Winnipeg Regional Health Authority / Office régional de la santé de Winnipeg Caring for Health / À l'écoute de notre santé	**REGIONAL** Applicable to all WRHA governed sites and facilities (including hospitals and personal care homes), and all funded hospitals and personal care homes. All other funded entities are excluded unless set out within a particular Service Purchase Agreement.		Level: 1
POLICY	Policy Name: **Ethical Conduct of Research**	Policy Number: 10.50.080	Page 1 of 13
	Approval Signature: *Original Signed by R.Cloutier*	Section: Governance & General Administration	
	Date: November 2017	Supercedes: January 2006	

1.0 PURPOSE:

1.1. To support and facilitate Research intended to create knowledge, to inform positive service provision changes, healthcare policy, and practice, whether directly or indirectly, while preserving the trust, privacy and dignity of human Research Participants.

1.2. To operationally define Research, Quality Improvement, Evaluation and Surveillance, and to establish clear criteria for determining the differences between the same.

1.3. To promote the highest ethical standards and principles of activities conducted within the WRHA or WRHA-funded facilities which meet the definition of Research as per this policy; and to establish that said Research be conducted at minimum in accordance with the guidelines articulated in the *Tri-Council Policy Statement 2: Ethical Conduct for Research Involving Humans*, (herein *TCPS 2*).

1.4. To foster compliance with all applicable regulatory requirements and standards for Research, Quality Improvement, Evaluation and Surveillance activities conducted within the WRHA or WRHA-funded facilities; and to outline the necessary approvals for conducting said activities within the WRHA or WRHA-funded facilities.

2.0 DEFINITIONS:

2.1. Evaluation: A systematic, ongoing and applied inquiry process for collecting and analyzing data at WRHA facilities and WRHA-funded facilities. Although the findings of Evaluation activities may be published or shared pending organizational approval, findings are primarily intended for use within the WRHA or WRHA-funded facilities. Evaluation activities:

a. judge the merit or worth of programs, policies, products, processes, procedures, practices, or interventions;

b. inform improvements to programs, policies, products, processes, procedures, practices, or interventions;

c. contribute to the design and development of programs, policies, products, processes, procedures, practices, or interventions;

d. lead to the creation of new knowledge within the organization.

2.1.1. Evaluation activities do not expose patients or staff to more than Minimal Risk:

a. participants continue to engage in routine care, program provision, or role performance; and

b. data is typically gathered in an unobtrusive/non-invasive manner (e.g. interviews, focus groups, questionnaires), and/or as part of existing protocols for the collection of data during the provision of programs or routine care.

2.2. Informed Consent for Research: An ongoing process of dialogue, understanding and trust between Participants or the Participant's legally authorized representative and Researchers, in which Participants are fully informed as to their potential role in the Research (including possible risks and benefits), and provided the opportunity to voluntarily choose whether to participate or not.

2.3. Minimal Risk: "Research in which the probability of and magnitude of possible harms implied by participation in the Research is no greater than those encountered by Participants in those aspects of their everyday life that relate to the Research." (See *TCPS 2* "Chapter 2: Scope and Approach" Section B)

2.4. Participant: An individual whose data, or responses to interventions or questions posed by a Researcher are relevant to answering a Research question; also referred to in policies and guidelines as 'subject' or 'Research subject'. (See Reference 5.2.)

2.5. Quality Improvement (QI): A systematic, data-guided activity undertaken at WRHA facilities or WRHA-funded facilities for the purposes of assessing, analyzing, and improving current health care practices and processes. QI activities produce local knowledge and local quality improvements. QI activities are typically observational and unobtrusive, and involve the collection and analysis of data to which QI personnel have legitimate access through their roles at the WRHA. QI activities:

a. are intended to produce improvements in healthcare delivery;

b. are designed to result in sustained and continuous improvements;

c. do not require rigid, fixed protocols; within QI activities it is expected that the project adapt over time as the institutional setting changes;

d. do not prevent or hinder the delivery of clinically-indicated care to patients, nor should they impose greater than Minimal Risk to patients;

e. do not delay feedback of the data obtained from monitoring to the implementation of the desired change.

