"Integrity is doing the right thing, even when no one is watching."
-British novelist C.S. Lewis

Faculty of Medicine Task Force Report on Research Integrity

I INTRODUCTION

Acting with integrity begins with a commitment to six fundamental values – honesty, trust, fairness, respect, responsibility and courage – even in the face of adversity.[1] As a national and global leader in education and research, the University of Toronto's Faculty of Medicine (FoM) must ensure this commitment is put into practice as it carries out its mission to develop leaders, contribute to our communities and improve the health of people and populations through the discovery, application and communication of knowledge. Underlying that mission, the FoM embraces the following values[2], all of which inform how research is conducted:

- Integrity in all endeavors;
- Commitment to innovation and excellence;
- Life-long learning and critical inquiry;
- Promotion of social justice, equity, diversity, inclusion, and professionalism;
- Effective partnership with all our stakeholders;
- Multi-professional and interdisciplinary collaboration;
- Supportive and respectful relationships;
- Accountability and transparency;
- Responsiveness to local, national, and international health needs.

For the purposes of this report, research is defined broadly to include, but not limited to all fundamental/basic science research; all clinical research, including clinical trials; education research; health services research and health policy; knowledge translation and dissemination; and quality improvement and patient safety. An expanded definition of research can be found in the University's *Policy on Research Administration.*[3]

Research activity at the University is governed by a range of University policies such as the *Policy on Ethical Conduct in Research,*[4] and informed by FoM and affiliated hospital harmonized guidelines and procedures, including the statement of *Principles and Responsibilities Regarding Conduct of Research*.[5] For a full list of University and FoM policies, guidelines or procedures governing research integrity and misconduct, see Appendix B: University Resources. In addition, the principles outlined in these policies or

[1] International Center for Academic Integrity
[2] Faculty of Medicine, University of Toronto, Vision/Mission/Values, November, 20, 2014, available online at:
http://www.medicine.utoronto.ca/about-faculty-medicine/vision-mission-and-values
[3] Research Administration Policy, University Governing Council, available online at:
http://www.governingcouncil.utoronto.ca/Assets/Governing+Council+Digital+Assets/Policies/PDF/p1030res.pdf
[4] Policy on Ethical Conduct in Research, March 28, 1991, available online at:
http://www.governingcouncil.utoronto.ca/Assets/Governing+Council+Digital+Assets/Policies/PDF/ppmar281991i.pdf
[5] Principles and Responsibilities Regarding Conduct of Research, October 11, 2002, available online at:
http://medicine.utoronto.ca/sites/default/files/Conduct%20of%20Research.pdf

guidelines are consistent with the Tri-Agency Framework[6] and other funding agencies' ethical codes with respect to research.

Research misconduct has many causes and can take many forms, including but not limited to: fabrication/misrepresentation of data, plagiarism, "text recycling" or self-plagiarism, image or statistical manipulation and image fraud. It can also be associated with a lack of supervisory rigor and failure to apply due diligence in the operation of a research study, laboratory or program. For further definitions of research misconduct, see the University's *Framework to Address Allegations of Research Misconduct (**https://www.sgs.utoronto.ca/Documents/Research+Misconduct+Framework.pdf**)*

Ensuring the highest ethical standards is essential to the academic research mission and to the FoM's standing as a national and global leader. The FoM, including its affiliated teaching hospitals, attracted in 2016 $790M in research funding, with $104M for on-campus research. A breach of research integrity not only damages the credibility of individuals, colleagues and collaborating programs and interferes with future science, but also confers extensive reputational risk to the FoM and University at large. Dissemination of fabricated results also has the potential to cause harm to patients and can negatively impact research conducted by others. The speed and ubiquity of digital media amplify these risks, particularly with the advent of social media savvy organizations such as Retraction Watch.

In 2009, University of Toronto formed the Research Oversight and Compliance Office (ROCO) in response to escalating sponsor and regulatory requirements in research as well as growing financial, legal and reputational risks: "ROCO was the first office of its kind in Canada and signaled important recognition of the need to achieve and sustain a level of distributed oversight and compliance consistent with the University's massive and highly decentralized research enterprise."[7] Over the last five years, research misconduct involving campus-based researchers across all faculties (as opposed to hospital-based researchers)[8] has been found in a total of five cases: one in 2011; four in 2012; zero in subsequent years.

It is important to recognize that fewer than 10 per cent of full-time faculty members in the FoM (~225 of more than 2,800) work on-campus at the University. Most work in affiliated teaching hospitals and research institutes normally engage in research under the hospital auspices. Accordingly, the FoM cannot systematically track research misconduct across all teaching hospitals. However, recent cases involving hospital-based researchers with FoM appointments have certainly attracted public media attention. Any case of research misconduct is important in its own right and also has the potential to damage institutional reputation and cause harm to individuals; therefore prevention must remain an important focus in all the settings in which our faculty conduct their work. Against this backdrop, the Dean of the FoM commissioned the Task Force on Research Integrity to examine the standards of training and practice with regard to the Responsible Conduct of Research among faculty members.

[6] Tri-Agency Framework: Responsible Conduct of Research, 2016, available online at: **http://www.rcr.ethics.gc.ca/eng/policy-politique/framework-cadre/**

[7] http://www.dlsph.utoronto.ca/2013/10/professor-lori-ferris-accepts-avp-position-for-research-oversight-and-compliance/

[8] Under the terms of the Research Misconduct Framework Addendum, used to determine whether the hospital or the affiliated site has jurisdiction, University of Toronto's affiliated teaching hospitals have jurisdiction over allegations of research misconduct at the hospitals

II TERMS OF REFERENCE

"Responsible Conduct of Research" is a concept which must encompass most of the professional activities that are part of research practice. As defined by the Tri-Council funding agencies, this practice encompasses aspects related to research collaborations, conflicts of interest, data acquisition/sharing, protection of human subjects, lab animal welfare, the responsible mentoring of researchers, publication practices/responsible authorship, and processes to investigate allegations of research misconduct.

