter of exemption, and (2) undergo a Department Impact Assessment.

SHR Resources means all services (diagnostic and non-diagnostic), equipment, supplies, financial assets and data owned or provided by SHR and SHR affiliates.

SHR Staff means:

- SHR and affiliate employees, practitioner staff and professional staff, and
- Contractors, vendors, students and volunteers while working for or providing services to SHR or affiliates.

Standard Operating Procedures (SOPs) means detailed, written instructions to achieve uniformity of the performance of a specific function (ICH 1996).

Study Coordinator means a person who works at a clinical research site under the immediate direction of a principal investigator performing activities such as site preparation, patient screening and recruitment, patient enrollment, conducting study visits, maintaining and dispensing drug supplies, completing and ensuring the quality of case report forms, maintaining source documents and ensuring site quality. Synonyms include clinical research coordinator, research coordinator, clinical coordinator and research nurse. (Adapted from ACRP definition[4] and Applied Clinical Trials 2009.)

Sub-investigator means any member of a clinical study team designated and overseen by the principal investigator at a study site to perform critical study-related procedures or to make important study-related decisions (or both). (Adapted from ICH 1996.)

1. PURPOSE

The purpose of this policy is to establish Saskatoon Health Region's position and requirements regarding research that is conducted in SHR or affiliate facilities or that involves SHR or affiliate resources, patients, long-term care residents or staff.

2. PRINCIPLES

2.1 Saskatoon Health Region affirms in this policy its commitment to working in partnership to generate knowledge and ideas with the belief that health research improves the quality of care provided to SHR patients and long-term care residents.

[4] Association of Clinical Research Professionals (http://www.acrpnet.org/MainMenuCategory/Certification/CRCCertification.aspx). Retrieved June 9, 2014.

2.2 SHR also affirms a commitment to ensuring the safety, privacy and well-being of research participants, patients, long-term care residents and SHR staff and departments.

3. POLICY

3.1. Scope

3.1.1. This policy encompasses:

- Research involving human participants; and
- Research involving human biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells. This applies to materials derived from living and deceased individuals.

3.1.2. Examples of research subject to this policy include, but are not limited to:

- Any research conducted by SHR staff as part of their job duties
- Studies where the research is conducted on any person while they are receiving services (e.g., diagnostic tests, treatment procedures) of an SHR or affiliate facility
- Studies that involve current or former patients or long-term care residents of SHR or their data. This includes current or retrospective review of medical or treatment records from any SHR or affiliate program or facility. This policy does not apply to data collected through institutions other than SHR (e.g., Ministry of Health, Canadian Institute for Health Information).
- Studies that involve SHR staff as research participants
- Studies where SHR resources, such as clinic visits, diagnostic imaging and laboratory tests (including off-hours use of clinical service equipment), are used to support research, including clinical research conducted from private offices
- Studies that occur in affiliate organizations or community-based organizations that receive funding from SHR and where the SHR-funded service is used to support the research

3.1.3. For the purposes of this policy, quality assurance, quality improvement and program evaluation studies, when used exclusively for assessment, management or improvement purposes within SHR, do not constitute research and may not be subject to this policy.[5]

[5] For assistance in determining whether a study is subject to this policy, contact the Research Approval Coordinator.

3.2. SHR Operational Approval

3.2.1. All research, funded or unfunded, that will be conducted in an SHR facility or will involve SHR resources, patients, long-term care residents or staff requires SHR Operational Approval before it can begin. The Vice President, Research and Innovation (or designee[6]) is responsible for granting Operational Approval.

3.2.2. Before approval of a proposed research study can be granted, the study must (1) undergo research ethics review and be granted ethics approval or a letter of exemption by a University of Saskatchewan Research Ethics Board and (2) undergo a Department Impact Assessment to identify the SHR departments whose services or support will be needed for the research and to determine each department's ability to provide the needed services or support.

3.2.3. Studies deemed exempt from research ethics review and approval by the REB may still be required to undergo a Department Impact Assessment in order to proceed.

3.3. Principal Investigators (PIs) shall ensure that the research is conducted in compliance with applicable international, federal and provincial legislation, regulations, standards and policies, including the following (where applicable):

- Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2nd Edition (TCPS2)[7]
- Tri-Agency Framework: Responsible Conduct of Research (the Framework).[8]
- Saskatchewan's Health Information Protection Act (HIPA)[9]
- Canada's Food and Drugs Act and Regulations and Medical Devices Regulations[10]
- Canada's Narcotic Controlled Drugs and Substances Act and Narcotic Control Regulations
- International Conference on Harmonisation (ICH) Guideline for Good Clinical Practice[11]