2.6. Research Ethics Board (REB): A membership of individuals duly comprised of interdisciplinary academics and Researchers, and community, ethical, legal and lay representatives established by an institution for the purpose of reviewing the ethical acceptability of all Research involving humans conducted within the jurisdiction or auspices of the institution.

2.7. Research: Any systematic investigation and/or disciplined inquiry, which may include social science, biomedical, behavioural, or epidemiological activity performed at WRHA facilities or WRHA-funded facilities (including pilot studies, exploratory studies, and feasibility studies) intended to test a hypothesis, establish facts and/or principles, or explore nuanced experiences and contexts, to develop or contribute generalizable findings and/or new knowledge for dissemination to the academic, scientific, and/or professional community. Generalizable knowledge consists of theories, principles or relationships, or the accumulation of information on which these are based that can be corroborated by accepted scientific methods of observation, inference and/or experiment.

2.7.1. Research possesses the following characteristics:

a. the primary intent of the activity is to contribute generalizable findings and new knowledge to the academic, scientific, or professional community;

b. the scope and design of the project may be determined and developed by the Researcher, a sponsor, a funder, or a combination of the participating Researchers and the funder; and

c. the primary method of dissemination is through publications and presentations and peer-reviewed research journals: this includes publication of the data, theory, methodology, and results of the study in question.

2.7.2. Activities considered Research for the purposes of this Policy include:

a. obtaining data about a participant(s) through both invasive (e.g. a medical procedure) and non-invasive (e.g. a survey/interview) means, through interventional or observational means, and/or the use of personal health information about the individual(s), who are the focus of the Research;

b. use of clinical data (e.g. information, such as medical records, collected for purposes other than the proposed Research) and/or patient information collected for purposes other than the primary purpose for which the information was collected. This may include identifying or potentially identifying information about an individual(s), or data linkage through which individuals may become identifiable; and

c. the use of any human biological materials such as: blood and blood components, urine, tissue, human embryos, foetuses, fetal tissue, reproductive materials and stem cells which have been derived from living and/or deceased individuals.

2.8. Researcher: Refers to the primary Researcher or principal investigator leading the Research team who is deemed responsible and ultimately accountable for: the ethical conduct of the Research in question; compliance with all applicable legal, ethical, regulatory, and contractual obligations, as well as professional standards, guidelines, policies and contractual obligations; and the actions of any member of the Research team.

2.9. Surveillance: The ongoing, systematic, and regular collection, analysis, interpretation and dissemination of data at WRHA facilities and WRHA-funded facilities designed to provide the information needed to achieve informed decision-making for appropriate and prompt public health action. Surveillance activities:

a. assess the status of public health and provide early warning of impending public health emergencies;

b. determine and specify both short and long-term public health priorities;

c. provide the data necessary to inform and evaluate particular programs; and

d. stimulate future Research and other enhanced Surveillance activities.

2.9.1. The findings of Surveillance activities are meant to inform direct and specific action within the WRHA or WRHA-funded facilities.

2.9.2. Surveillance typically possesses an explicit mechanism through which the findings of Surveillance activities are directly and immediately deployed in the development of an operational response.

2.9.3. Surveillance activities are characterized by the use of observational data collection methods which do not expose patients and/or staff to greater than Minimal Risk.

2.10. Tri-Council Policy Statement (TCPS 2): A joint policy developed by Canada's three federal granting agencies (Tri-Council) intended to promote the ethical conduct of Research involving humans. These agencies include: Canadian Institutes of Health Research (CIHR), Natural Sciences and Engineering Council of Canada (NSERC), and Social Sciences and Humanities Research Council of Canada (SSHRC). To be eligible to receive and administer Tri-Council funding, both Researchers and Canadian Research Institutions must comply with all Tri-Council policies as outlined in TCPS 2. TCPS 2 has been adopted throughout Canada as the minimum standard for ensuring the ethical conduct of Research involving humans.

