

UNIVERSITY COUNCIL
RESEARCH, SCHOLARLY AND ARTISTIC WORK COMMITTEE
REQUEST FOR INPUT

PRESENTED BY: Stephen Urquhart, Chair

DATE OF MEETING: May 16, 2013

SUBJECT: *Human Research Ethics Policy*

COUNCIL ACTION: For input only

PURPOSE

The *Human Research Ethics Policy* articulates the requirements for ethical conduct of research with human participants in any capacity at the University of Saskatchewan and applies to all members of the University as defined in the policy. The policy document is intended to replace the policy on *Research Involving Human Subjects* approved by Council in 2000.

DISCUSSION SUMMARY

The University of Saskatchewan follows the national standards articulated in the current *Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans* under the new agreement on the *Administration on the Administration of Agency Grants and Awards by Research Institutions*. The new policy brings the University into compliance with this Tri-Agency policy statement.

The previous policy committed the University to the national standards for research involving human subjects and laid out an administrative structure for the ethical review of such research. The new policy sets forth the requirements for ethical conduct of research for those involved in any capacity in research with humans under the auspices of the University and commits the University to following the national standards and principles articulated in the current Tri-Agency policy. The new policy also outlines the principles for research involving human participants as articulated in the Tri-Agency policy statement. These are respect for persons and their autonomy, concern for the welfare of research participants, and justice related to the fair and equitable treatment of all people. The new name reflects that participants in research are no longer referred to as subjects.

The policy outlines the responsibilities of the University, University Council, the University Committee for Ethics in Human Research, the Research Ethics Office, the University's Research Ethics Boards and the responsibility of researchers to ensure research at the University of Saskatchewan is conducted under the highest standards of

Human Research Ethics Policy (effective July 1, 2013)

Category: Research and Scholarly Activities
Responsibility: Vice-President Research
Authorization: University Council
Approval Date: (proposed) June 20, 2013, effective date July 1, 2013

1.0 Purpose:

To set forth the requirements for ethical conduct of research with human participants for all those involved in any capacity in research under the auspices of the University of Saskatchewan

2.0 Principles:

When humans, human tissues or human data are used in the course of research or other comparable activities, it is the primary concern of the University that the rights of the participants are respected and protected and that the procedures followed comply with ethical, scientific, methodological, medical, and legal standards.

The University of Saskatchewan follows the national standards articulated in the current *Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans*. The guiding principles of this policy statement are:

- Respect for persons, including the recognition of the intrinsic value of human beings and respect for the autonomy of research participants. Respect for autonomy is normally reflected in the requirement to seek free and informed consent from participants both prior to and during their participation in a research project.
- Concern for welfare is broadly construed to mean all aspects of a person's life, including their physical and mental health, spiritual well-being, and other elements of their life circumstances. Concern for welfare includes respect for the person's privacy and confidentiality and requires that Research Ethics Boards (REB) and researchers adopt an attitude that aims to protect the welfare of research participants, minimize foreseeable risks to those participants and their communities, and inform research participants of those risks.
- Justice requires that people be treated equitably and fairly. The principle of justice takes into account the vulnerability of the person, the difference in power between participant and researcher, and seeks to equitably distribute the risks and benefits of research participation.

3.0 Scope of this Policy:

For the purposes of this policy, research is defined as "an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation".

45 This policy applies to all members of the University involved in research with human
46 participants, tissues or data. Members of the University of Saskatchewan include but are
47 not limited to, faculty, professors emeriti, sessional lecturers, staff, trainees, clinical faculty,
48 graduate and undergraduate students, adjunct professors, visiting professors, visiting
49 scholars, professional affiliates, associate members, residents, and postdoctoral fellows
50 (PDFs) at the University of Saskatchewan.

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52 This policy also applies to research with human participants, tissues or data undertaken by
53 any person or Institute/Centre associated with the University of Saskatchewan, or using any
54 University of Saskatchewan resources inclusive of persons (i.e., students, staff, faculty), or if
55 funds for such purposes be accepted or accounts established.

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57 In addition, this policy applies to those institutions that have entered into affiliation
58 agreements with the University of Saskatchewan for purposes of ethics review of research
59 with human participants.

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61 4.0 Policy:

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63 Research at the University of Saskatchewan will be conducted under the highest standards
64 of ethical integrity and in accordance with the following responsibilities:

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66 4.1 Responsibilities:

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68 a. The University of Saskatchewan is responsible for establishing the Research Ethics
69 Boards, defining their reporting relationships, ensuring the REBs have sufficient
70 support to carry out their duties and supporting and promoting the independence of
71 the REBs in their decision making.