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[6] The designee for granting of Operational Approval is the Research Approval Coordinator.
[7] Compliance with the TCPS2 is mandatory for all SHR research.
[8] Compliance with the Framework is mandatory for all SHR research.
[9] Compliance with HIPA is mandatory for all research in Saskatchewan that uses personal health information. Section 29 of HIPA pertains to use and disclosure of personal health information for research.
[10] Researchers conducting Phase I, II, and III clinical trials must comply with Canada's Food and Drugs Act and Food and Drug Regulations. Researcher's conducting research using medical devices must also comply with Canada's Medical Devices Regulations. These requirements apply to clinical trials involving products (e.g., pharmaceuticals, biologics, natural health products, devices) that have not yet been approved for marketing in Canada as well as clinical trials involving marketed products where the proposed use of the product is outside the parameters of the approved Notice of Compliance (NOC), Drug Identification Number (DIN) or medical device license application. *(Health Canada 2003, 2008)*

- U.S. Food and Drug Administration (FDA) regulations[12]
- U.S. Office for Human Research Protections (OHRP) regulations[13]
- Canada's Personal Information Protection and Electronic Documents Act (PIPEDA)
- Saskatchewan's Occupational Health & Safety provincial legislation

3.4. Clinical trials conducted in SHR must include a local PI, i.e., a PI who is employed or contracted by SHR or who has a University of Saskatchewan faculty appointment. For research other than clinical trials, a local PI may or may not be required, and the need will be determined on a case-by-case basis. Researchers intending to conduct a study in SHR can contact the Office of the Vice President, Research and Innovation for an evaluation of whether a local PI will be required.

3.5. Saskatoon Centre for Patient-Oriented Research (SCPOR)

3.5.1. When conducting a clinical trial, researchers who receive their initial appointment to the SHR practitioner staff after January 1, 2015, and who are not conducting the trial under the auspices of the Saskatchewan Cancer Agency must use SCPOR's services for reviewing the contract, negotiating the budget, applying for research ethics approval and obtaining SHR operational approval.

3.5.2. PIs are encouraged to use study coordinators provided by SCPOR to conduct their clinical trials. If a PI chooses to use non-SCPOR personnel in the conduct of a clinical trial, the PI is responsible for ensuring they meet qualifications needed to comply with regulations and good clinical practice guidelines (see Section 3.3).

3.6. PIs shall ensure that adequate liability protection is in place for their clinical research. SHR's requirements for liability protection are as follows:

3.6.1. University of Saskatchewan (U of S), University of Regina and Saskatchewan Institute of Applied Science and Technology (SIAST) faculty, students, postdoctoral researchers and research staff conducting research under the auspices of their institution (e.g., U of S faculty conducting research that is funded through a U of S account and/or where the U of S is signatory to a clinical trial agreement or research agreement) are covered by a combination of Canadian Medical Protective Association (CMPA) protection (for physicians) and their institutional liability insurance.

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[11] Researchers conducting clinical trials in Canada must comply with the ICH Guideline for Good Clinical Practice.
[12] Compliance with U.S. FDA regulations is required if stipulated in the contract or funding agreement with the sponsor or funding agency.
[13] Compliance with OHRP regulations is required if stipulated in the contract or funding agreement with the sponsor or funding agency.

3.6.2. SHR employees, including investigators employed by SHR and their research staff, conducting research as part of their SHR responsibilities are covered by a combination of CMPA protection (for physicians) and SHR liability insurance.

3.6.3. Saskatchewan Cancer Agency (SCA) employees, including investigators employed by SCA and their research staff, conducting research as part of their SCA responsibilities are covered by a combination of CMPA protection (for physicians) and SCA liability insurance.

3.6.4. Health Quality Council (HQC) employees, including investigators employed by HQC and their research staff, conducting research as part of their HQC responsibilities are covered by HQC liability insurance.

3.6.5. All other physician investigators (those not covered in Sections 3.6.1-3.6.4) and their research staff are protected through the investigator's membership in the CMPA when conducting studies within Canada involving patients with medical conditions. The investigator must provide SHR with documentation of CMPA membership before SHR Operational Approval will be granted. The investigator must also show proof within 30 days of membership expiration that the membership is renewed annually. Failure to show proof of renewal will result in revocation of SHR Operational Approval.

3.6.6. Any investigator not covered in Sections 3.6.1-3.6.4 conducting a study (e.g., phase I trial) involving healthy volunteers must obtain separate general and medical malpractice liability insurance providing $5,000,000 per occurrence and $10,000,000 total per year. SHR and the investigator's research staff involved in the study must be included as additional insureds on the policy. The investigator must provide SHR with documentation of this insurance before SHR Operational Approval will be granted. The investigator must also show proof within 30 days of policy expiration that the insurance is renewed annually. Failure to show proof of renewal will result in revocation of SHR Operational Approval.