2.11. Vulnerable Individuals: Includes but is not limited to individuals with cognitive impairments or intellectual disabilities who lack the capacity to decide independently whether to participate in Research: as well as those individuals who possess full decision-making capacity but whose situation or circumstances increase their vulnerability to inequitable, unfair, or unethical treatment in the context of the proposed Research.

2.12. WRHA Research Access and Approvals Committee (RAAC): A regional committee tasked with reviewing all Research and Research related proposals for Research activities to be conducted within WRHA corporate or community areas, WRHA funded agencies that do not have their own institutional review committee, as well as Research studies involving regional programs and

services, studies that involve multiple care facilities, and studies that require access to electronic patient health information for which the WRHA is a trustee of that patient information.

3.0 **POLICY:**

3.1. Policy Statement:

3.1.1. This policy shall apply to all potential Researchers both internal and external to the WRHA who are conducting Research within the WRHA and/or a WRHA funded program or agency.

3.1.2. Generalization and dissemination of any evidence derived from data collected during the course of an Evaluation, Quality Improvement, and/or Surveillance activity shall be subject to a Privacy review (i.e., a brief review of the content and/or data elements within the proposed dissemination) to ensure privacy and confidentiality are maintained by the project teams. Privacy reviews are conducted and/or coordinated by the WRHA Research Access and Approval Committee, and may be subject to an REB review prior to publication and/or presentation for audiences outside of the WRHA and/or WRHA-funded facilities.

3.1.3. If data is initially collected for Evaluation, Quality Improvement, or Surveillance purposes, but later employed for Research purposes, such use shall be considered secondary use of data and shall then fall under the definition of Research as per this policy.

3.1.4. All Research conducted within the WRHA or WRHA-funded facilities shall be conducted in accordance with the highest ethical standards as outlined in the most recent version of the TCPS2 and this policy.

3.1.4.1. *TCPS 2* and all applicable local, provincial and federal legislation and guidelines represent the minimum standards for conducting Research involving human Participants. The WRHA hereby holds the right and discretion to establish and enforce higher standards where appropriate.

3.1.5. All data collected and/or provided by the Trustee in the course of Research, Evaluation, Quality Improvement, or Surveillance activities shall be subject to the requirements for the ethical, confidential, and secure management of Research data as outlined in relevant WRHA Policies.

3.1.6. Researchers shall comply with all applicable legal, ethical, regulatory, and contractual requirements, as well as professional standards, guidelines, and policies pertaining to the Research being undertaken.

3.1.7. Prior to the conduct of Research at WRHA or WRHA-funded facilities, Researchers shall obtain ethics approval from the appropriate REB.

3.2. Statement of Ethical Principles:

3.2.1. Researchers shall adhere to, at minimum, the three core ethical principles of *TCPS 2*:

a. Respect for persons: Respect for Persons recognizes the intrinsic value of human beings and the respect and consideration that they are due.

b. Concern for Welfare: The welfare of a person is the quality of that person's experience of life in all its aspects. Welfare consists of the impact on individuals of factors such as their physical, mental and spiritual health, as well as their physical, economic and social circumstances.

c. Justice: Justice refers to the obligation to treat people fairly and equitably.

3.2.2. Researchers shall consult *TCPS 2*, Article 1.1. for further guidance on the practical application of the above ethical principles to the conduct of human Research.

3.3. Obtaining Consent from Research Participants:

3.3.1. Researchers shall obtain free and Informed Consent from each prospective Participant or the Participant's legally authorized representative prior to commencing any proposed Research.

