Thunder Bay Regional Health Sciences Centre **Policies, Procedures, Standard Operating Practices**		No. RA-03
Title: Research Integrity	☒ **Policy**	☒ **Procedure** ☐ **SOP**
Category: General **Dept/Prog/Service:** Research: Research Administration	Distribution: Organization Wide	
Approved: Vice President Research **Signature:**	**Approval Date:** **Next Review Date:** **Reviewed/Revised Date:**	Apr. 5, 2016 Apr. 5, 2019

CROSS REFERENCES: (RA-01) Research Oversight; COI in Research policy – in draft, (ADMIN-19) Whistleblower policy

1. PURPOSE

Thunder Bay Regional Health Sciences Centre (The Hospital) and its research arm, Thunder Bay Regional Health Research Institute (The Research Institute), recognize the need to maintain the highest ethical standards in the conduct of research. A Researcher must strive to follow the best research practices honestly, accountably, openly and fairly when proposing, seeking support for, conducting and reporting research, and must respect the rights of others in these activities.

Research standards must be rigorously maintained, ethically irreproachable, and reinforced by example and regulation. Although research integrity is managed at an individual level, the lack thereof could have serious ramifications for the entire research community.

The purpose of this policy is to set out the principles and procedures for conducting research with integrity, as well as addressing Misconduct in research and other scholarly activity. Formal procedures are essential to determine how Allegations should be handled and to protect the rights of individuals, each of the Institutes, their partners - LU and NOSM - and any outside funding agency.

2. POLICY STATEMENT

The individual Researcher has the responsibility to conduct research in an ethical manner and avoid Misconduct. The Institutes have the responsibility to provide an environment that enables ethical research, as well as the responsibility to deal with Misconduct should it occur.

3. SCOPE

This policy applies to all Researchers conducting research at or with The Hospital or The Research Institute.

This policy is not intended to replace procedures that may fall under other policies or procedures. See policies: Admin 19-Whistleblower; Conflict of Interest in Research (CR-05); Research Oversight (RA-01).

4. DEFINITIONS

"Allegation" is a declaration, statement or assertion communicated in writing to one or both Institutes to the effect that there has been, or continues to be, Misconduct, the validity of which has not been established.

"CEO" means the chief executive officer of The Research Institute and/or The Hospital, as applicable. *[Note: Please consider each use of CEO and determine which CEO is intended.]*

"Investigative Committee" means an investigative committee that reviews Allegations and provides a final report with its findings and recommendations.

"Complainant" means the person making an Allegation.

"Conflict of Interest" is a real, potential or perceived situation where an objective observer might reasonably question if actions or decisions taken by the Researcher (including the use of resources or proprietary information of one or both Institutes) are influenced by considerations of private interest of the Researcher, in some cases, to the disadvantage of one or both Institutes. These private interests include business, commercial or financial interests of the Researcher, his/her family members, friends or their former, current or prospective professional or academic associates.

Examples of a Conflict of Interest are:

(a) a Researcher's paid professional activities undermine rather than enhance the Researcher's ability to meet the Researcher's duties and responsibilities to one or both Institutes; or

(b) a Researcher's non-professional activities in which he/she is engaged in for personal gain undermine rather than enhance the Researcher's ability to meet the Researcher's duties and responsibilities to one or both Institutes; or

(c) a Researcher's private interests conflict with the Researcher's duties and responsibilities to one or both Institutes, for example, where a private interest would directly and significantly affect the design, conduct and reporting of grant-funded activities.

"Institute" means one of The Hospital or The Research Institute, and "Institutes" means both of them.

"Lead Researcher" means the person who has ultimate responsibility for a research project; (i) in the case of a project funded by an external or internal grant, the holder of the grant or site lead for a clinical trial (the "Principal Investigator"); and (ii) in clinical trials the "Qualified Investigator".

"LU" means Lakehead University.

"MAC" means the Medical Advisory Committee of The Hospital.

"Misconduct" generally includes a breach in research integrity, research misconduct or fraud in academic research, and specifically includes:

(a) *Fabrication*: Making up data, source material, methodologies or findings, including graphs and images.

(b) *Falsification*: Manipulating, changing or omitting data, source material, methodologies or findings, including graphs and images, without acknowledgement, which results in inaccurate findings or conclusions.

