

	POLICY Number: 7311-100-002 Title: RESPONSIBLE CONDUCT OF RESEARCH
Authorization <input type="checkbox"/> President and CEO <input checked="" type="checkbox"/> Vice President, Finance and Corporate Services	Source: Vice President, Research and Innovation Cross Index: 7311-100-001, 7311-30-005 Date Approved: November 27, 2013 Date Revised: Date Effective: November 29, 2013 Date Reaffirmed: Scope: SHR and Affiliates

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OVERVIEW

This policy applies to all Saskatoon Health Region (SHR) and affiliate employees, practitioner staff, professional staff, contractors, and students. 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. The application of this policy is subject to the provisions of collective agreements covering the employment of such persons. In case of any disagreement between language in this document and that of an appropriate collective agreement, the language of the collective agreement will apply. If the collective agreement does not cover the matter, this document will apply. The guiding documents used to develop this policy include: The Tri-Agency Framework: Responsible Conduct of Research¹ and the University of Saskatchewan Responsible Conduct of Research Policy².

DEFINITIONS

Allegation means an assertion of wrongdoing. Allegations can be based on suspicion or suspecting something is wrong with little or no proof.

Complainant means person or persons reporting an allegation of a breach of the SHR Responsible Conduct of Research Policy.

Funder means source of funds for a research study. Examples include a for profit company (i.e. industry), a not-for-profit foundation (i.e. Heart and Stroke Foundation, Kidney Foundation, etc.), one of the Tri-Agencies (CIHR, NSERC, SSHRC), the National Institute of Health, a Cooperative Group (i.e. National Cancer Institute of Canada, Radiation Therapy Oncology Group, etc.) and internally funded (i.e. University of Saskatchewan, Saskatoon Health Region)³.

¹ Tri-Agency Framework: Responsible Conduct of Research

http://www.rcr.ethics.gc.ca/_doc/Framework-CadreReference_eng.pdf

² University of Saskatchewan Responsible Conduct of Research Policy, 2013

³ Adapted from the University of Saskatchewan Application for Biomedical Research Ethics Review

Principal investigator means the person who directs a research project or program using SHR facilities, resources, patients, long term care residents or staff.

Research means an undertaking designed to extend knowledge through a disciplined inquiry or systematic investigation⁴.

Research misconduct means any act by a researcher that is a breach of research integrity, this includes⁵:

- The intentional fabrication or falsification of data, research procedures, or data analysis; misappropriation of data; plagiarism; or other fraudulent or improprieties in proposing, conducting, reporting, or reviewing research.
- The re-publication of one's own previously published work or part thereof, or data, in the same or another language, without adequate acknowledgment of the source, or justification.
- The destruction of one's own or another's research data or records to specifically avoid the detection of wrongdoing or in contravention of the applicable funding agreement, institutional policy and/or laws, regulations and professional or disciplinary standards.
- Failure to comply with federal, provincial or SHR guidelines for the protection of researchers, human subjects, or the public, or for the welfare of laboratory animals, or failure to meet other legal requirements that relate to the conduct of research.
- Failure to reveal any conflict of interest when asked to undertake reviews of research grant applications or to test products for sale or distribution to the public.
- Failure to appropriately manage any real, potential or perceived conflict of interest.
- Failure to conduct research in the manner in which it has been approved by a University of Saskatchewan Research Ethics Board.
- Failure to appropriately recognize contributions of others in a manner consistent with their respective contributions and authorship policies of relevant publications.
- Inaccurate attribution of authorship, including attribution of authorship to persons other than those who have contributed sufficiently to take responsibility for the intellectual content, or agreeing to be listed as author to a publication for which one made little or no material contribution.
- Failure to reveal to SHR any financial interest in a company that contracts with SHR to undertake research, particularly research involving the company's products, or to provide research-related materials or services. Financial interest means ownership, direct or indirect beneficial interest, substantial stock holding, a directorship, significant honoraria or consulting fees, but does not include minor stock (< \$10,000) held in publicly traded corporations.
- Misuse of funds acquired for the support of research or failure to comply with the terms of research funding agreements.
- Failure to comply with SHR's Fraud and Irregularity Policy (#7311-10-002).

The definitions of misconduct in research should not be interpreted as including differences of opinion regarding research methodologies, analysis of data and theoretical frameworks.