The Dean's Task Force on Research Integrity consulted within the Faculty of Medicine. (See Appendix A). The focus of this Task Force is to examine the current state of the Responsible Conduct of Research in the FoM, with the goal of promoting a culture of ethical research practice among all our faculty members. The following are the specific Terms of Reference for this Task Force:

1. To carry out an internal scan of the FoM to identify the current required and recommended training for faculty members across campus and Toronto Academic Health Science Network hospitals with regard to the Responsible Conduct of Research.
2. To carry out an external scan of relevant training programs within Canada and the U.S. to identify best practices and the highest quality training programs.
3. To clarify reporting processes when questions/concerns related to scientific misconduct are suspected at the University.
4. Based on the information obtained from these scans, to recommend standards of required training for all faculty members who are currently engaged in – or who may in the future engage in – research activities.
5. To recommend actions the FoM should take to help foster a ubiquitous culture of ethical research practice for all faculty members.

The scope of this report focuses on faculty members currently conducting (or in the future, may conduct) research activity across all sectors – basic sciences, clinical, and rehabilitative sciences – associated with the FoM. This report provides the Dean of the FoM with concrete recommendations designed to prevent research misconduct.[9]

III ENVIRONMENTAL SCAN

The FoM currently does not mandate a centralized training program regarding Responsible Conduct of Research for faculty members. This is due to the decentralized nature of the research enterprise, which involves scholarly activities conducted not only on University of Toronto campuses but throughout the fully-affiliated sites and associate member hospitals of the Toronto Academic Health Sciences Network (TAHSN) and their research institutes, as well as at community-affiliated sites. Research conduct is generally governed by the policies and practices of each site.[10] Some research integrity training is

[9] The scope of this report does not address prevention or training specifically aimed at students or trainees.
[10] Harmonized research guidelines as between the University and TAHSN sites are detailed in Appendix B.

mandated by University Departments and takes place on campus; other activities takes place at TAHSN sites.

TAHSN has a Research Committee (TAHSNr) co-chaired by Dr. Michael Julius (Vice-President, Research, Sunnybrook Research Institute) and Dr. Richard Hegele (Vice Dean, Research and Innovation, FoM). Membership on TAHSNr includes each VP Research (or equivalent) representing each affiliated site within TAHSN and representatives from the University, including from the Vice-President, Research and Innovation's portfolio. In the spring of 2016, Drs. Julius and Hegele asked each fully-affiliated and community-affiliated site representative to answer the following questions:

1. Does your Research Institute offer faculty members who do research specific training sessions, didactic lectures, online modules or other learning approaches provided to promote research integrity?

2. How are these materials/sessions offered and by whom?

3. What is communicated to faculty members about the consequences if research integrity is breached and how is that messaged conveyed?

Eleven of thirteen member sites within TAHSNr responded. Results indicate there are already considerable efforts in place at the majority of TAHSN sites in training faculty members in research integrity, including web-based training and e-learning, orientation activities, in-class training, symposia, rounds and other forums. One VP Research summarized general aspirations as follows: "The focus of training is intended to promote responsible practice by establishing quality standards."

Although there is variability between sites in the approaches used locally for training faculty members in research integrity, several themes emerged:

- Seven of the affiliated sites alluded to research investigators completing online modules on the Responsible Conduct of Research, of which 12 modules are available via the Collaborative Institutional Training Initiative Canada website (discussed further below). Institutional membership in the Network of Networks (N2) allows these modules to be completed at no cost to the investigator. There is variability between sites as to whether completion of some or all related modules is mandatory, ranging from "strongly recommended" to "Research Ethics Board approval is not given until all applicants have completed the N2 training."
- Other online resources relevant to clinical research include the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Good Clinical Practice and Tri-Council Policy Statement 2 (TCPS2)—Ethical Conduct of Research. For investigators doing research involving human subjects, completion of TCPS2 is mandated by all sites.
- In those institutions that mandate refresher training, this ranges from every 2-5 years.
- Some institutions have found it useful to separate training for basic science researchers from training for clinical researchers. (See Task Force Recommendation #12, p. 15)

- Institutions make their investigators aware of policies and procedures in place for addressing allegations of research misconduct, with revisions and updates communicated electronically.
- At least one of the affiliated sites stated that research integrity training should not be made a mandatory requirement, as this would unduly burden the many for the actions of a few.

In addition to online modules, there are other approaches to research conduct training across TAHSN, including:

- Offering free access to online plagiarism detection software;
- Research orientation sessions for new personnel and research investigators; and
- Annual research retreats or periodic research integrity forums and other in-house professional development.

At the national level, the federal Secretariat on Responsible Conduct in Research has, since late 2011, had a policy on "consent to disclosure" for engaging in a serious breach of Agency policy for all researchers seeking Tri-Council funding.[11] This policy requires all researchers applying for CIHR, NSERC or SSHRC grant funding to consent to the Agency disclosing any information relevant to the breach that is in the public interest, including the:

- Name of the individual who committed the breach;
- Nature of the breach;
- Institution where the individual was employed at the time of the breach;
- Institution where the individual is currently employed; and
- Recourse imposed by the Agency against the respondent.