(c) *Falsification of credentials*: Misrepresenting qualifications, awards and/or achievements, misrepresenting the status of publications, or reporting non-existent work.

(d) *Suppression*: Failure to take timely and pro-active steps to publish corrections or retractions to a Researcher's previous results when a significant error or deficit is identified in such work after publication.

(e) *Destruction of research records*: 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, laws, regulations or professional or disciplinary standards.

(f) *Plagiarism*: Presenting and using another's published or unpublished work, including theories, concepts, data, source material, methodologies or findings, including graphs and images, as one's own, without appropriate referencing and, if required, without permission.

(g) *Redundant publications*: 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.

(h) *Invalid authorship*: 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.

(i) *Inadequate acknowledgement*: Failure to appropriately recognize contributions of others in a manner consistent with their respective contributions and authorship policies of relevant publications.

(j) *Mismanagement of Conflict of Interest:* Failure to appropriately manage any Conflict of Interest, in accordance with The Hospital's policy on Conflict of Interest in research.

(k) *Misrepresenting information*: Providing incomplete, inaccurate or false information in a grant or award application or related document, such as a letter of support or a progress report or listing of co-applicants, collaborators or partners without their agreement.

(l) *Abuse of authority*: Intimidation or exploitation of subordinates in a research context that encourages influences or coerces the subordinate to commit or be complicit in an instance of breaching this policy.

(m) *Mismanagement of grants or award funds*: Using grant or award funds for purposes inconsistent with the policies of the funding agencies; misappropriating grants and award funds; contravening funding agency financial policies, namely the Tri-Agency Financial Administration Guide, agency grants and awards guides; or providing incomplete, inaccurate or false information on documentation for expenditures from grant or award accounts.

(n) *Breaches of sponsor policies or ethical requirements for certain types of research*: Failure to comply with terms of research funding agreements or research policies; failure to comply with pertinent federal, provincial, international, or Institute policies for the protection of researchers, human participants, the public and the welfare of animals; failure to meet other legal requirements that relate to the conduct of research; and/or failure to obtain appropriate approvals, permits or certifications before conducting research and scholarly activities.

Factors intrinsic to the process of academic research such as honest error, conflicting data, or differences in interpretation or assessment of data or of experimental design do not constitute fraud or Misconduct.

"NOSM" means Northern Ontario School of Medicine.

"Professional Staff" means those physicians, dentists (including oral and maxillofacial surgeons), midwives and registered nurses in the extended class who are appointed by the Board of Directors of The Hospital and who are granted specific privileges to practice.

"Researcher" means anyone who participates in research related work, study or development activities at one or both Institutes using, in any way, facilities or resources owned, operated, rented or administered by one or both Institutes and/or funds of, or funds administered by, one or both Institutes and includes employees, Professional Staff, individuals with scientific appointments in part or in whole at one or both Institutes, research associates, research assistants, clinicians, technologists,

trainees/students, and any person with temporary privileges (e.g. visiting researchers, affiliated scientists, etc.) who participate in work, study, research or development activities at one or both Institutes. **"The Research Institute or The Hospital Researcher"** is a subset of Researchers who have a formal affiliation with one or both Institutes through employment, contract, or an affiliation agreement.

"Respondent" means the person alleged to have engaged in Misconduct.

"Supervisor" means the person most responsible for the day-to-day oversight of a person.

"The Hospital" means Thunder Bay Regional Health Sciences Centre.

"The Research Institute" means Thunder Bay Regional Health Research Institute.

"VPR" means Vice-President Research for The Hospital/The Research Institute.

5. PROCEDURE

5.1 Ethical Conduct of Research

5.1.1 Research Involving Human Participants

(a) Any research or study conducted that involves human participants must be reviewed and approved by a research ethics board. See RA-01 "Research Oversight". The requirements are contained in the TCPS2 (Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans).

(b) The Institutes require that Good Clinical Practice is followed when generating clinical trial data that are intended to be submitted to regulatory authorities. See Good Clinical Practices.

5.1.2 Research Involving Animals

(a) All animal users must submit an Animal Utilization Protocol through LU for approval by LU's Animal Care Committee.

(b) The LU Animal Care Committee's terms of reference are governed by the Canadian Council on Animal Care and Ontario's *Animals for Research Act* as overseen by the Ontario Ministry of Agriculture and Rural Affairs.

(c) See the Policy for Research with Animals [*NB: Policy in draft*].