3.6.7. Any investigator not covered in Sections 3.6.1-3.6.4 who is the lead investigator for an investigator-initiated study to be conducted outside of Canada must obtain separate general and medical malpractice liability insurance providing $5,000,000 per occurrence and $10,000,000 total per year to cover claims made from outside Canada. SHR and the investigator's research staff involved in the study must be included as additional insureds on the policy. The investigator must provide SHR with documentation of this insurance before SHR Operational Approval will be granted. The investigator must also show proof within 30 days of policy expiration that the insurance is renewed annually. Failure to show proof of renewal will result in revocation of SHR Operational Approval.

3.6.8. Faculty, students, postdoctoral researchers and staff from Canadian post-secondary institutions outside of Saskatchewan conducting health systems research (e.g., surveys, qualitative interviews) in SHR are covered by their institutional liability insurance.

3.6.9. Anyone who does not fall within the above categories may not normally carry out research in SHR. A researcher who wants to have his or her eligibility to do research in SHR reviewed may contact the Office of the Vice President, Research and Innovation.

3.7. PIs shall ensure that they and their staff have the proper education, training and experience to assume responsibility for a research study at SHR.

3.8. PIs conducting clinical trials must complete and receive certification of training in Good Clinical Practice (GCP).[14] PIs shall also ensure that all those participating in the conduct of the trial (sub-investigators, study coordinators, etc.) are qualified by education, experience and training (including appropriate training in GCP) to perform the respective tasks.

3.9. PIs conducting clinical trials shall ensure that they have standard operating procedures (SOPs) in place to guide their clinical trial operations and that the SOPs are followed.[15]

3.10. All PIs and researchers must conduct themselves ethically and with integrity during the course of the research study. They must abide by the following ethical standards, where applicable:

- The code of ethics endorsed by their profession
- Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2nd Edition (TCPS2)
- Tri-Agency Framework: Responsible Conduct of Research (the Framework)

3.11. SHR Policies and Procedures[16]

3.11.1. All PIs and researchers must abide by the following SHR policies and procedures:

- Privacy and Confidentiality

[14] SHR offers training in Good Clinical Practice through the Network of Networks (N2). Those interested in the N2 GCP training can contact the Office of the Vice President, Research and Innovation for further information

[15] SHR maintains a standard set of clinical research SOPs through the Network of Networks (N2). All SHR researchers are welcome to adopt these SOPs for their clinical trials according to the following policy regarding their use: (1) SHR researchers may print and use the N2 SOPs within their own clinical research site(s); (2) It is prohibited to sell, distribute, export, lease, loan or rent the N2 SOPs to any third/external party; (3) When required, study sponsors, regulatory inspectors or auditors may be granted access to view, but not copy, the N2 SOPs at the researcher's site; and (4) The N2 SOPs must be used as they are (without changes), and researchers may not substitute their own SOPs for any of those in the N2 set; researchers are free, however, to add their own SOPs for topics not covered by the N2 SOPs. Those interested in using the N2 SOPs can contact the Office of the Vice President, Research and Innovation for further information.

[16] SHR policies are available on the SHR Policies and Procedures website: https://www.saskatoonhealthregion.ca/about/Pages/Policies-and-Procedures.aspx.

- Critical Incident Reporting
- Fraud Policy
- Our Values in Action/Code of Conduct
- Speaking up – Protection of Persons Reporting Wrongdoing
- Responsible Conduct of Research

3.11.2. PIs and researchers should be aware of and follow applicable situation- and context-specific SHR policies and procedures. For example:

- For studies that involve surgery, diagnostic procedures or treatment procedures, the *SHR Consent for Surgery Diagnostic and Treatment Procedures Policy and Procedure* must be followed.
- Researchers conducting certain types of mental health studies should be aware of and follow the *SHR Violence Management Policy and Procedure*.
- During influenza outbreaks, the *SHR Management of Employees, Physicians and Other Health Care Workers during Influenza Outbreaks in Health Care Facilities Policy and Procedure* should be followed.

3.12. There may be times when an SHR facility or program may be approached to participate in a research study that conflicts with its religious beliefs or moral or ethical precepts. In these instances, the Office of the Vice President, Research and Innovation will work with the PI and the facility or program to seek resolution of the issue. If the issue cannot be resolved and the proposed research cannot be accommodated in another SHR facility or program, SHR Operational Approval may not be granted for the study.

3.13. Cost Recovery for SHR Services that Support Research

3.13.1. When SHR services are used to support research, SHR will be reimbursed for all costs for the research-specific services provided by SHR that were agreed to during SHR Operational Approval.

3.13.2. All costs for services to be provided by SHR and SHR affiliates will be determined prior to applications for grants or sponsored research.

3.13.3. The PI and the managers (or their designees) of the departments that will participate in the research will reach agreement regarding compensation of the departments for the research-specific services, including in-kind contributions. They will identify which services are required as part of standard patient care and which services are required strictly for the research study.

3.13.4. In the event that a disagreement arises between the PI and an SHR department or affiliate about what is considered standard patient care and what is required strictly for research, it will be addressed by a dispute resolution process (see Section 3.19).