Given this regulatory requirement, it is ever more important that institutions that rely on Tri-Council funding for research – including FoM – proactively work to educate faculty members on the Responsible Conduct of Research and foster a culture that rewards and recognizes integrity in research as a key aspect of faculty member recognition, including promotion and awards.

Looking beyond Canada, the Collaborative Institutional Training Initiative (CITI) is a nonprofit organization based at the University of Miami that offers comprehensive training on the Responsible Conduct of Research. Founded in 2000, CITI materials on the Responsible Conduct of Research constitute the most comprehensive and utilized training in elite institutions in the US. Its mission*:*

> *"*To promote the public's trust in the research enterprise by providing high quality, peer reviewed, web based, research education materials to enhance the integrity and professionalism of investigators and staff conducting research."

In 2010, the Network of Networks (N2) in Canada – an alliance of 90+ clinical research entities and institutions including University of Toronto – partnered with CITI to establish a source of high quality, web-based Canadian instruction around safe, responsible, ethical research conduct. Most applicable to the

[11] http://www.nserc-crsng.gc.ca/NSERC-CRSNG/governance-gouvernance/consentFAQ-consentementFAQ_eng.asp#10

scope of this report are the Responsible Conduct of Research modules (see below under "Recommendations") offered through N2; written at a general level and suitable to researchers in all disciplines, these modules provide a solid foundation relating to the norms, principles and rules governing responsible research practice in Canada.[12] The N2 member institution may set the number and list of modules required for certification; an administrator receives automated reports of individual training completion and can generate further reports.

The University of Toronto is a N2 member through the Office of the Vice President for Research and Innovation. Anyone with an institutional email account (@utoronto.ca) may sign in and use the Canadian version of the CITI modules.

IV Research Misconduct Definitions & Examples

The University of Toronto's ***Framework to Address Allegations of Research Misconduct*** defines research misconduct as:

> *"…any research practice that deviates seriously from the commonly accepted ethics/integrity standards or practices of the relevant research community and includes but is not limited to intentional fabrication, falsification, and plagiarism as defined by the University's Code of Behaviour on Academic Matters…..due regard is given for honest errors, honest differences in methodology, interpretation or judgement, or divergent paradigms in science; what is at issue are genuine breaches of the integrity of the research process."* [13]

Research misconduct most often falls into the following three broad categories:

1. Fabrication: Making up data or results and recording or reporting them.
2. Falsification: Manipulation of research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
3. Plagiarism: The appropriation of another person's ideas, processes, results, or words without giving appropriate credit. This includes self-plagiarism: Recycling or re-using one's own work without appropriate disclosure and/or citation.

However, other types of research misconduct are also recognized in the Framework. These include, but are not limited to:

[12] http://n2canada.ca/the-collaborative-institutional-training-initiative-citi-canada/#more-390

[13] http://www.research.utoronto.ca/wp-content/uploads/documents/2013/09/Research-Misconduct-Framework-Jan-1-2013.pdf

Impropriety of authorship: Claiming undeserved authorship on one's own behalf, excluding material contributors from co-authorship, including non-contributors as authors, e.g. ghostwriting, or submitting multi-author papers to journals without the consensus of all named authors.

Misappropriation of ideas: Taking the intellectual property of others, perhaps as a result of reviewing someone else's article or manuscript, or grant application and proceeding with the idea as one's own.

Violation of generally accepted research practices: This can include the manipulation of experiments to generate preferred results, deceptive statistical or analytical practices to generate preferred results, or improper reporting of results to present a misleading outcome.

Suppression of publication: Failing to publish significant findings due to the results being adverse to the interests of the researcher or his/her sponsor(s).

Inappropriate behavior in relation to suspected misconduct: Failure to cooperate with any claims of misconduct made against a faculty member, failure to report known or suspected misconduct, destruction of any evidence related to any claim of misconduct, retaliation against any persons involved in a claim of misconduct, knowingly making false claims of misconduct.

V UNIVERSITY REPORTING PROCESSES

Addressing Suspicions of Research Misconduct:

Bringing forward concerns about research misconduct may be a daunting prospect for members of the University community. A variety of mechanisms exist within the University and the FoM to alleviate the stress associated with whistleblowing.

The University's **Framework to Address Allegations of Research Misconduct** (the "Framework") permits allegations to be lodged anonymously in limited circumstances. All allegations of research misconduct are centralized and should be submitted in confidence to the University's Vice-President, Research and Innovation at **research.integrity@utoronto.ca** (see below and Appendix C). Anonymous complaints should be submitted with enough information to allow the allegations, including supporting facts and evidence, to be assessed by the University, without requiring additional information from the individual who made the complaint. It should be noted that the University may elect not to proceed with anonymous allegations, particularly where there is insufficient supporting material. If the University elects to proceed with an anonymous complaint, the individual who lodged the complaint is not entitled to participate in the process set out in the Framework.

Assurances regarding confidentiality are also an integral element of the University's Framework, which requires the highest possible degree of confidentiality be maintained regarding the allegations, inquiries and investigations, subject to required disclosures (ex. pursuant to law or policy). The commitment to

confidentiality applies both to the individual bringing forward the complaint, as well as the subject of the complaint, with the Framework identifying the confidentiality obligations of all involved parties at various stages of the process.

Additionally, there are a number of avenues for individuals concerned about suspected research misconduct to obtain support and advice within FoM, including:

- Contacting the applicable Department Chair(s);
- Conferring with relevant FoM senior leaders based in the hospitals or on campus; and
- Speaking to the Clinical Faculty Advocate.

Initiating a Complaint:

As a preliminary matter, the University's Framework encourages individuals concerned about a potential case of research misconduct to seek an explanation from the suspected individual, if appropriate, to ensure no misunderstanding.