5.1.3 Duties of the Researcher

(a) The Lead Researcher is ultimately responsible for careful supervision and effective communication, which considers the best interests of the research project, the research team, the Institutes, the research sponsor and the academic community.

(b) Further, under the Tri-Council Policy Framework: Responsible Conduct of Research, Researchers are responsible for:

(i) using a high level of rigour in proposing and performing research; in recording, analyzing, and interpreting data; and in reporting and publishing data and findings;

(ii) keeping complete and accurate records of data, methodologies and findings, including graphs and images, in accordance with the applicable funding agreement, institutional policies, laws, regulations and professional or disciplinary standards in a manner that will allow verification or replication of the work by others. [Reference: Admin 04-Record Retention Policy]. When a Researcher leaves an Institute, arrangements for the safekeeping of records and/or products of research must be made with his/her immediate supervisor;

(iii) referencing and, where applicable, obtaining permission for the use of all published and unpublished work, including data, source material, methodologies, findings, graphs and images;

(iv) including as authors, with their consent, all those and only those who have materially or conceptually contributed to, and share responsibility for, the contents of the publication or document, in a manner consistent with their respective contributions and authorship policies of relevant publications; [Reference: CR-03].

(v) acknowledging, in addition to authors, all contributors and contributions to research, including writers, funders and sponsors;

(vi) appropriately managing any Conflicts of Interest, in accordance with the Institutes' policy on Conflict of Interest in Research. [Reference: CR-05].

5.2 Process for Investigation

5.2.1 ALLEGATIONS

(a) A person making or providing information about an Allegation in good faith will be protected from reprisal to the extent possible in a manner consistent with applicable laws. It is the responsibility of the VPR to take whatever actions may be necessary to protect the person making, or providing information about, the Allegation from possible acts of coercion or retribution by the Respondent.

(b) Anonymous Allegations will only be accepted if the VPR deems the issue to be sufficiently serious and credible. In all such inquiries, care will be taken to ensure that those contacted understand that the process is both informal and confidential, and that no inference should be made concerning the validity of the Allegation. If there is no evidence that the Allegation has substance, all documentation concerning it will be destroyed. If the Allegation has substance, it will be investigated.

(c) Before making an Allegation, a Complainant must consult with his/her Supervisor. The Supervisor will maintain confidentiality in dealing with the Allegation so as to protect the reputation and careers of all involved, as well as the reputation of the Institutes.

(d) If the Allegation is against the Supervisor, or no suitable action is being taken, the Allegation is to be submitted to the VPR. If the Allegation is against the VPR, submission is to be made to the CEO. The same process as outlined below would then be followed with the substituted leads.

(e) The Supervisor must make the VPR immediately aware (which in no case should be more than five working days) of the Allegation through a written summary of the Allegation.

5.2.2 INQUIRY

(a) The VPR and Supervisor must immediately assess (which in no case should be more than ten working days) and determine if the Allegation is valid or responsible. The VPR will provide the Complainant and Respondent with an opportunity to be heard as part of determining the validity of the Allegation.

(b) An assessment will be made for every Allegation received. Possible outcomes of an assessment are:

(i) the Allegation is not determined to be responsible and is therefore dismissed; or

(ii) the Allegation is determined to be responsible but the Misconduct is not substantiated; or

(iii) the matter is resolved; that is, the Allegation is determined to be responsible, Misconduct is confirmed (e.g., the Respondent accepts responsibility) and further investigation would not uncover any new information pertinent to the matter; or

(iv) the Allegation is determined to be responsible, Misconduct is confirmed but issues identified through the inquiry warrant a formal investigation (e.g., other individuals in addition to the Respondent; other possible Misconduct suspected).

(c) If there is an immediate potential risk to persons, research animals or property, the VPR will stop all research related to the Allegation until a resolution is achieved. This may include freezing of granting funds, restriction of facility access, etc.

(d) If it is determined that the Allegation has merit and that there is no immediate risk to persons, research animals or property, nor destruction of research products (at the discretion of the VPR), then work will be allowed to continue with appropriate safeguards in place to ensure all information related to the investigation is preserved and work during the investigation is carried out in an appropriate manner.

(e) If it is determined that the Allegation has no merit, the VPR will immediately take all practical steps to redress any harm that may have been caused by the Allegation. The Complainant may discuss the issue in confidence with the VPR if he/she believes that the consultation has not adequately dealt with the Allegation.