Researcher means all those persons involved in any capacity in a research study. This includes all research staff such as the principal investigator, co-investigator, sub-investigator, research coordinator, research assistant, technical staff, and students.

⁴ TCPS2- Ethical Conduct for Research Involving Humans, 2010

⁵ Tri-Agency Framework: Responsible Conduct of Research
http://www.rcr.ethics.gc.ca/_doc/Framework-CadreReference_eng.pdf

Respondent means person or persons named in an allegation of a breach in the SHR Responsible Conduct of Research Policy.

SHR staff means SHR employees, practitioner staff, professional staff, affiliate employees, contractors and students. SHR staff can be researchers.

Student means an individual enrolled in an undergraduate, post-graduate, post-doctoral, residency or fellowship program. Students can be researchers.

Tri-Agency means Canada's federal research granting agencies – Canadian Institutes of Health Research (CIHR), Natural Sciences and Engineering Research Council of Canada (NSERC), and Social Sciences and Humanities Research Council of Canada (SSHRC).

1. PURPOSE

The purpose of this policy is to establish SHR's responsible conduct of research requirements while conducting research on behalf of, or under the administration of, SHR. This includes requirements related to applying and managing research funds, performing research, and disseminating results, and the processes that SHR will follow in the event of a breach in responsible conduct of research.

2. PRINCIPLES

- 2.1 Research conducted in SHR will be conducted in a manner that is ethical, rigorous and responsible as to uphold SHR's integrity.
- 2.2 Responsible conduct of research includes stewardship of resources, transparency and complying with all SHR and research funder policies and regulatory requirements.
- 2.3 It is also expected that the research environment be one that is fair and respectful for all those who work therein.
- 2.4 Allegations of research misconduct will be dealt with in a manner that ensures fairness and protects both those who have brought forward the allegation and those whose integrity is brought into question.
- 2.5 SHR will provide ongoing educational opportunities for those engaged in research in order to "foster and maintain an environment that supports and promotes the responsible conduct of research"⁶

3. POLICY

- 3.1 SHR is committed to ensuring that the highest standards of research integrity are understood and practiced.
- 3.2 SHR staff applying for research funding shall comply with the conditions for applying for funding grants or awards as required by the funder.

⁶ Tri-Agency Framework: Responsible Conduct of Research
http://www.rcr.ethics.gc.ca/_doc/Framework-CadreReference_eng.pdf

- 3.3** SHR staff awarded research funds shall manage the funding grant or award in accordance with the funding application and policies of the funder.
- 3.4** SHR staff applying or receiving research funding, such as Tri Agency funding, which requires a specified University of Saskatchewan appointment or position shall comply with all applicable University of Saskatchewan policies related to Research Integrity⁷ and administration of research funds including: Administration of Research Funds⁸ and Administration of Research Grants and Contracts⁹.
- 3.5** SHR staff conducting research shall follow the best research practices honestly, accountably, openly and fairly.
 - 3.5.1 SHR staff shall comply with applicable professional or disciplinary standards, ethical standards, all laws and regulations applicable to their research as well as SHR Policies: Research and Conflict of Interest.
- 3.6** All allegations of research misconduct shall be reported to the Vice President, Research and Innovation.
 - 3.6.1 Allegations will be treated seriously, including those that are received anonymously.
 - 3.6.2 The ability to conduct a thorough investigation into anonymous allegations will depend on the amount of detail provided, if it is insufficient, a thorough investigation may not be able to be initiated and cannot be guaranteed.
 - 3.6.3 Every effort will be made throughout the review process to ensure the confidentiality of the proceedings as a means to protect both those who make an allegation and those who are accused.
 - 3.6.4 Confidentiality and protections extends, where reasonably possible, to all meetings, meeting notes, documents, and conversations. SHR's Speaking Up – Protection of Persons Reporting Wrongdoing Policy (#7311-10-003) also applies.