Complaints should be directed to the University's Vice-President Research and Innovation portfolio (VPRI) using the confidential email of **research.integrity@utoronto.ca.** The University's Associate Vice-President, Research Oversight and Compliance handles the complaints on behalf of the VPRI.

Complaints should be made in writing, set out all relevant information and include supporting evidence, if available. Unless brought forward anonymously, the complaint should identify and be signed and dated by the complainant and provide appropriate contact information. Allegations must be made in good faith and declare any conflict of interest.

Reporting and Responding to Research Misconduct:

The Task Force has developed a high level overview of the Framework's process to assist faculty members in reporting and responding to allegations of research misconduct. **NB: The following overview should not be used without reference to the corresponding Framework.**

	Framework Reference[14]	Step	Explanation	Responsible University Party[15]
1	Submission of Complaints	**File Complaint**	Allegations must be in writing, set out relevant information and evidence, and be signed and dated by, and identify Complainant.	Complaints should be directed to VPRI: **research.integrity@utoronto.ca**

[14] Review for further details.
[15] Responsible party indicated is from the University, unless otherwise indicated.

	Framework Reference[14]	Step	Explanation	Responsible University Party[15]
2	**Framework Addendum**	**Determine Jurisdiction**	Determine if hospital or University has jurisdiction over complaint of Research Misconduct, in accordance with **the Addendum to the University's Framework** . If complaint falls within the University jurisdiction, process unfolds as per below.[16]	Associate Vice-President, Research Oversight and Vice-Provost, Relations with Healthcare Institutions; Affiliated Hospital's Vice-President, Research, or delegate.
3	Submission of Complaints	**Referral to Vice-President, R&I**	Complaint forwarded to Office of Vice-President, Research & Innovation ("R&I").	Individual in receipt of Complaint
4	Submission of Complaints	**Referral by Vice-President, R&I**	Vice-President, R&I will notify and provide the subject of the complaint (the "Respondent") with a full copy of complaint and refer complaint to Dean(s)[17] normally within **7 days**[18] of receipt.	Vice-President, R&I
5	Processing of Complaints	**Administrator Appointed**	Dean appoints an Administrator[19] to conduct a preliminary inquiry, normally to begin within **20 days** of the Dean's receipt of complaint.	Dean
6	Timelines	**Preliminary Inquiry**	Administrator gathers information and provides recommendation as to	Administrator appointed by Dean

[16] If complaint falls within hospital's jurisdiction, the hospital may commence its own inquiry, and if the individual has a U of T appointment will report its findings to the University.
[17] Reference to "Dean(s)" in this overview means the Dean of the academic division in which the Respondent holds their primary appointment. If the Respondent holds primary appointments in different divisions (e.g. FoM and School of Graduate Studies), the referral is to both Deans, who will decide which will serve as Dean for purpose of the complaint and will keep the other informed of the complaint's status.
[18] All timelines refer to maximum number of working days allowable.

[19] Reference to "Dean(s)" in this overview means the Dean of the academic division in which the Respondent holds their primary appointment. If the Respondent holds primary appointments in different divisions (e.g. FoM and School of Graduate Studies), the referral is to both Deans, who will decide which will serve as Dean for purpose of the complaint and will keep the other informed of the complaint's status

	Framework Reference[14]	Step	Explanation	Responsible University Party[15]
			whether complaint should proceed to an investigation normally within **60 days** of Vice-President, R&I's receipt of complaint.	
7	Investigation	**Appointment of Investigation Committee**	Dean appoints Investigating Committee normally within **15 days** of receipt of Administrator's recommendation that Investigation should be conducted (composition of which is detailed in Framework).	Dean
8	Authority and Responsibilities of the Investigating Committee	**Committee Convenes**	Investigating Committee convenes normally within **30 days** of appointment.	Investigating Committee
9		**Reporting Commencement of Investigation**	Dean informs Vice-President, R&I that an investigation of a complaint of research misconduct has commenced.	Dean
10	Reference to "Dean(s)" in this overview means the Dean of the academic division in which the Respondent holds their primary appointment. If the Respondent holds primary appointments in different divisions (e.g. FoM and School of Graduate Studies), the referral is to both Deans, who will decide which will	**Notice of Committee's Appointment**	Investigating Committee notifies Respondent and Complainant of the investigation process, including their respective rights and obligations, namely: • Complainant may provide written materials to supplement complaint; • Respondent may comment on any supplementary material from Complainant;	Investigating Committee

	Framework Reference[14]	Step	Explanation	Responsible University Party[15]
	serve as Dean for purpose of the complaint and will keep the other informed of the complaint's status		• Complainant may review the response of Respondent to supplementary material.	
11	Process for Investigating Complaints of Research Misconduct	**Other Steps in Investigative Process**	Investigating Committee: • will set deadline for submission of responses and evidence; • may conduct interviews, which will be summarized and provided to interviewed party; • will provide Respondent with access to documents to enable a fair opportunity to respond to relevant material.	Investigating Committee
12		**Interim Findings**	Committee will provide interim findings to Dean, if it's of the view that such must be reported to fulfil University's obligations to its community or third parties.	Chair of Investigating Committee
13		**Investigation Complete**	Investigation to be complete normally within **60 days** of Committee's first meeting.	Investigating Committee
14	Reports of the Investigating Committee	**Final Report**	Committee delivers final report to Complainant, Respondent, Dean and Vice-President, R&I normally within **30 days** of completed investigation (content of final report detailed in Framework).	Investigating Committee
15		**Respondent and Complainant Opportunity to**	Respondent and Complainant have up to **15 days** to make	Respondent / Complainant