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73 b. University Council, through the Research, Scholarly and Artistic Work Committee of
74 Council is responsible for receiving annual reports of the Research Ethics Boards, and
75 for maintaining governance oversight over University research ethics policies.

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77 c. The University Committee for Ethics in Human Research (UCEHR) reports to the Vice-
78 President, Research through the Director, Research Ethics and is responsible for
79 adopting codes, guidelines, standards, and policies, with respect to research ethics
80 review. In this adoption, the Committee must adhere to the Tri-Agency guidelines
81 and other applicable policy and legislation. UCEHR is responsible for hearing appeals
82 of REB decisions.

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84 d. The Research Ethics Office (REO) is responsible for supporting the University's
85 Human and Animal Research Protection Programs to ensure the rights of research
86 participants and animals are protected and that the University is in compliance with
87 funding agencies, national guidelines, and international standards.

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89 e. Research Ethics Boards (REB) are responsible for the review of the ethical
90 acceptability of research under the auspices of or within the jurisdiction of the

91 University of Saskatchewan, including approving, rejecting, proposing modification
92 to, or terminating any proposed or ongoing research involving humans. The
93 University of Saskatchewan REBs will adhere to the Tri-Agency MOU, the Tri Council
94 Policy Statement on the Ethical Conduct for Research Involving Humans and, where
95 required, to provincial, national and international guidelines and regulations.
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- 97 f. Researchers are responsible for conducting their research according to the principles
98 and procedures found in the relevant university, provincial, national and
99 international guidelines including:
- 100 i. obtaining all the required approvals prior to the inclusion of human
101 participants, tissues or data in the research.
 - 102 ii. ensuring that their research, scholarly, and artistic work is conducted in
103 accordance with these approved protocols.
 - 104 iii. adhering to all reporting requirements.
 - 105 iv. ensuring that students and research staff are carefully trained and supervised
106 in the conduct of research.
 - 107 v. protecting the privacy of any individuals whose personal information has
108 been obtained as part of any research activities as required under the
109 University's Freedom of Information and Protection of Privacy Policy, *the*
110 *Local Authority Freedom of Information and Protection of Privacy Act* and *the*
111 *Health Information Protection Act* and any other relevant legislation.
 - 112 vi. Adhering to the University of Saskatchewan Responsible Conduct of Research
113 Policy and the Procedures on the Stewardship of Research Records at the
114 University of Saskatchewan.

115 116 5.0 Non-Compliance:

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118 Failure to comply with pertinent federal, provincial, international, or University guidelines
119 for the protection of human research participants and/or failure to conduct research in the
120 manner in which it has been approved by the University's Research Ethics Boards is defined
121 as a breach of the Responsible Conduct of Research Policy and will be handled under the
122 procedures of that policy.
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124 6.0 Procedures:

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126 Application guidelines, composition of the REB's, review procedures, appeal procedures,
127 activities requiring REB review, and information pertaining to all aspects of the review of
128 research protocols are described in the Research Ethics Office Standard Operating
129 Procedures (SOPs). SOPs are issued and maintained by the Research Ethics Office.
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131 7.0 Contact:

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133 For further information please contact the Director, Research Ethics, phone: 966-2975;
134 email: ethics@usask.ca
135

Effective date July 1, 2013

ethical integrity. The policy refers to the Responsible Conduct of Research policy for non-compliance and the Research Ethics Office Standard Operating Procedures, which outline the day-to-day working of the Research Ethics Office and Research Ethics Boards.

CONSULTATION:

The University Committee on Ethics in Human Research undertook the policy revisions in consultation with the Policy Oversight Committee, the Associate Deans Research and the Research, Scholarly and Artistic Work Committee of Council. The policy was also made available for comment on the University website.

FURTHER ACTION REQUIRED:

The revisions to the policy and procedures will be incorporated into graduate student academic integrity and ethics education and the ongoing educational efforts of the Research Ethics Office. The policy will be available on the Research Ethics Office website, the policy website and communicated to the Associate Deans Research.

ATTACHMENTS:

1. *Human Research Ethics Policy*

The University's existing policy on *Research Involving Human Subjects* can be found at: http://www.usask.ca/university_secretary/policies/research/8_02.php