3.13.5. The PI will be regularly billed for SHR services used during the research study, including baseline and screening tests that are beyond standard patient care, as agreed to during SHR Operational Approval.

3.13.6. In the event that a PI has any outstanding bills, SHR Operational Approval may be delayed for any pending studies and may be suspended for any existing studies until the outstanding bills are resolved.

3.14. If a sponsor requires that a confidential disclosure agreement (CDA) or non-disclosure agreement (NDA) be signed, the document must be reviewed by the Vice President, Research and Innovation (or designate[17]) before it is signed.

3.15. All clinical research contracts must be reviewed by the Vice President, Research and Innovation (or designate[18]) before they are signed.

3.16. SHR reserves the right to randomly audit any study that has been granted SHR Operational Approval. The purpose of the audit is to ensure that the PI has followed this policy while planning and conducting the study. It is also to ensure that the Department Impact Assessment was thoroughly and appropriately conducted by SHR.

3.17. When the PI responsible for a study that involves SHR facilities, resources, patients, long-term care residents or staff is informed that the study is to be audited by Health Canada, the U.S. Food and Drug Administration or the research ethics board, the PI must promptly notify the Research Approval Coordinator. After the audit is completed, the PI must provide the audit results to the Research Approval Coordinator.

3.18. When SHR equipment or services are used for a research study, the PI or his or her designee must follow internal SHR policies and procedures for their use. Any damage, excluding normal wear and tear, to SHR property as a result of a research study, caused directly or indirectly by the PI or designee, will be the responsibility of the PI. The PI should report damage to the appropriate SHR manager. If necessary, the Vice President, Research and Innovation will discuss such issues with the appropriate representative of the PI's sponsoring organization to resolve the issue of property repair or replacement (see Section 3.19).

[17] The designee of the Vice President, Research and Innovation for CDA and NDA review is the Saskatoon Centre for Patient-Oriented Research (SCPOR).
[18] The designee of the Vice President, Research and Innovation for contract review is the Saskatoon Centre for Patient-Oriented Research (SCPOR).

3.19. Dispute Resolution: While every attempt is made to facilitate research studies, there may be times when a conflict arises. If such a conflict occurs, the Office of the Vice President, Research and Innovation will work with the parties involved, in consultation with their employer(s) or sponsoring organization(s) and the managers of the SHR departments that are involved in the research, to resolve the issue. (See Section 5 of the *SHR Research Policy Procedures*, later in this document.)

4. ROLES AND RESPONSIBILITIES

4.1. SHR Managers and Departments

4.1.1. The manager (or the manager's designee) of the SHR department or unit is responsible for evaluating and approving research through the Department Impact Assessment.

4.1.2. The managers (or designees) of the SHR departments that will provide services for a research study are responsible for determining the costs associated with those services and providing the PI with an estimate of those costs within a reasonable amount of time, preferably within 10 business days of receiving the request for the estimate from the PI.

4.2. Principal Investigators

4.2.1. The PI named on the research ethics Certificate of Approval or Notice of Exemption is the individual responsible for ensuring that they and all persons carrying out the research on their behalf comply with the SHR Research Policy.

4.2.2. PIs and their research staff are accountable for exercising due diligence in carrying out the ethical and legal requirements for their research.

4.2.3. PIs are responsible for:

- Obtaining cost estimates for services to be rendered by SHR and SHR affiliates *prior* to applications for grants or sponsored research
- Initiating research ethics review[19] and Department Impact Assessment and obtaining the required SHR Operational Approval
- Ensuring that each SHR (or affiliate) department whose services or support may be needed for the research has all the appropriate study-specific information necessary for them to (1) provide their approval for the study to proceed and (2) provide the requested services or support

[19] The Research Ethics Boards of record for SHR are the University of Saskatchewan (U of S) Biomedical Research Ethics Board and the U of S Behavioural Research Ethics Board.

- Negotiating, once SHR Operational Approval has been granted, the start date of data collection with the managers (or designees) of the SHR departments that will be involved in the research
- Ensuring that adequate liability protection is in place for their clinical research
- Ensuring that they and their staff have the proper education, training and experience to assume responsibility for a research study at SHR
- If they conduct clinical trials, ensuring that they and those to whom they have delegated responsibility for those clinical trials (e.g., sub-investigators, study coordinators) have completed and received certification of training in Good Clinical Practice
- Having all confidential disclosure agreements, non-disclosure agreements and clinical research contracts undergo review by the Vice President, Research and Innovation (or designee) before they are signed
- Ensuring the safety and well-being of SHR research participants in the context of the research
- Compensating SHR for all research-specific costs that were agreed to during SHR Operational Approval
- Ensuring that the research is conducted in compliance with applicable international, federal and provincial legislation, regulations, standards and policies (see Section 3.3)
- If they conduct clinical trials, having SOPs in place to guide their clinical trial operations and ensuring that the SOPs are followed
- Promptly informing the Research Approval Coordinator when the PI is informed that a study for which the PI is responsible is to be audited by Health Canada, the U.S. Food and Drug Administration or the research ethics board, and providing the audit results to the Research Approval Coordinator when the audit is completed