	Framework Reference[14]	Step	Explanation	Responsible University Party[15]
		Respond to Final Report	submissions to the Dean regarding the findings, in advance of any administrative action recommended to be taken by the Dean.	
16		**Report of the Dean**	Dean informs Vice-President, R&I of the findings of the investigation and the Dean's decision about administrative action.	Dean
17	Administrative Action & Reporting Requirements	**Where no Research Misconduct Found**	Dean sends letter confirming finding of no Research Misconduct to Respondent, with copy to Complainant and, at Dean's discretion, to other persons.	Dean
18		**Where Research Misconduct is Found**	Dean decides on remedial/disciplinary action, in consultation with Vice-President, R&I and Provost within **15 days** of Dean's receipt of submissions from Respondent in response to the Final report. For Research Misconduct involving faculty member, action may include proceedings leading to sanctions under University's *Code of Behaviour on Academic Matters* or *Policy and Procedures on Academic Appointments* or other University policies and/or agreements and related procedures.	Dean
19		**Communication about Outcome**	Vice-President, R&I may communicate outcome of	Vice-President, R&I

	Framework Reference[14]	Step	Explanation	Responsible University Party[15]
			investigation to other parties within or external to University.	
20	Appeal Process	**Reviews**	Respondent may have rights of review, grievance or appeal related to sanction pursuant to University policy or a collective agreement. Where a Respondent has no access to any other process for review of the administration action or sanction, they may seek review by the Vice-President, R&I, which must be sought within **5 days** of the decision regarding the administration action or sanction.	Applicable tribunal, adjudicator or Vice-President, R&I

VI TASK FORCE RECOMMENDATIONS

After thorough consultations and a review of best practices, the Task Force has compiled a series of recommendations designed to ensure the FoM reflects its position as a national and international leader through the highest standards of research integrity. Recognizing the complexity of FoM research – across scientific domains, multiple campuses, hospitals and sites – there are some core strategies recommended for immediate implementation under three categories: data management, training initiatives and facilitating a culture of integrity.

DATA MANAGEMENT:

To adhere to best practices, faculty members engaged in research should:

1. Follow national guidelines with respect to digital data management, e.g. Tri-Agency Statement of Principles on Digital Data Management.[20]

[20] Found online at: http://www.science.gc.ca/default.asp?lang=En&n=83F7624E-1.

2. Consult international guidelines on clinical trial protocols, clinical trials registration and reporting of trials, cohort studies, systematic reviews, etc. according to the relevant recommendations, e.g. the Consolidated Standards of Reporting Trials (CONSORT) Statement.[21]
3. Outline hypotheses and data analysis plan prior to conducting a research study in order to guide the responsible collection, formatting, preservation and sharing of data throughout the entire lifecycle of a research project and beyond.[22]
4. Use electronic data systems wherever possible for data collection and management, e.g., use of computer assisted data entry, such as through use of a data management system like REDCAP[23]. Funding to cover the costs of a data management system should be incorporated into grant applications.
5. Ensure data collection/data entry is not performed by the investigator (e.g. instead, a research assistant or data entry clerk); funding for this should be incorporated into grant applications.
6. Put into place a formal plan for data quality control (e.g. double data entry, source document comparisons, etc.). Data quality control should not be performed by the investigators. Funding for this should be incorporated into grant applications.
7. In cases where there are no laws, regulations, policies or REB requirements mandating it, still consider, consider using a Data Safety Monitoring Board (DSMB) as an independent review/advisory committee for clinical research where human subjects are being recruited, in trials and even possibly cohort studies. [24]
8. Ensure the project raw dataset is stored securely as per the data retention requirements (by either the PI or by research institute, as appropriate).
9. Provide the analysis dataset to a statistician responsible for analysis (post coding of variables and quality control using raw data).
10. Provide an opportunity for other members of the research team to review coding, analytic output and/or redo modelling to ensure consistency of findings prior to dissemination and publication.

<u>TRAINING INITIATIVES:</u>

11. The Task Force strongly recommends that for all faculty members engaged in research the N2 modules should be completed every 3 years (see below). For faculty involving human subjects, N2 modules 1-11 should be completed[25] every 3 years. For all faculty engaged in animal research, modules 1- 4 and 6-12 should be completed every 3 years.

[21] CONSORT Statement and resources are found available online at: http://www.consort-statement.org/
[22] See Tri-Agency Statement of Principles on Digital Data Management, *supra* note 22.
[23] Found online at: https://projectredcap.org/
[24] A DSMB complements the role of a Research Ethics Board (REB) and has a much broader scope for oversight of data.
[25] Any faculty member can access the N2 modules by registering as a user on the CITI site: **https://www.citiprogram.org/** and click on the "Register" button under "Create an account". As long as the individual has a UTOR email address, s/he should be able to create the account and access the modules.

1) Research Misconduct
2) Introduction to the Responsible Conduct of Research
3) Ethics and the Responsible Researcher
4) Conflicts of Interest in Research
5) Human Participants Research and Ethics
6) Writing with Integrity
7) Data Acquisition and Management
8) Publication Practices and Responsible Authorship
9) Peer Review: Role and Process in Life Sciences Research
10) Responsible Mentoring
11) Collaborative Research
12) Animal Care and Use

12. This training recommendation should be part of the applicable annual faculty member review process (i.e. credentialing, or reappointment or review).

Faculty members who have no expectation of engagement in any aspect of research may be exempt from the recommended training modules. The FoM should aim to collaborate with affiliated sites to review annually the activities of exempted faculty members, and remove exemptions for those who may be engaged in research, as broadly defined previously.