5.2.3 FORMAL INVESTIGATION

(a) Within ten working days of the confirmation that an Allegation is responsible but the Misconduct is not yet substantiated or further investigation is warranted, the VPR will initiate an investigation.

(i) Refer to the table at the end of this policy to identify the Institute that will lead the investigation. The policy of the lead Institute will govern the investigation. In cases where Researchers have joint appointments, the lead Institute will inform the other institutions listed in the table of the investigation and its outcome.

(ii) If the Allegations involve Professional Staff, the process for mid-term action regarding revocation/suspension/restriction of privileges as per The Hospital's Professional Staff By-Laws will be followed. However, if the matter is purely academic in nature (i.e. would/does not involve a patient's management or outcome), the matter will be referred to NOSM.

(iii) For external institute-led investigations, the Investigative Committee will determine if Misconduct has occurred.

(iv) The The Research Institute or The Hospital Investigative Committee will consist of three members and include members who have the necessary expertise and who are without conflict of interest, whether real, potential or perceived, and at least one external member who has no current affiliation with the Institutes. The VPR will appoint one of these individuals as Chair of the Committee.

(b) The intent of this policy is to protect the privacy of the Complainant(s) and Respondent(s) as far as is possible. However, in the event of a formal investigation, it may not be possible to protect the identity of the Complainant(s) or Respondent(s).

5.2.4 DUTIES OF THE INVESTIGATIVE COMMITTEE AT TBRHSC & TBRRI

(a) The VPR will present the Investigative Committee with the Allegation and turn over all relevant materials. The Respondent will have the right to full disclosure of all information or evidence relevant to the Allegation. This right includes the right to examine documents or material before the hearing as well as have the right to submit relevant materials to the Investigative Committee.

(b) The Investigative Committee will address the Allegation and determine whether it has merit. The Investigative Committee will ensure that it is cognizant of all actual, potential or perceived conflicts of interest. It may seek impartial expert opinions, as necessary and appropriate, to ensure that the investigation is thorough and authoritative.

(c) The VPR will appoint administrative support for the Investigative Committee. The Investigative Committee will assemble copies of all materials it has collected and meeting minutes, which will be kept on file in the office of the VPR and in Human Resources once the investigation is complete.

(d) The Investigative Committee will aim to review all research with which the Respondent has been involved during the period of time considered pertinent in relation to the Allegation. A special audit of research accounts may also be performed on the sponsored research of the Respondent.

(e) The Respondent, any co-investigator(s) or immediate Supervisor related to the investigation, will have the right to present information to the Investigative Committee.

(f) The Respondent, any co-investigator(s) or immediate Supervisor related to the investigation, will be given the opportunity to review and comment on a draft of the report. Their remarks will be included as appendices in the final report.

(g) The decision of the Investigative Committee will normally be made by consensus; however, if necessary, the decision will be based on majority vote.

5.2.5 COMPLETION OF AN INVESTIGATION

(a) The Investigative Committee, upon reviewing all the elements of the Allegation, will communicate its decision to the VPR in writing through a final report – ideally within 30 days of commencing the investigation. If an extension is required, the Committee will make a written request to the VPR.

(b) The VPR will inform the Respondent of the Committee's decision and of any actions that are to be taken, including disciplinary action, if any, within 14 days of receiving the final report.

(c) If the Committee finds that there are not sufficient grounds for the Allegation to be substantiated, then any work that was stopped will be allowed to continue and/or restart and the VPR will immediately take all practical and reasonable steps to protect and restore the reputation of the Respondent.

(d) The VPR will advise the Complainant of the finding from the final report. The Complainant may discuss the issue in confidence with the VPR if he/she believes that the investigation has not adequately dealt with the Allegation.

(e) If in the final report it is found that there are reasonable grounds to believe that Misconduct has occurred, then any work still ongoing will be stopped and within 14 days of receiving the final report, will:

(i) for The Research Institute, the VPR will notify the CEO and COO, along with the Science and Research and the Finance, Audit and Risk Management Committees of the Board of Directors;

(ii) for The Hospital, the VPR will notify the CEO, Senior Director of Quality and Risk Management, along with the Quality Committee of the Board of Directors. If the Misconduct involved finances, then the VPR will also inform the CFO and Resource Planning Committee of the Board of Directors.