4. ROLES AND RESPONSIBILITIES

4.1 SHR Staff

- 4.1.1 When applying for research funding, ensure that all information included in a funding application is accurate and that all co-applicants, collaborators or partners have agreed to be listed on the application. The applicant must be eligible to apply for, and/or hold, funds from the research or research funding organization.
- 4.1.2 When receiving research funding, maintain complete, accurate information on documentation for expenditures from grant or award accounts. All original financial records must be maintained for seven years.
- 4.1.3 When conducting research, carefully supervise all research staff, including students, for whom they have responsibility. The design of research activities, including experiments, processing of acquired data, recording

⁷ Tri-Agency Framework: Responsible Conduct of Research
http://www.rcr.ethics.gc.ca/_doc/Framework-CadreReference_eng.pdf

⁸ http://www.usask.ca/university_secretary/policies/research/8_22.php

⁹ http://www.usask.ca/university_secretary/policies/research/8_20.php

- of data and other results, interpretation of results and advice on the storage of data and results are included in this supervision.
- 4.1.4 When acting as the principal investigator or sub-investigator, be able to verify the authenticity of all data, or other factual information, generated in his or her research, while ensuring that confidentiality is protected where required.
 - 4.1.5 Set guidelines for how data will be recorded in his or her research group. Electronic storage of data stored must be done in ways that preserve their confidentiality and integrity of the data.
 - 4.1.6 Protecting the privacy of any individuals whose personal information has been obtained as part of any research activities as required under *The Local Authority Freedom of Information and Protection of Privacy Act*, the *Health Information Protection Act* and SHR's Privacy and Confidentiality Policy.
 - 4.1.7 When acting as the principal investigator of a research study, SHR staff are responsible for the long-term storage of data and associated material. Such material will not be destroyed while there is reasonable probability of questions from other investigators, colleagues or readers of resulting publications which could require access to the primary data or may require a re-analysis of the data. The data will be stored, at minimum, for five years post publication and longer if required by specific federal or provincial regulations. The data must be stored in a protected environment that limits access only to the researcher and/or their immediate supervisor.
 - 4.1.8 Ensure that any person who has made a substantial intellectual contribution to a research study being reported in a publication, either in the conception, design, or execution of the experimental work, interpretation of data or drafting the article, is included as an author or is given other appropriate acknowledgement. Specific requirements for authorship and acknowledgement will be determined by the ethical guidelines or procedures established by the journal(s) where publication is sought¹⁰
 - 4.1.9 Reporting any research misconduct of which they have become aware whether or not it is specifically included within this Policy to the Vice President, Research and Innovation.

4.2 Vice President Research and Innovation

- 4.2.1 Encourages activities that support responsible conduct of research.
- 4.2.2 Manages all allegations of breaches of the SHR Responsible Conduct of Research Policy. This includes:
 - Receiving allegations of breaches of the SHR Responsible Conduct of Research Policy;
 - Ensuring timely investigations are made into all allegations;
 - Providing final ruling on investigations; and
 - Facilitating appeals on the outcome of an investigation.
- 4.2.3 Informs the relevant funder and, where applicable, external institutions of any allegations related to activities that may involve significant financial, health and safety, or other risks.

¹⁰ The majority of medical journals adhere to the ICMJE guidelines pertaining to authorship http://www.icmje.org/ethical_1author.html

4.3 Investigations Committee (See Procedure 2.5)

- 4.3.1 Conducts investigations into allegations of breaches of the SHR Responsible Conduct of Research Policy.
- 4.3.2 Determines if a breach of the SHR Responsible Conduct of Research Policy has occurred and in cases where it has occurred recommend appropriate sanctions.
- 4.3.3 Reports their findings to the Vice President, Research and Innovation.

5. POLICY MANAGEMENT

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

6. NON-COMPLIANCE/BREACH

Non-compliance with this policy will result in a review of the incident. A review for non-compliance may result in disciplinary action, up to and including termination of employment/privileges.

7. REFERENCES

University of Saskatchewan Responsible Conduct of Research Policy, 2013
The Tri-Agency Framework: Responsible Conduct of Research, 2011
SHR Policy Conflict of Interest
SHR Policy Fraud and Irregularity
SHR Policy Research
SHR Policy Speaking-Up- Protection of Persons Reporting Wrongdoing
SHR Policy Privacy and Confidentiality

PROCEDURE

Number: 7311-100-002

Title: RESPONSIBLE CONDUCT OF RESEARCH

Authorization

President and CEO

Vice President, Finance and Corporate Services

Source: Vice President, Research and Innovation
Cross Index: 7311-10-002, 7311-10-003

Date Approved: November 27, 2013

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Scope: SHR and Affiliates

1. PURPOSE

The purpose of this procedure is to establish the process for responding to an allegation of a breach of the SHR Responsible Conduct of Research Policy.