FACILITATING A CULTURE OF INTEGRITY:

13. Institute formal and encourage informal mentoring programs for undergraduate students, trainees and fellows to ensure the next generation of researchers is fully versed in research integrity principles

14. Create educational opportunities to promote integrity values among faculty members through ongoing in-person engagement and communication on these issues, for example:
    a. Training in appropriate practices for supervisors of research in the FoM;
    b. Review of principles of data management and training obligations for all faculty;
    c. Recurring key messages in speaking remarks to appropriate research audiences;
    d. Annual research integrity forum with external speakers and case discussions;
    e. Ensuring any faculty members funded through national funding agencies are aware of all policies they are subject to, e.g., Tri-Council-funded faculty members are aware of the Tri-Council Framework, including mandatory consent to disclosure policy for serious RCR breaches.

15. Review current research award criteria across FoM Departments and Units to ensure criteria relating to an individual's values, professionalism and citizenship are included in adjudication.

16. Ensure support and protection for those who bring forward suspicions of research misconduct and communicate the FoM's expectation that, consistent with University policy, any retaliation

against complainants will be dealt with accordingly. Such retaliation is considered research misconduct under the Framework.

17. The University of Toronto will be posting an annual anonymized update of summarizing findings of misconduct. U of T with other Canadian Universities are working with the Responsible Conduct of Research Secretariat to establish a community of practice in this regard.

18. Seek increased coordination between University and affiliated hospitals and clinical sites with respect to administrative procedures to ensure appropriate and timely communication regarding research misconduct investigations and findings, as permitted by applicable law, policy and agreements.

19. Encourage strengthened communications between the VPR&I, Dean and Department Chairs to ensure Chairs have appropriate information regarding candidates for faculty appointments or promotions with respect to research misconduct.

20. Develop an annual ethics scorecard as an internal tracking tool under the auspices of the FoM's Vice Dean, Research and Innovation. This scorecard would track, for example, percentage of faculty who comply with N2 training requirements, the number and type of research misconduct cases reported that year, the number and type of educational events across the FoM for faculty and trainees that address aspects of the responsible conduct of research.

Although a complex matter, the Responsible Conduct of Research at the institutional level requires an ongoing commitment to facilitate a culture of integrity and provide access to resources that enable best practices in the conduct of research. The Task Force believes that the adoption of the foregoing recommendations will significantly foster the ability of FoM faculty members to conduct research to the highest ethical standard, underscoring the University of Toronto's position as a national and international leadership in education and research. The FoM is committed to collaborating with its faculty members and affiliated institutions in disseminating these recommendations, and providing faculty development and other supports to facilitate their adoption.

APPENDIX A: Task Force membership and stakeholders consulted

Allan S. Kaplan, MSc., MD, FRCPC (Chair)
Vice Dean Academic and Graduate Affairs, Faculty of Medicine; Professor, Department of Psychiatry, University of Toronto

John Bohnen, MD
Senior Advisor to the Dean on Clinical Affairs; Professor, Department of Surgery**,** University of Toronto

Sara Gottlieb
Legal Counsel, Faculty of Medicine/Office of the Vice Provost, Relations with Health Care Institutions, University of Toronto

Gillian Hawker, MD, MSc., FRCPC
Sir John and Lady Eaton Professor and Chair, Department of Medicine, University of Toronto

Richard Hegele, MD, FRCPC, PhD
Vice Dean Research and Innovation, Faculty of Medicine; Professor, Department of Laboratory Medicine and Pathobiology, University of Toronto; Chief, Department of Paediatric Laboratory Medicine, SickKids

Michael Julius, PhD
Vice President, Research Sunnybrook Health Sciences. Previous TAHSNr Co-Chair

Paula Rochon, MD, MPH, FRCPC
Vice President, Research, Women's College Hospital. Current TAHSNr Co-Chair

James Rutka, MD, PhD, FRCSC, FACS, FAAP, FAANS
RS McLaughlin Professor and Chair, Department of Surgery, University of Toronto

Linda Quattrin
Executive Director, Office of Communications, Faculty of Medicine, University of Toronto

Lynn Wilson, MD, CCFP, FCFP
Vice Dean, Partnerships, Faculty of Medicine; Associate Vice Provost, Relations with Health Care Institutions; Professor, Department of Family and Community Medicine, University of Toronto

Stakeholders consulted:

Basic Science Chairs Committee
Clinical Chairs Committee
Dean's Executive Committee, Faculty of Medicine
Dean's Advisory Group, Faculty of Medicine
Graduate Chairs Committee
Rehab Science Chairs Committee
TAHSN Research Committee (VPs of hospital-based research institutes and University representatives)

Professor Lori Ferris, Associate Vice-President for Research Oversight and Compliance

Professor Sioban Nelson, Vice Provost Academic Programs
Professor Vivek Goel, Vice President Research and Innovation
Professor Jay Rosenfield, Vice Dean, MD Program (prior to July 1, 2016)
Professor Sal Spadafora, Vice Dean, Post MD Education

Susan Zimmerman, Executive Director, Secretariat on Responsible Conduct of Research
Government of Canada