(iii) The CEO of The Hospital/The Research Institute, will notify other groups/agencies as appropriate (affiliated institutes, REB, funding agency, regulatory bodies, etc.) depending on the scope of the Misconduct and jurisdictions governing the activity. All parties will provide any and all assistance and data collected to the other agencies as required.

(f) The lead Institute and the VPR will appoint a team to recommend corrective measures to ensure Misconduct will not be repeated.

(g) The Respondent found guilty of Misconduct will not resume research until corrective measures, as outlined by the Institute in writing are in place and all agencies (e.g. Institutes, REB etc.) give approval for work to resume.

(h) All parties to the investigation will treat all information as confidential and not provide it to anyone outside the investigation. All parties will give full cooperation to ensure a true and fair conclusion can be achieved in a timely manner. Confidentially will be of utmost important and will be strictly enforced, while taking into account applicable privacy laws and regulations, and the need to inform all affected parties in a timely manner of the decision reached by the Committee and of any recourse to be taken by the Institute(s).

5.2.6 DUTIES OF The Hospital and The Research Institute

The Institutes will take such steps as may be necessary and reasonable to:

(a) protect the reputation and credibility of Respondents wrongfully accused of Misconduct, including written notification of the decision to all agencies, publishers or individuals who were informed of the investigation;

(b) protect the rights, reputation and credibility of Complainants who in good faith make Allegations and persons who are called as witnesses in an investigation. Such protection will include, as a minimum, legal counsel and other legal costs should the persons be sued for their participation in any investigation or in arbitration proceedings; and

(c) minimize disruption to the research of the Complainant and of any third party whose research may be affected by the securing of evidence relevant to the Allegation during the course of the investigation.

5.2.7 APPEAL

(a) A Respondent may appeal any disciplinary action imposed by an Institute through the appropriate human resource channel and discipline appeal policy of that Institute.

(b) Appeals of actions to or from outside agencies must follow the policies and procedures of that governing body.

(c) An appeal of the Committee's findings or the disciplinary action will be submitted to the CEO. The CEO may refer the further review to an external committee or arbiter at his/her discretion.

(d) Appeals involving Professional Staff and/or MAC will be under the purview of the MAC's processes.

6. RELATED PRACTICES AND/OR LEGISLATIONS

Researchers must comply with all applicable agency requirements, laws and regulations for the conduct of research, including:

- Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans (TCPS 2)
- The RCR Framework (2011) -- Tri-Agency Framework: Responsible Conduct Of Research
- Canadian Council on Animal Care Policies and Guidelines
- Animals for Research Act - Ontario Ministry of Agriculture and Rural Affairs
- Agency policies related to the *Canadian Environmental Assessment Act*
- Canadian Biosafety Standards and Guidelines
- Good Clinical Practices
- Controlled Goods Program
- Canadian Nuclear Safety Commission (CNSC) Regulations
- Canada's *Food and Drugs Act*

Table: RESEARCH OVERSIGHT

Primary Appointment or Employer	*Lead Institute*	*Accountable for Researcher - on-site*	*Responsible for Research Quality Oversight*
TBRHSC Physician	TBRHSC	COS	MAC
TBRHSC Employee	TBRHSC	TBRHSC Supervisor	Professional Practice Head
TBRHSC-TBRRI Clinician Scientist	TBRHSC	COS & Scientific Director	MAC - primary (& Scientific Director)
TBRRI Scientist & Staff	TBRRI	Scientific Director	Scientific Director
LU Professor & TBRRI Appointment	LU	Scientific Director	VPR LU - primary (& Scientific Director)
LU Professor (LUFA)	LU	Through LU AA	VPR LU
LU Student	LU	Supervisor	VPR LU
Other LU Staff	LU	Supervisor	VPR LU
NOSM Professor (CA)	NOSM	Through NOSM AA	Assoc Dean Research NOSM
NOSM Student/Learner	NOSM	Academic Affairs & Supervisor	Assoc Dean Research NOSM
Other NOSM Employee	NOSM	Through NOSM AA	Assoc Dean Research NOSM
External	External - per agreement	Pending written agreement	Pending written agreement

Notes:
- AA - affiliation agreement
- MAC - Medical Advistory Committee (TBRHSC); COS - Chief of Staff (TBRHSC)