2. PROCEDURE

2.1 Reporting

- 2.1.1 All staff should forward allegations of research misconduct in writing to their immediate supervisor. It is the responsibility of the supervisor to ensure that the allegations of research misconduct are forwarded to the Vice President, Research and Innovation.
- 2.1.2 Any person(s) suspected of research misconduct should not be confronted prior to the commencement of the review/investigative process. Records related to the activity may need to be examined before the suspected person(s) becomes aware of any review.
- 2.1.3 Allegations made toward any student will be forwarded by the Vice President, Research and Innovation to the Dean of Graduate Studies and Research/College Dean/Program Head at their home institution to determine collaboratively how the investigation will be conducted.
- 2.1.4 The Vice President, Research and Innovation reviews the written allegation to determine whether an informal or formal review is required. Informal review focuses on resolving the problem as opposed to taking disciplinary action. Formal review will be used when allegations, if proven, would constitute a breach in responsible conduct of research.
- 2.1.5 This process shall take place no more than ten (10) working days from receipt of the allegation.
- 2.1.6 Once it has been determined whether an informal or formal review is required the respondent will be informed of the allegation in writing by the Vice President, Research and Innovation.
- 2.1.7 Informal review of allegations will include consultation, raising the matter directly with the respondent or mediation.
- 2.1.8 Formal review of an allegation will be performed by an Investigations Committee appointed by the Vice President, Research and Innovation.
- 2.1.9 In the event that the allegation involves the Vice President, Research and Innovation, the President and CEO will carry out the functions of the Vice President, Research and Innovation in this policy.

2.5 Formal Review by an Investigations Committee

- 2.5.1 The Investigations Committee shall consist of three (3) senior SHR employees, each with either relevant research or academic expertise, one of whom to be appointed Chair by the Vice President, Research and Innovation. These committee members should, as much as possible, include appropriate representation from the respondent's peer group and have sufficient expertise to address the issues involved. Whenever possible, members of this committee will be from a different department than that of the respondent. Ex-officio members may include SHR Legal Counsel and the Department Heads/Manager/Director/Vice President of the respondent and complainant.
- 2.5.2 Within ten (10) working days after the Investigations Committee has been struck, the Vice President, Research and Innovation will notify both the complainant and respondent about the composition of the committee and advise the respondent and the complainant of the allegations, any evidence brought forward (to date) and the investigation process.
- 2.5.3 Any objection to the composition of this committee will be made to the Vice President, Research and Innovation within five (5) working days. The Vice President, Research and Innovation may adjust the composition of the Investigations Committee based on feedback from both the respondent and the complainant. The final decision on the composition of this committee rests with the Vice President, Research and Innovation.
- 2.5.4 Once the composition of the committee has been finalized, the Investigations Committee will meet within ten (10) working days to assess the nature and scope of the allegation and to determine the course of action.
- 2.5.4.1 After the initial meeting, the Chair will inform the Vice President, Research and Innovation of the decision of the Investigations Committee, who will inform both the complainant and respondent.
- 2.5.5 If the Investigations Committee determines that there is sufficient information to warrant a full investigation, an investigation will continue as outlined below. If the Investigations Committee determines that there is insufficient information to warrant a full investigation, the Chair will inform the Vice President, Research and Innovation who then informs both the complainant and respondent that the investigation is unable to proceed at that time.
- 2.5.6 The investigation into an allegation of a breach of the SHR Responsible Conduct of Research Policy will include:
- Review of all relevant documentation from both the complainant and the respondent.
 - Disclosure of all relevant documentation to both the complainant and respondent.
 - Opportunities for both the complainant and respondent to respond to the allegations and any presented evidence to the Investigations Committee, both in person and in writing.
 - Interviews with the complainant, respondent and other research staff/team members.
- 2.5.7 During the course of the investigation, the Investigations Committee may request additional documentation from the complainant, respondent, their respective Department Heads/Managers/Directors/Vice Presidents,

other research team members, or from other departments/individuals within SHR (as appropriate), including the Vice President Research and Innovation. In the event that this information is not submitted by the deadline set by the Investigations Committee, the Committee may exercise its right to access the requested information.