APPENDIX B: University Resources

Core University Policies and Framework Relating to Research Integrity	
Policy /Framework	Application
Research Administration Policy (University)	Defines "Research" and sets out University's general principles and procedures for research proposals and agreements and the roles and responsibilities of relevant parties.
Policy on Ethical Conduct in Research (University)	Establishes institutional commitment to "highest standards of ethical conduct in every aspect of research including applications, proposals, the research itself, reports and publication."
Framework to Address Allegations of Research Misconduct (University)	Sets out process under which University responds to allegations of research misconduct.
Research Misconduct Framework Addendum, Procedures for Determining Jurisdiction in Complaints Involving Certain Non-University Institutions (University)	Clarifies whether University or hospital institution has jurisdiction over a research integrity complaint involving individual with an appointment at, or conducts research in a fully or community affiliated teaching hospital.
Code of Behaviour on Academic Matters (University)	Defines forms of research misconduct, including intentional fabrication, falsification, and plagiarism and reviews and procedures for addressing such, including appeal rights.
Policy on Research Involving Human Subjects (University)	Sets out University's principles relating to research projects involving human subjects undertaken or under auspices of University, regardless of whether project funded or administered by University.
Publication Policy (University)	Sets out qualifications for publication of research undertaken at the University.
Policy on Conflict of Interest - Academic Staff (University)	Sets out what constitutes a conflict of interest, describes procedures to follow when faculty members engage in professional work for supplementary income, and establishes procedures for other situations which could give rise to an apparent conflict of interest.
Statement on Conflict of Interest and Conflict of Commitment (University)	Provides a number of principles affirming the commitment of the University to the identification and management of real and perceived conflicts of interest and conflicts of commitment.

Policy and Procedures on Academic Appointments (University)	Sets out grounds and procedures for terminating employment of tenured faculty for faculty members charged with academic offences.
Guidelines for Research Involving Possible External Pressure to Disclose Participant Data (University)	Sets out principles to be followed in University research where external pressure to disclose is reasonably foreseeable.
Statement of Protection for Intellectual Freedom and Publication Rights (FoM and Affiliated Institutions)	Details the University and hospital commitment to principles of intellectual freedom, including agreement to prohibit practices with sponsors or otherwise that negatively impact integrity of pursuit of academic freedom.
Policy on the Offer and Acceptance Of Finders Fees or Completion Fees In Research Involving Human Subjects (FoM)	Addresses the issue of finders' fees and completion fees in research involving human subjects.
Standards of Professional Behaviour for Medical Clinical Faculty (FoM)	Articulates expectations for the standards of professional behavior and ethical conduct of clinical faculty members in carrying out professional duties, including in research practices.
Statement of Principles and Responsibilities Regarding Conduct of Research (FoM)	Provides Faculty of Medicine's principles, as of 2002, for preventing research misconduct and outlines the responsibilities of faculty members in conducting their research.
Relationships with Industry and the Educational Environment in Undergrad and Postgrad Medical Education (FoM)	Sets out standards of best practices between Faculty of Medicine and industry, including disclosure measures.
Relevant External Policies Relating to Research Integrity	
Policy /Framework	Application
International Committee of Medical Journal Editors Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly work in Medical Journals	The ICMJE provides recommendations regarding best practice and ethical standards in the conduct and reporting of research and other material published in medical journals, and are intended primarily for use in submissions to ICMJE member journals.
TCPS 2 (2014) – latest edition of **Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans**	Developed by the three federal granting agencies (CIHR, NSERC and SSHRC), this document sets out the University's obligations to comply with requirements for review, oversight and conduct of research involving human participants and/or personal information.
CONSORT Statement	Comprises a 25-item checklist to report how trial was designed, analysed and interpreted and flow diagram to display progress, to assist reporting of trial findings in a transparent and critical manner.
Tri-Agency Statement of Principles on Digital Data Management	Outlines funding agencies' expectations for research data management and responsibilities of researchers, research communities, institutions and funders in meeting such expectations.
Access to N2 Training Module	
https://www.citiprogram.org/ and click on the "Register" button under "Create an account". Enter UTOR email address to create the account and access the modules.	

Questions Involving Research Integrity	
Type of Question	Contact
General Research Policies / Questions	Vice Dean Research and Innovation, Faculty of Medicine
Application of **University Framework to Address Allegations of Research Misconduct**	Associate Vice-President, Research Oversight and Compliance
Other Applicable Guidelines, Policies,	**Office of Research and Innovation** **Research Office, Faculty of Medicine**

APPENDIX C: Research Misconduct Investigation Timelines

Research Misconduct Investigation Timelines

Timeline	Actions
Receipt and Referral of Allegation: normally within 7 working days	• VPRI receives and reviews complaint • Determination made whether an affiliated hospital or University has jurisdiction, or whether both do jointly • If hospital has jurisdiction, hospital commences its own inquiry and reports its findings to University; process does not proceed further • If University has jurisdiction, VPRI notifies Respondent and refers complaint to relevant Dean and process continues; if complaint may involve significant risk, relevant Tri-Council Agency is notified if appropriate • If joint jurisdiction, hospital and University continue process jointly
Inquiry: normally within 60 working days Normally begins within 20 working days of Dean's receipt of complaint; Normally completed within 60 working days of VPRI's receipt of complaint.	• Dean assigns complaint to administrator • Administrator initiates inquiry under the Framework • With the consent of all involved parties, the Administrator may conduct non-binding, without prejudice, confidential mediation • Report of administrator's recommendation is given to Dean, Complainant, Respondent and VPRI • Report is sent to any Tri-Council Agency that was notified of complaint • If administrator recommends that an investigation be conducted, then process continues
Investigation: normally within 135 working days (approximately 6.5 months) Committee normally appointed within 15 working days of Inquiry report;	• Dean informs VPRI that investigation will occur and appoints investigating committee • Chair of investigating committee notifies Respondent and Complainant of complaint and process • Investigating committee investigates complaint, which may include documentation review and