4.3. The Vice President, Research and Innovation (or designee) is responsible for:

4.3.1. Working with the PI and the SHR facility or program to seek resolution if the PI has approached the facility or program to participate in a research study that conflicts with its religious beliefs or moral or ethical precepts

4.3.2. Reviewing confidential disclosure, non-disclosure agreements, clinical research contracts and clinical study budgets[20]

4.3.3. If necessary, helping resolve issues of repair or replacement of SHR property damaged as a result of a research study by discussing the issue with the appropriate representative of the PI's sponsoring organization

4.3.4. If a conflict arises, working with the parties involved, in consultation with their employer(s) or sponsoring organization(s) and the managers of the affected SHR departments, to resolve the issue

4.3.5. Ensuring that allegations of non-compliance with or breach of the *SHR Research Policy* are reported to the Privacy and Compliance Department, as required by the *SHR Fraud Policy*

4.3.6. If the person responsible for an alleged non-compliance or breach of the *Research Policy* is affiliated with another institution, reporting the alleged non-compliance or breach to the appropriate department, college or faculty of that institution

4.4. The Research Approval Coordinator is responsible for:

4.4.1. Granting Operational Approval (as the designee of the Vice President, Research and Innovation)

4.4.2. Providing assistance with Operational Approval and Department Impact Assessment, including identifying the SHR departments whose services or support may be needed for the research project

4.4.3. Reviewing Applications for Operational Approval to Conduct a Research Study, confirming that all required information has been provided, that all of the SHR departments that will be involved in the research have been identified and that all required signatures have been obtained

4.4.4. When Operational Approval is granted, sending a letter to the PI notifying the PI of the approval and sending a copy of the letter to each of the departments that will participate in the research

4.4.5. Providing assistance with determining costs for services to be rendered by SHR and SHR affiliates

4.4.6. Providing assistance in determining whether a study is subject to this policy

[20] The designee of the Vice President, Research and Innovation for CDA, NDA and contract review is the Saskatoon Centre for Patient-Oriented Research (SCPOR).

4.5. Saskatoon Centre for Patient-Oriented Research (SCPOR) is responsible for:

4.5.1. Reviewing confidential disclosure agreements, non-disclosure agreements and contracts, negotiating budgets, applying for research ethics approval and obtaining SHR operational approval for clinical trials on behalf of PIs.

5. POLICY MANAGEMENT

The management of this policy, including education, monitoring, implementation and amendment, is the responsibility of the Office of the Vice President, Research and Innovation.

6. NON-COMPLIANCE/BREACH

In the event that a PI or a member of his or her research staff does not comply with this policy, SHR may take disciplinary action. Sanctions will be determined on a case-by-case basis and will depend on the severity of the breach. For SHR employees, sanctions may include (but are not limited to) reprimand, suspension or dismissal. Studies currently underway by the PI using SHR facilities, resources, patients, long-term care residents or staff may have their Operational Approval revoked, and studies by the PI that have been applied for but not yet granted SHR Operational Approval may be delayed or denied.

7. REFERENCES

Applied Clinical Trials. December 2009. *Clinical Data Interchange Consortium (CDISC) Clinical Research Glossary*, *Version 8.0*

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Saskatoon Health Region Policies & Procedures, *Confidentiality - Health Information,* #7311-75-003

Saskatoon Health Region Policies & Procedures, *Consent for Surgery Diagnostic and Treatment Procedures,* #7311-50-002

Saskatoon Health Region Policies & Procedures, *Critical Incident Reporting,* #7311-50-008

Saskatoon Health Region Policies & Procedures, *Fraud Policy,* #7311-10-002

Saskatoon Health Region Policies & Procedures, *Management of Employees, Physicians and Other Health Care Workers during Influenza Outbreaks in Health Care Facilities,* #7311-30-017

Saskatoon Health Region Policies & Procedures, *Our Values in Action/Code of Conduct,* #7311-10-001

Saskatoon Health Region Policies & Procedures, *Responsible Conduct of Research,* #7311-100-002

Saskatoon Health Region Policies & Procedures, *Speaking up - Protection of Persons Reporting Wrongdoing,* #7311-10-003

Saskatoon Health Region Policies & Procedures, *Violence Management,* #7311-30-007

PROCEDURE Number: 7311-100-001 Title: Research	
Authorization [ ] President and CEO [X] Vice President, Finance and Corporate Services	Source: Vice President, Research and Innovation Cross Index: Date Approved: December 1, 2011 Date Revised: December 23, 2014 Date Effective: December 23, 2014 Date Reaffirmed: Scope: SHR & Affiliates

1. PURPOSE

The purpose of these procedures is to establish a consistent and efficient process that facilitates research within SHR and ensures equal opportunity for researchers in accessing resources required for their study, while minimizing potential and unintentional impact on system performance, efficiency and efficacy.