3.3.1.1. Whereby Research involves the use of information primarily collected for clinical use and contains identifiable or potentially identifiable data, the Researcher shall seek Informed Consent or clearly demonstrate to the WRHA why obtaining Informed Consent for Research from the Participants whom the information is about is impossible or impractical. (See *PHIA* 23(3)c.)

3.3.2. Researchers shall adhere to the Informed Consent guidelines as outlined in *TCPS 2* "Chapter 3: The Consent Process", which details the ethical requirements for consent in Research involving human Participants.

3.3.3. All Informed Consent forms provided to prospective Participants shall be reviewed and approved by a Research Ethics Board and contain, at minimum, the consent form elements as outlined in *TCPS 2*, Article 3.2.

3.4. Conflict of Interest:

3.4.1. Researchers shall disclose any real or perceived conflict(s) of interest to the applicable REB of record, Institutional Impact Committee and/or RAAC in accordance with WRHA Regional Policy #20.10.010 "Conflict of Interest", which provides guidance as to the proper identification and definition of conflict of interest situations, and outlines WRHA procedures for the proper handling of conflict of interest situations.

3.4.2. Researchers shall adhere to all applicable legal obligations, professional code(s) of ethics, and standards of conduct and/or guidelines relating to the identification and handling of conflict of interest situations.

3.5. Fair and Equitable Treatment of Vulnerable Individuals and Minors:

3.5.1. Special consideration shall be given to the ethical inclusion and fair and equitable treatment of Vulnerable Individuals who are legally or otherwise not competent to provide Informed Consent for participation in Research.

3.5.1.1. The participation of Vulnerable Individuals in Research shall be considered ethically acceptable only if it can be shown that their

inclusion is both necessary and appropriate to address the Research question. Participation of Vulnerable Individuals in Research may be considered if the proposed Research cannot be conducted effectively using a legally-competent or less vulnerable population.

3.5.1.2. Researchers shall not unnecessarily exclude Vulnerable Individuals who lack decision-making capacity. (See Appendix for further clarification)

3.5.2. Special consideration shall be given to the Research design and Informed Consent process when minors are involved.

3.5.2.1. Researchers shall not unnecessarily exclude minors from Research solely on the basis of their age or developmental stage. (See Appendix for further clarification)

3.6. Requirement for Research Ethics Review and Approval:

3.6.1. Pursuant to Article 3.1.7. prior to the commencement of Research involving human Participants (including staff) conducted within the WRHA or WRHA-funded facilities, Researchers shall obtain:

a. approval, by way of a Certificate of Approval from the University of Manitoba Research Ethics Board. In limited circumstances, approval from a Research Ethics Board at another recognized TCPS 2 compliant institution may be accepted at the discretion of the WRHA Research Access and Approval Committee. All REB approvals must come from a Research Ethics Board that, at minimum, conforms to the ethical standards outlined in *TCPS 2,*

b. approval from the relevant Institutional Impact and/or Research Access and Review Committee, which includes a review regarding compliance with *The Personal Health Information Act* (Manitoba) and *The Freedom of Information and Protection of Privacy Act* (Manitoba), for each facility or program in which the Research is to be conducted unless otherwise instructed by the WRHA Research Access and Approval Committee;

c. other approvals as required by law, policy, process or agreement (i.e. Health Canada, Health Information Privacy Committee (HIPC) etc.); and

d. a completed and signed researcher agreement as per *PHIA* 24(4). Researcher agreements shall be duly signed data sharing agreements between the trustee(s) of the data and the representative person or organization(s) tasked with ensuring the protection and storage of the data disclosure. The WRHA Research Access and Approval Committee administers and manages researcher agreements where the WRHA is the trustee of the Personal Health Information.

3.6.2. The RAAC shall review all Research and Research related proposals for Research activities to be conducted within WRHA corporate or community areas, WRHA funded agencies that do not have their own institutional review committee, as well as Research studies involving regional programs and services, studies that involve multiple care facilities, and studies that require access to electronic patient health information for which the WRHA is a trustee of that patient information.