- 2.5.8 As much as possible, the Investigations Committee will attempt to protect the anonymity of other individuals (beside the complainant and respondent) involved in the investigation. However, this may not always be possible and the Investigations Committee will inform other individuals of their rights in this process.
- 2.5.9 Any information collected during the investigation will be shared with both the complainant and respondent during the course of the investigation.
- 2.5.10 Prior to reaching its final decision, the Investigations Committee will invite the complainant and respondent to respond to any new information presented during the course of the investigation.
- 2.5.11 During the investigation process, both the complainant and respondent may choose to have legal counsel and/or union representation (if appropriate) present.
- 2.5.12 Within sixty (60) working days of being appointed, the Investigations Committee shall complete its investigation and submit its recommendation/final report to the Vice President, Research and Innovation. The Vice President, Research and Innovation will rule on the allegation based on the recommendation/final report of the Investigations Committee. This ruling shall be considered final.
- 2.5.13 The Vice President, Research and Innovation will immediately inform the complainant, the respondent and the respondent's direct report.
- 2.5.14 In the event that the allegation or complaint is upheld, the Vice President Research and Innovation will discuss with Labour Relations to determine appropriate sanctions/disciplinary actions.
- 2.5.15 When the allegation is not substantiated, all reasonable steps to repair any damage to the reputation of either the complainant or respondent that may have occurred during the course of the investigation or as a result of the allegation.
- 2.5.16 If an allegation is found to have been made in bad faith, the Vice President, Research and Innovation will forward the case to the Privacy and Access Office and it will be investigated under the SHR Fraud and Irregularity Policy.

2.6 Appeals

- 2.6.1 Complainants and respondents may appeal the decision to the Vice President, Research and Innovation. This appeal must be made in writing, and it must include reasons for the appeal. This appeal must be made within (ten) 10 working days after the final decision has been presented to the parties involved.
- 2.6.2 Within (ten) 10 working days of receiving an appeal, the Vice President Research and Innovation will contact the Vice President, Research of another health region, and ask them to review the letter of appeal and all relevant documentation. The Vice President, Research and Innovation will take the recommendations from this Vice President under advisement and make a final decision that will be binding.

2.7 Notification of Funding Agencies and Research Collaborators

- 2.7.1 In the event that an allegation of research misconduct is upheld, the Vice President, Research and Innovation shall inform any research collaborators as well as any agency or institution that has sponsored the research. If the research is funded by a Tri-Agency Council, a summary report of the allegations, investigation, and follow-up actions will be forwarded to their appropriate representative.
- 2.7.2 If an allegation of a breach of the SHR Responsible Conduct of Research Policy has been brought forward by a funding or sponsoring agency, that organization will receive a summary report of the allegations, investigation, and follow-up actions taken, regardless of the outcome of the inquiry within thirty (30) days following the completion of the report.

2.8 Follow-Up on Investigation Report

- 2.8.1 During the investigation, the Investigations Committee may present a number of recommendations, in addition to their final report. If an investigation report includes other recommendations, the Vice President, Research and Innovation shall strike a committee of no less than 3 people to an Investigations Follow-up Committee. The Vice President, Research and Innovation may seek input from the complainant and respondent as to the composition of this committee and may choose to invite either or both to participate in this process as well.
- 2.8.2 Within sixty (60) days of being struck, the Investigation Follow-up Committee shall prepare an implementation plan for the report recommendations. This implementation plan will include timelines and an action plan, if appropriate, for each recommendation.
- 2.8.3 The Vice President, Research and Innovation will be responsible for ensuring that the action plans are implemented for the recommendations.

2.9 Documentation

- 2.9.1 All documentation and communication related to an investigation of a breach / suspected breach is considered highly confidential.
- 2.9.2 Detailed records will be kept of the investigation process including minutes of all meetings and interviews, and copies of all relevant documentation provided by the complainant, respondent and other individuals.
- 2.9.3 All documentation and communication related to an investigation of a breach/suspected breach will be retained by the Vice President, Research and Innovation for seven (7) years.

3. PROCEDURE MANAGEMENT

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

4. NON-COMPLIANCE/BREACH

Non-compliance with this procedure will result in a review of the incident. A review for non-compliance may result in disciplinary action, up to and including termination of employment/privileges.

5. REFERENCES

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