2. PROCEDURE[1]

2.1. Confidentiality and Non-Disclosure Agreements: If a sponsor requires that a confidential disclosure agreement (CDA) or non-disclosure agreement (NDA) be signed, the document must be sent to the Vice President, Research and Innovation (or designee[2]) for review before it is signed. The Vice President, Research and Innovation (or designee) will complete the review as soon as reasonably possible upon receipt of the document.

2.2. Contract Review: All clinical research contracts must be sent to the Vice President, Research and Innovation (or designee[3]) for review before they are signed. The Vice President, Research and Innovation (or designee) will complete the review as soon as reasonably possible upon receipt of the document.

2.3. Budget Review: PIs conducting investigator-initiated research are strongly encouraged to submit clinical study budgets for review by the Vice President, Research and Innovation (or designee[4]) prior to submitting grant applications. The purpose of the budget review is to ensure that there will be sufficient funds to carry out the research project. The Vice President, Research and Innovation (or designee) will complete the budget review as soon as reasonably possible upon receipt of the budget.

[1] Contact the Office of the Vice President, Research and Innovation for further guidelines and additional information relevant to these procedures.
[2] The designee of the Vice President, Research and Innovation for CDA and NDA review is the Saskatoon Centre for Patient-Oriented Research (SCPOR).
[3] The designee of the Vice President, Research and Innovation for contract review is the Saskatoon Centre for Patient-Oriented Research (SCPOR).
[4] The designee of the Vice President, Research and Innovation for budget review is the Saskatoon Centre for Patient-Oriented Research (SCPOR).

2.4. All costs for services to be rendered by SHR and SHR affiliates must be determined *prior* to applications for grants or sponsored research or negotiations for other funding.[5]

2.5. SHR Operational Approval[6]

2.5.1. To receive Operational Approval, the proposed study must first undergo research ethics review and a Department Impact Assessment.

2.5.2. Research Ethics Review[7]

- SHR has an agreement[8] with the University of Saskatchewan Research Ethics Boards (REBs) to provide research ethics review and approval for all research that involves SHR facilities, resources, patients, long-term care residents or staff. To receive Operational Approval, the study must be granted a Certificate of Approval or a Notice of Exemption by the appropriate University of Saskatchewan REB.
- Studies deemed exempt from research ethics review and approval by the REB may still be required to undergo a Department Impact Assessment in order to proceed. Contact the Research Approval Coordinator for assistance in determining whether a Department Impact Assessment is required.

2.5.3. Department Impact Assessment

- The purpose of the Department Impact Assessment is to identify the SHR departments whose services or support will be needed for the research and to determine each department's ability to provide the needed services or support.[9]
- The Department Impact Assessment allows all SHR departments that may be involved in the research the opportunity to review the research study, assess the operational impact of the study, determine how the proposed research will affect their functions and, where appropriate, prepare a budget for cost-recovery. This ensures that the research proceeds smoothly in each department.
- The PI discusses the potential impact of the research study with the Manager or designee from each department. When the Manager or designee agrees to support the research and matters such as cost recovery and protocol concerns have been addressed, the Manager or designee signs the Application for Operational Approval to

[5] Contact the Research Approval Coordinator for assistance with determining costs.
[6] Additional information about SHR Operational Approval is available at https://www.saskatoonhealthregion.ca/locations_services/Services/research/Pages/Research-Approval.aspx). For further assistance, contact the Research Approval Coordinator.
[7] See the University of Saskatchewan Research Ethics Office website (http://www.usask.ca/research/ethics_review/) for information about obtaining ethics approval.
[8] Subsidiary Agreement to the Affiliation Agreement between the University of Saskatchewan and the Saskatoon Regional Health Authority.
[9] For assistance in determining the SHR departments whose services or support may be needed for a research project, contact the Research Approval Coordinator.

Conduct a Research Study (or provides email approval in lieu of signature; see Section 2.5.6).

- It is not necessary to wait for ethics approval before beginning the Department Impact Assessment. The Department Impact Assessment may be conducted simultaneously with preparation and submission of the ethics application.

2.5.4. For clinical trials involving drugs, biologics and natural health products, the PI must consult with the RUH Special Services Pharmacy about how the drugs, biologics or natural health products will be managed.