3.7. Ongoing Research:

3.7.1. A Research study shall be considered ongoing when:

a. data continues to be collected directly from Participants (including follow-up data after recruitment is closed) beyond the approval expiration date as listed on the most current certificate of approval as provided by the REB of record, or;

b. data continues to be collected from secondary sources including, but not limited to, medical records and linked datasets, beyond the approval expiration date as listed on the most current certificate of approval as provided by the REB of record, or;

c. human biological samples, including human tissue, continue to be withdrawn from a tissue bank or acquired from the research participant beyond approval expiration date as listed on the most current certificate of approval as provided by the REB of record.

3.7.2. Researchers shall suspend all Research-related activities including the recruitment of new Research Participants, the collection of data, and the collection of biological samples upon expiration of the certificate of approval granted by the REB of record. Researchers may resume their activities once the certificate of approval for ongoing conduct of the study has been obtained from the REB of record. (See Article 4.4. for further clarification)

3.7.3. All certificates of approval awarded, as well as annual approvals, by an REB to a Researcher shall be promptly submitted to the relevant Institutional Impact and/or RAAC.

3.7.4. Researchers shall report any suspension or termination of Research due to a lapse in approval or otherwise to the applicable Institutional Impact and/or RAAC. The WRHA reserves the right to cancel, terminate, or suspend part or all Research activities conducted within the WRHA or WRHA-funded facilities.

3.8. Researcher Responsibilities:

3.8.1. All Researchers who conduct Research within the WRHA or WRHA-funded facilities shall:

a. protect the rights and welfare of all Research Participants, including ensuring the security and confidentiality of data containing potentially identifying information (i.e., data elements that are non-identifying when presented in isolation, but may become identifiable information when combined with other non-identifying data elements);

b. comply with the Research proposal and protocol as reviewed and approved by the appropriate Research Ethics Board and relevant Institutional Impact and/or Research Access and Approval Committee;

c. comply with all applicable regulations and legislation relating to the protection and security of personal health information and Research data. Including but not limited to local, provincial, and federal laws such as *The*

Personal Health Information Act; *Freedom of Information and Protection of Privacy Act*; all applicable WRHA and confidentiality policies;

d. comply with all reporting requirements in accordance with local, provincial, and federal laws; REB requirements; funder requirements (i.e. CIHR); and all applicable WRHA reporting policies;

e. comply with applicable local, provincial and federal laws and regulations regarding: proper maintenance, storage and retention of all Research documentation, including source documents and essential documents for the conduct of a clinical trial.

f. confirm the entire Research staff is fully qualified by education, training (including PHIA), and experience to undertake the responsibilities for which they have been assigned during the course of the Research, and monitor the work performed by all members of the Research team;

g. shall adhere to *TCPS 2* and all other applicable legal, ethical, regulatory, and contractual requirements, as well as professional standards, guidelines, and policies pertaining to the Research being undertaken.

h. create a work environment that promotes and supports the ethical conduct of Research at all stages of the Research process and among all members of the Research team;

i. obtain REB approval and the relevant Institutional Impact and/or RAAC approvals prior to Research-related activities being conducted within the WRHA or WRHA-funded facilities; and

j. continue their commitment to the ethical conduct of Research even upon completion of the Research in question.

4.0 **PROCEDURE:**

4.1. Research Involving Participants Identified as Vulnerable Individuals and Minors:

4.1.1. Researchers intending to include people who are identified as Vulnerable Individuals as Participants in a Research study shall ensure that Informed Consent for Research is obtained from a legally authorized representative in compliance with all applicable legal requirements (including but not limited to: *The Vulnerable Persons Living with a Mental Disability Act*; and *The Mental Health Act*). Particular attention shall be paid to the prevention of real or apparent coercion, constraint or undue inducement to participate. (See *TCPS 2,* Article 4.6.)

