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**ADMINISTRATION**

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| Policy Name: | **RESEARCH** | Effective Date: | **FEBRUARY 18, 2013** |
| Policy #: | **AD-01-150** | Revision Date: | **MAY 13, 2014** |
| Approved By: | **CHIEF EXECUTIVE OFFICER** | Signature: | ***Original signed by H. Bryant*** |
| Managed By: | **VP MEDICAL SERVICES & CHIEF MEDICAL OFFICER** | | |

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| 1.0 | **PURPOSE:**  The Northern Regional Health Authority (NRHA) recognizes the importance of research within the health field and supports research dissemination and utilization, particularly those projects which further the NRHA Mission. The Authority encourages staff to initiate research projects and to accommodate requests for participation in research studies whenever possible, within the context of available human and fiscal resources. |

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| 2.0 | DEFINITIONS: | |
|  | 2.1 | Research: A systematic investigation designed to establish facts, principles or contribute to general knowledge. It does not include routine program evaluation. (See section 4.) |
|  | 2.2 | Tri-Council Statement on Minimal Risk: “If potential subjects can reasonably be expected to regard the probability and magnitude of possible harms implied by participation in the research to be no greater than those encountered by the subject in those aspects of his or her everyday life that relate to the research then the research can be regarded as within the range of minimal risk.”  For example, for a research project targeting diabetes management, “minimal risk” is satisfied if it is reasonably expected that the subject will encounter no more harm by participating in the research than they would encounter in the diabetes management of their everyday life. |

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| 3.0 | **POLICY:**  All requests for research projects undertaken within the Northern Regional Health Authority or that require the collection, utilization or analysis of Northern Regional Health Authority data or information must have the approval of the Northern Regional Health Authority Executive Leadership Council (ELC) and be signed off by the Chief Executive Officer or designate. (The Chief Executive Officer is authorized to act in place of the Executive Leadership Council if circumstances require notifying the ELC of any approved research). All research project applicants will be referred to the NRHA Research Policy (AD-01-150) to assist in the preparation of their application. |