2.5.5. Liability Protection

- Documentation of liability protection is not required for University of Saskatchewan (U of S), University of Regina (U of R) and Saskatchewan Institute of Applied Science and Technology (SIAST) faculty, students, postdoctoral researchers and research staff conducting research under the auspices of their institution (e.g., U of S faculty conducting research that is funded through a U of S account and/or where the U of S is signatory to a clinical trial agreement or research agreement)

- Documentation of liability protection is not required for SHR, Saskatchewan Cancer Agency and Health Quality Council employees, including investigators employed by the institution and their research staff, conducting research as part of their institutional responsibilities.

- All other physician investigators (those not covered above) conducting studies within Canada involving patients with medical conditions must provide the SHR Research Approval Coordinator with documentation of Canadian Medical Protective Association (CMPA) membership before SHR Operational Approval will be granted. The investigator must also show proof within 30 days of membership expiration that the membership is renewed annually. Failure to show proof of renewal will result in revocation of SHR Operational Approval.

- An investigator not covered above conducting a study (e.g., phase I trial) involving healthy volunteers must provide the SHR Research Approval Coordinator with documentation of general and medical malpractice liability insurance providing $5,000,000 per occurrence and $10,000,000 total per year before SHR Operational Approval will be granted. SHR and the investigator's research staff involved in the study must be included as additional insured's on the policy. The investigator must also show proof within 30 days of policy expiration that the insurance is renewed annually. Failure to show proof of renewal will result in revocation of SHR Operational Approval.

- An investigator not covered above who is the lead investigator for an investigator-initiated study to be conducted outside of Canada must provide the SHR Research Approval Coordinator with documentation of general and medical malpractice liability insurance providing

$5,000,000 per occurrence and $10,000,000 total per year to cover claims made from outside Canada before SHR Operational Approval will be granted. SHR and the investigator's research staff involved in the study must be included as additional insureds on the policy. The investigator must also show proof within 30 days of policy expiration that the insurance is renewed annually. Failure to show proof of renewal will result in revocation of SHR Operational Approval.

- Documentation of liability protection is not required for faculty, students, postdoctoral researchers and staff from Canadian post-secondary institutions outside of Saskatchewan conducting health systems research (e.g., surveys, qualitative interviews) in SHR.
- Anyone who does not fall within the above categories may not normally carry out research in SHR. A researcher who wants to have his or her eligibility to do research in SHR reviewed may contact the Office of the Vice President, Research and Innovation.

2.5.6. Application for Operational Approval to Conduct a Research Study[10]

- The results of the research ethics review and Department Impact Assessment should be recorded on the Application for Operational Approval to Conduct a Research Study form.
- The PI must provide copies of the following documents associated with the research ethics review along with the application:
  - Certificate of Approval or Notice of Exemption
  - Research Ethics Application
  - Approved Consent Form, if applicable
- Signatures of the following people are required on the application:
  - The PI
  - The managers (or designees) of the participating departments. (An email from the manager or designee's SHR email account confirming approval is acceptable in lieu of the manager's signature.)
- If the research is being conducted by a student, the application must be submitted under the name of the student's research supervisor and signed by the supervisor.
- The completed application is submitted to the Research Approval Coordinator.
- The Research Approval Coordinator will confirm that all required information has been provided, that all of the SHR departments that

[10] The application form is available at https://www.saskatoonhealthregion.ca/locations_services/Services/research/Pages/Research-Approval.aspx.

will provide services or support for the research have been identified and that all required signatures have been obtained.

- Notification of Operational Approval
    - If all of the required information is provided, Operational Approval is usually granted within 3-5 workings days after the Research Approval Coordinator receives the completed application.
    - A letter notifying the PI of Operational Approval is sent to the PI, and a copy is sent to all of the departments that will participate in the research as listed on the application.

2.6. If a PI needs access to data in order to determine the feasibility of a future study, the PI should contact the manager(s) of the relevant department(s) to request the information. Only data that are not patient-identifiable will be provided.[11]

2.7. Conflicts with Religious Beliefs or Moral or Ethical Norms

2.7.1. If a situation arises in which a study may conflict with the religious beliefs or moral or ethical norms of an SHR facility or program, the facility or program may contact the Office of the Vice President, Research and Innovation for resolution. The issue may also be discussed with an SHR Ethics Consultant.[12]

2.7.2. The Office of the Vice President, Research and Innovation will work with the PI and the facility or program to seek resolution of the issue.

2.7.3. If resolution is not reached, the Office of the Vice President, Research and Innovation will work with the PI to find accommodation for the research within another SHR facility or program. If the proposed research cannot be accommodated in another SHR facility or program, SHR Operational Approval may not be granted for the study.

2.8. Random Operational Approval Audits

2.8.1. During an audit, the PI will be asked to provide SHR with study-related documents that support their adherence to the *SHR Research Policy*. Documents that may be requested include but are not limited to:

- Records of study participant consent
- Medical and diagnostic test records
- Participant enrollment records
- SHR budget-related records

2.8.2. SHR recognizes that confidentiality agreements exist between a PI and the research sponsor, which may delay or prevent access to certain records.