4.1.2. Researchers intending to include minors as Participants shall obtain the Informed Consent for Research of parents or a legally authorized representative prior to commencing any Research activities and minors shall be afforded the ability to consent/decline participation independently when applicable and appropriate given the potential unique context and nature of the proposed study. All information provided to minors in the course of the Research shall be comprehensible and appropriate to their age and level of development. Particular attention shall be paid to the prevention of real or apparent coercion, constraint or undue inducement to participate. (See *TCPS 2*, Article 4.4.)

4.1.3. For further guidance on the ethical conduct of Research involving Vulnerable Individuals and minors, Researchers should consult *TCPS 2* "Chapter 4: Fairness and Equity in Research Participation" which provides guidance on the ethical inclusion in Research of individuals and groups that might be unnecessarily excluded, or are at greater risk of incurring Research-related harm on the basis of their culture, language, gender, race, ethnicity, age and/or disability.

4.2. Research Involving First Nations, Inuit, and Métis Peoples:

4.2.1. The WRHA acknowledges the unique status of Indigenous peoples of Canada and affirms the guidance provided by *TCPS 2* "Chapter 9: Research Involving the First Nations, Inuit, and Métis Peoples of Canada", which serves as a framework for the ethical conduct of Research involving Indigenous peoples. In endorsing the guidance provided in *TCPS 2* "Chapter 9", the WRHA does not intend to supplant the ethical guidance provided by Indigenous peoples themselves, but seeks to assert the WRHA's commitment to encouraging and supporting respectful and ethical collaboration and engagement between Researchers, Indigenous Participants and their communities.

4.2.2. The guidance provided in *TCPS 2* "Chapter 9" is premised on the idea that engagement with the community is a critical component of the ethical conduct of Research involving Indigenous peoples. Research involving Indigenous Participants should ensure that the diverse and distinct world views of First Nation, Inuit and Métis peoples are considered and incorporated throughout the entire Research process. Moreover, Researchers should respect community customs and codes of Research practice to ensure a balanced relationship between Researchers and Participants, and mutual benefit in Researcher-community relations.

4.2.3. Researchers planning to involve Indigenous peoples as participants in their Research should consult *TCPS 2* "Chapter 9: Research Involving the First Nations, Inuit, and Métis Peoples of Canada" for additional guidance as to the conditions under which community engagement is required, and the particular forms of engagement that should be sought.

4.3. Data Safety Monitoring (DSM):

4.3.1. For Research involving human Participants that is deemed high-risk, or involves Vulnerable Individuals, minors, and/or First Nations, Inuit, or Métis peoples, Researchers should consider the creation and implementation of a Data Safety Monitoring Plan (DSMP). A DSMP is a plan that ensures the progress of a study and the safety of participants through monitoring. A DSMP also ensures data accuracy and protocol compliance, as well as provides a clear process for reporting adverse events and/or non-compliance concerns to established research governance bodies (e.g., REB of record, Institutional Review Committee(s), funding body, etc.). The DSMP shall be submitted to the applicable REB for review and approval prior to being implemented. Researchers are encouraged to consult *TCPS 2*, Article 11.7. for guidance on the development and implementation of a DSMP.

4.3.2. Researchers are encouraged to consider the establishment of a Data Safety Monitoring Board (DSMB) when appropriate. A DSMB is typically employed in high-risk Research and consists of an independent advisory body formed

under the authority of the sponsor. A DSMB is primarily responsible for assessing data during the entire course of a study in order to monitor and ensure the scientific and ethical integrity of the Research being conducted. Further guidance on the establishment of a DSMB can be found in the following non-binding guidelines:

a. World Health Organization. *Operational Guidelines for the Establishment of Data and Safety Monitoring Boards*. 2005. Available at www.who.int/tdr/publications/tdr-research-publications/operational-guidelines/en/

b. US Food and Drug Administration. *Establishment and Operation of Clinical Trial Data Monitoring Committees*. 2006. Available at http://www.fda.gov/RegulatoryInformation/Guidances/ucm 127069.htm

4.4. Renewal of Previously Approved Research:

4.4.1. If the Researcher desires to continue the Research project/study beyond the approval expiry date listed on the most current certificate of approval, the Researcher shall submit an application to the REB of record (the REB where the original submission was reviewed and approved) requesting renewal of ongoing approval for the Research project/study. The Researcher shall submit this application to the REB of record IN ADVANCE of the approval's expiration date.