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| 4.0 | PROCEDURE:  PROCESS FOR RESEARCH PROJECT APPLICATION | | | | |
|  | 4.1 | Application for research projects will be made in the following manner: | | | |
|  |  | 4.1.1 | NRHA employees will submit research proposals to the appropriate VP, who will forward them to the NRHA Research Lead. | | |
|  |  | 4.1.2 | Outside agencies, individuals, students or residents/fellows will submit research proposals to the NRHA Chief Executive Officer (CEO) who will refer the proposal to the Research Lead. | | |
|  |  | 4.1.3 | The Research Lead will review the proposal and assign an NRHA representative to review and advise on the impact of the proposed research on the organization and to act as the research project contact. | | |
|  |  | 4.1.4 | The Research Lead will send the completed application form to the Ethics Committee for review of the research proposal through an ethical lens. | | |
|  |  | 4.1.5 | The Research Lead will present the application to ELC for approval, denial or comments. | | |
|  |  | 4.1.6 | The CEO will sign off on the application. The CEO may designate this signing authority to the Research Lead. | | |
|  |  | 4.1.7 | The Research Lead will communicate in writing, on behalf of the CEO with the applicant/principal investigator, the final decision regarding the application. | | |
|  |  | 4.1.8 | The Research Lead will maintain a log of research projects and outcomes. | | |
|  | 4.2 | All research applicants will include the following documentation (as applicable) to satisfy the requirements of this policy: | | | |
|  |  | 4.2.1 | Letter requesting permission to conduct research at a NRHA facility/site; | | |
|  |  | 4.2.2 | Copy of the detailed Research Project Proposal including the following: | | |
|  |  |  | 4.2.2.1 | Purpose of the study | |
|  |  |  | 4.2.2.2 | Proposed timeline | |
|  |  |  | 4.2.2.3 | Identification of researcher/research team | |
|  |  |  | 4.2.2.4 | Design methodology | |
|  |  |  | 4.2.2.5 | Process for data collection and analysis | |
|  |  |  | 4.2.2.6 | Protocols for data storage and safeguards for security | |
|  |  |  | 4.2.2.7 | Provision for confidentiality of data resulting from the research (i.e. PHIA; FIPPA) | |
|  |  |  | 4.2.2.8 | Dissemination plan | |
|  |  | 4.2.3 | Copy of the ethical review and approval from any affiliated educational institution or approving agency; | | |
|  |  | 4.2.4 | Copies of Informed Consent form(s), survey tool(s), and any other documents to be utilized in the course of the research | | |
|  |  | 4.2.5 | Research Proposal Summary (Appendix A); | | |
|  |  | 4.2.6 | Agreement for Access to Personal Health Information for Research Purposes document (Appendix C). | | |
|  |  | 4.2.7 | Copy of the principal investigator’s Tri-Council Policy Statement 2 core certificate of completion. Information on this course can be found at: http://tcps2core.ca/welcome. | | |
|  |  | 4.2.8 | If applicable; documentation that the appropriate first nations organizations have communicated their support to the research being undertaken with their community members. | | |
|  | 4.3 | The *Research Proposal Assessment* form (Appendix B) will be completed by the RHA Research Project Contact or designate who will then give recommendations for action on the research project proposal application to the ELC. | | | |
|  |  | 4.3.1 | In completing the Assessment form, input will be sought from the NRHA Ethics Committee. The Ethics Committee will approve/deny and provide feedback to the Research Lead who will communicate with the researcher. | | |
|  |  | 4.3.2 | Medical Advisory Committee input may be sought for clinical trials and other staff with expertise or those who may be affected by the proposed research may also be consulted. | | |
|  | 4.4 | The ELC will make a determination on the research project proposal application based on the recommendations contained in the *Research Proposal Assessment* form, reserving the right to establish limits on the proposal, to require changes to the proposal, and to approve or not approve the proposal. | | | |
|  |  | 4.4.1 | The researcher will be notified in writing of this determination by the RHA Research Project Contact. | | |
|  |  | 4.4.2 | If approved, the RHA Research Project Contact will be assigned primary responsibility for the supervision and/or support of the research project, monitoring the research project and ensuring compliance with legislated and regional requirements. | | |
|  |  | 4.4.3 | Upon notification of approval, the Researcher will submit a letter to the RHA Research Project Contact, responding to any additional requirements identified in the review process, declaring an intent to proceed (or not) with the research project, and the probable start date. | | |
|  |  | 4.4.4 | The researcher/research team are required to sign a NRHA Oath of Confidentiality and abide by the policies and procedures of the NRHA. | | |
|  |  | 4.4.5 | Any changes to the project in the course of the research must be discussed with the RHA Research Project Contact. If proposed changes are substantive, a new application must be submitted. If actual time frames vary significantly from the projected time frames included in the initial proposal, the RHA Research Project Contact will determine whether a new application must be submitted. | | |
|  | 4.5 | STANDARDS FOR DATA COLLECTION, STORAGE, ANALYSIS AND INTERPRETATION | | | |
|  |  | 4.5.1 | The following standards shall govern all data collection, data analysis and interpretation, and the storage and dissemination of data. | | |
|  |  | 4.5.2 | Prior to the collection of data from individuals, the purpose/process/assurance of confidentiality must be clearly communicated to the subject(s) through the informed consent process and the data must be used, processed and kept confidential exactly as stated. | | |
|  |  | 4.5.3 | Information potentially identifiable to an individual will be kept confidential and securely safeguarded, entered into an encrypted data base that does not identify individuals, stored in a secure area for a predetermined period and then destroyed by shredding at the earliest opportunity consistent with the purpose of the project. | | |
|  |  | 4.5.4 | The requested personal health information will be used solely for the purposes of the approved research project. | | |
|  |  | 4.5.5 | The requested personal health information will not be published in a form that could reasonably be expected to identify the individuals concerned. | | |
|  |  | 4.5.6 | Data collection, analysis and interpretation must be carried out according to established scientific principles. | | |
|  |  | 4.5.7 | The integrity (quality, accuracy and reliability) of information under the NRHA control must be maintained. | | |
|  |  | 4.5.8 | Information collected for research must not be used in a way that might harm the individual concerned. | | |
|  | 4.6 | RESEARCH OUTCOMES | | | |
|  |  | 4.6.1 | Research findings will be handled in the following manner: | | |
|  |  | 4.6.2 | The researcher will provide the Research Lead with semiannual update who will provide these to ELC. | | |
|  |  | 4.6.3 | Unless otherwise agreed in advance, research undertaken by staff during working hours becomes the property of the NRHA. | | |
|  |  | 4.6.4 | A copy of the final report will be provided to the Research Lead prior to public release. The Research Lead will provide the report to ELC. Researchers will give the Research Lead a minimum of ten business days’ notice prior to research publication or presentation. | | |
|  | 4.7 | QUALITY IMPROVEMENT AND PROGRAM EVALUATION | | | |
|  |  | 4.7.1 | NRHA quality improvement and program evaluation activities are subject to the following principles: | | |
|  |  | 4.7.2 | A Quality Improvement or Program Evaluation project that involves human subjects and meets any of the following criteria shall require approval through the process outlined in this research policy: | | |
|  |  |  | 4.7.2.1 | | is part of a Masters, Ph.D, medical student, undergraduate, resident or fellow research project; or |
|  |  |  | 4.7.2.2 | | presents a risk or burden to participants; or |
|  |  |  | 4.7.2.3 | | requires participants to take medication, undergo invasive procedures, protocols, psychometric testing or provide biological samples or give sensitive information, that is not routine to the program, service or care provided; or |
|  |  |  | 4.7.2.4 | | is intended to be published in peer-review literature; or |
|  |  |  | 4.7.2.5 | | has the potential to infringe on the privacy rights or professional reputation of participants. |
|  |  | 4.7.3 | A Quality Improvement or Program Evaluation project that does not fall within s. 4.1 shall be approved through standard internal processes. | | |
|  |  | 4.7.4 | Publication or presentation of Quality Improvement or Program Evaluation results outside the NRHA shall require the approval of ELC. | | |

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| 5.0 | REFERENCES: | |
|  | 5.1 | Personal Health Information Act [Paragraph 24(1) to 24(4)] |
|  | 5.2 | Tri-Council Policy 2: Ethical Conduct for Research Involving Humans (February 1, 2005) |
|  | 5.3 | Many thanks to the RHA’s which graciously shared their research policies, from which large portions of this document were taken: Former Parkland, Interlake, NOR-MAN, Burntwood and Winnipeg |

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| 6.0 | APPENDICES: |
|  | Appendix A – Research Proposal Summary |
|  | Appendix B – Research Proposal Assessment Form |
|  | Appendix C – Agreement for Access to Personal Health Information for Research Purposes |