[11] Patient-identifiable data are data that identify the patient or can reasonably be used to identify the patient.
[12] To contact an SHR Ethics Consultant, call the Royal University Hospital Switchboard (655-1000) and ask for the Ethics Consultant on call.

3. PROCEDURE MANAGEMENT

The management of this procedure including education, monitoring, implementation and amendment is the responsibility of the Vice President, Research and Innovation.

4. NON-COMPLIANCE/BREACH

4.1. As described in the *SHR Speaking-Up – Protection of Persons Reporting Wrongdoing Policy*, SHR staff are free to make known, without fear of reprisal, reports of wrongdoing within SHR. This includes non-compliance with or a breach of the *SHR Research Policy*.

4.2. Allegations of non-compliance with or breach of the *SHR Research Policy* should be reported to the supervisor or to the Compliance Line, as described in the *SHR Fraud Policy*. The allegations should also be forwarded in writing to the Vice President, Research and Innovation, who will confirm that the allegations have been reported to the Privacy and Compliance Department, as required by the *Fraud Policy*.

4.3. The allegations will be investigated and addressed according to the procedures described in the *SHR Fraud Policy*.

4.4. If the person responsible for the alleged non-compliance or breach is affiliated with another institution (e.g., University of Saskatchewan, University of Regina, SIAST), the Vice President, Research and Innovation will report the alleged non-compliance or breach to the appropriate department, college or faculty of that institution.

4.5. In the event that a PI or a member of his or her research staff is found in non-compliance with this policy, SHR may revoke SHR Operational Approval of studies currently underway by the PI , and studies by the PI that have been applied for but not yet granted SHR Operational Approval may be delayed or denied.

4.6. If it is suspected that there has been a breach of privacy, the potential breach will be reported to SHR's Privacy and Compliance Department. A breach of privacy is defined as the unauthorized[13] collection, use or disclosure of personal health information.

4.7. If it is concluded that the non-compliance involves failure to conduct the research in the manner in which it has been approved by the REB or involves a breach of privacy, the non-compliance will be reported to the REB.

5. DISPUTE RESOLUTION

5.1. A dispute may be referred by any party to the Vice President, Research and Innovation.

5.2. Within 7 days after notification of the dispute, each party shall deliver to the Vice President, Research and Innovation a written summary of that party's position with respect to the dispute, together with the name of the representative of the party who will serve as a contact with the Vice President, Research and Innovation.

[13] Activities that contravene any provisions of HIPA are considered unauthorized.

5.3. The Vice President, Research and Innovation will convene a meeting within 21 days after the notification to work with the parties to resolve the dispute. If they are not able to resolve the dispute, it will be referred to a mediator who is to be chosen by all of the parties.

6. REFERENCES

Saskatoon Health Region Policies & Procedures, *Fraud Policy,* #7311-10-002

Saskatoon Health Region Policies & Procedures, *Speaking up - Protection of Persons Reporting Wrongdoing,* #7311-10-003

Appendix A. Special-care Homes Owned and Operated by Saskatoon Health Region (as of June 2014)[14]

Name	Location
Central Parkland Lodge	Lanigan
Cudworth Nursing Home	Cudworth
Golden Acres	Wynyard
Last Mountain Pioneer Home	Strasbourg
Manitou Lodge	Watrous
Nokomis Health Centre	Nokomis
Parkridge Centre	Saskatoon
Pleasant View Care Home	Wadena
Quill Plains Centennial Lodge	Watson
St. Mary's Villa	Humboldt

[14] The current list of long-term care homes is available at https://www.saskatoonhealthregion.ca/locations_services/locations/Pages/Long-Term-Care-Homes.aspx.

Appendix B. Saskatoon Health Region-Affiliated Special - care Homes (as of June 2014)[15]

Name	location
Bethany Pioneer Village	Middle Lake
Central Haven Special Care Home	Saskatoon
Circle Drive Special Care Home	Saskatoon
Extendicare Special Care Home	Saskatoon
Goodwill Manor	Duck Lake
Lakeview Pioneer Lodge	Wakaw
Langham Senior Citizen Home	Langham
Luther Special Care Home	Saskatoon
Mennonite Nursing Home	Rosthern
Oliver Lodge	Saskatoon
Porteous Lodge	Saskatoon
Saskatoon Convalescent Home	Saskatoon
Sherbrooke Community Centre	Saskatoon
Dalmeny Spruce Manor Special Care Home	Dalmeny
Samaritan Place	Saskatoon
St. Anne's Home	Saskatoon
St. Joseph's Home	Saskatoon
Stensrud Lodge	Saskatoon
Sunnyside Adventist Care Home	Saskatoon
Warman Mennonite Special Care Home	Warman

[15] The current list of long-term care homes is available at https://www.saskatoonhealthregion.ca/locations_services/locations/Pages/Long-Term-Care-Homes.aspx.