4.4.2. Non-compliance with Article 4.4.1. of this Policy may result in suspension of the Research project in question until such time as renewal of research ethics approval has been obtained.

5.0 REFERENCES:

5.1. Canadian Institutes of Health Research, Natural Sciences and Engineering Council of Canada, and Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, December, 2014.

5.2. Dalhousie University. Dalhousie Research Ethics Boards. *Guidelines for Differentiating Among Research, Program Evaluation and Quality Improvement*. November, 2013. Retrieved from: http://www.dal.ca/content/dam/dalhousie/doc/research-services/Guidelines%20research%20PE%20QI%20%2828%20Nov%202013%29.pdf

5.3. Evaluation Platform, George and Fay Yee Centre for Healthcare Innovation. Evaluation Misconceptions: *April Note in recognition of 2015 International Year of Evaluation.* http://cme02.med.umanitoba.ca/assets/chi/assets/attachments/322/original/april-note.pdf?1430413549

5.4. International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. *ICH Harmonised Tripartite Guideline: Guideline for Good Clinical Practice E6(R1)*. June, 1996. http://www.ich.org/products/guidelines/efficacy/article/efficacy-guidelines.html

5.5. Lussier, Marie-Therese, MD MSc FCSP, et. al. “Surveillance or Research: What’s in a Name?” *Canadian Family Physician* 58 (January, 2012): 117. Retrieved from: http://www.cfp.ca/content/58/1/117.full

5.6. Morris, Peter E., MD, and Kathleen Dracup, RN, DNSc. “Quality Improvement or Research? The Ethics of Hospital Project Oversight.” *American Journal of Critical Care* 16, no. 5 (September, 2007): 424-426. Retrieved from: http://ajcc.aacnjournals.org/content/16/5/424.full

5.7. *The Freedom of Information and Protection of Privacy Act (Manitoba)*

5.8. *The Mental Health Act (Manitoba)*

5.9. *The Personal Health Information Act (Manitoba)*

5.10. *The Vulnerable Persons Living with a Mental Disability Act (Manitoba)*

5.11. United Kingdom. Department of Health. *Public Health Surveillance: Towards a Public Health Surveillance Strategy for England*. December, 2012. Retrieved from: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/213339/Towards-a-Public-Health-Surveillance-Strategy.pdf

5.12. University of Manitoba. Research Policy. *The Ethics of Research Involving Humans*. December, 2011, revised July, 2013. Retrieved from: http://umanitoba.ca/admin/governance/governing_documents/research/373.html

5.13. World Health Organization (WHO). “Public Health Surveillance.” *Health Topics*. Retrieved from: http://www.who.int/topics/public_health_surveillance/en/

5.14. WRHA Policy #20.10.010 - *Conflict of Interest*.

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APPENDIX

Inclusion of Vulnerable Individuals and Minors in Research:

- Further to Article 3.5.1.2. Researchers are encouraged not to overlook the inclusion of Vulnerable Individuals in Research, as their participation can provide benefits to both the individual and group they represent if done ethically and in compliance with all requirements for the Informed Consent of Vulnerable Individuals.

- Further to Article 3.5.2.1. Researchers are encouraged not to overlook the inclusion of children in Research, as their participation can advance our understanding of, and ability to respond to the unique needs of children at each stage of their development if done ethically and in compliance with all requirements for the Informed Consent of children.

***This appendix is not to be considered as policy. In all cases, reference to the policy shall be made.**