Committee normally convenes within 30 working days of its appointment; Investigation normally completed within 60 working days of Committee's first meeting; Report normally delivered within 30 working days of completion of investigation.	interviews with Complainant, Respondent or other relevant people • During investigation process, both Complainant and Respondent have opportunities to provide comment • Investigating committee delivers report of its decision to Complainant, Respondent, Dean and VPRI • Next step in process depends on whether misconduct found
If <u>NO</u> Research Misconduct Found	• Dean confirms finding in writing to Respondent, Complainant, VPRI and, in Dean's discretion, others with knowledge of complaint • Relevant Tri-Council Agency is notified if appropriate
If Research Misconduct Found: normally within 35 working days Respondent and Complainant normally have 15 working days to make submissions; Dean normally decides about actions to be taken within 15 working days of any submissions; Respondent may seek review of actions to be taken normally within 5 working days of the decision.	• Dean confirms finding in writing to Respondent, Complainant, VPRI and, in Dean's discretion, others with knowledge of complaint • Respondent and Complainant may each make submissions to Dean, in advance of any recommended remedial and/or disciplinary action being taken • Dean decides about actions to be taken, in consultation with VPRI and in accordance with policies and procedures, and advises Respondent • Respondent may seek review of the proposed actions from VPRI • Dean takes remedial and/or disciplinary action • Relevant Tri-Council Agency and/or any other relevant parties are notified if appropriate

From the University of Toronto's Research Oversight and Compliance Office, Office of the Vice-President, Research and Innovation. September 2017

APPENDIX D: FREQUENTLY ASKED QUESTIONS*:*

What kinds of scholarly work are considered 'research'?

In brief, all types of research! Research is defined broadly to include all fundamental/basic science research; all clinical research, including clinical trials; education research; health policy research; knowledge translation and dissemination; and quality improvement and patient safety. An expanded definition of research can be found in the University's Policy on Research Administration (link).

What constitutes research misconduct?

The University of Toronto's Framework to Address Allegations of Research Misconduct defines research misconduct as: "…any research practice that deviates seriously from the commonly accepted ethics/integrity standards or practices of the relevant research community and includes but is not limited to intentional fabrication, falsification, and plagiarism as defined by the University's Code of Behaviour on Academic Matters…..due regard is given for honest errors, honest differences in methodology, interpretation or judgement, or divergent paradigms in science; what is at issue are genuine breaches of the integrity of the research process."

What is….?

1. Fabrication: Making up data or results and recording or reporting them.

2. Falsification: Manipulation of research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.

3. Plagiarism: The appropriation of another person's ideas, processes, results, or words without giving appropriate credit. This includes self-plagiarism: Recycling or re-using one's own work without appropriate disclosure and/or citation.

4. Impropriety of authorship: Claiming undeserved authorship on one's own behalf, excluding material contributors from co-authorship, including non-contributors as authors, e.g. ghostwriting, or submitting multi-author papers to journals without the consensus of all named authors.

5. Misappropriation of ideas: Taking the intellectual property of others, perhaps as a result of reviewing someone else's article or manuscript, or grant application and proceeding with the idea as one's own.

6. Violation of generally accepted research practices: This can include the manipulation of experiments to generate preferred results, deceptive statistical or analytical practices to generate preferred results, or improper reporting of results to present a misleading outcome.

7. Suppression of publication: Failing to publish significant findings due to the results being adverse to the interests of the researcher or his/her sponsor(s).

8. Inappropriate behavior in relation to suspected misconduct: Failure to cooperate with any claims of misconduct made against a faculty member, failure to report known or suspected misconduct, destruction of any evidence related to any claim of misconduct, retaliation against any persons involved in a claim of misconduct, knowingly making false claims of misconduct.

If I suspect research misconduct by another individual, who should I speak to?

Bringing forward concerns about research misconduct may be a daunting prospect for members of the University community. A variety of mechanisms exist within the University and the FoM to alleviate the stress associated with whistleblowing.

Concerns about research misconduct can be made directly to the University at **researchintegrity@utoronto.ca** . They will be happy to discuss the issue with you to help determine best next steps. However, we recognize that depending on your role in the University or Hospital, you may first wish to discuss the concern with your direct report, e.g. your undergraduate course director, residency or fellowship program director, vice-president research at your hospital, or clinical chief. This individual can help you determine if a complaint should be made.

Can I lodge a complaint anonymously?

The University's Framework to Address Allegations of Research Misconduct (the "Framework") permits allegations to be lodged anonymously in limited circumstances. Anonymous complaints should be submitted with enough information to allow the allegations, including supporting facts and evidence, to be assessed by the University, without requiring additional information from the individual who made the complaint. It should be noted that the University may elect not to proceed with anonymous allegations, particularly where there is insufficient supporting material. If the University elects to proceed with an anonymous complaint, the individual who lodged the complaint is not entitled to participate in the process set out in the Framework.

What about confidentiality, both for the person lodging the complaint and the person who is the subject of the complaint?

Assurances regarding confidentiality are an integral element of the University's Framework. The highest possible degree of confidentiality must be maintained regarding the allegations, inquiries and investigations, subject to required disclosures (ex. pursuant to law or policy). The commitment to confidentiality applies both to the individual bringing forward the complaint, as well as the subject of [need sentence finished]

As a preliminary matter, the University's Framework encourages individuals concerned about a potential case of research misconduct to seek an explanation from the suspected individual, if appropriate, to ensure no misunderstanding.

How do I go about lodging a complaint regarding research misconduct?

Complaints should be directed to the University's Vice-President Research and Innovation at **research.integrity@utoronto.ca** . Complaints should be made in writing, set out all relevant information and include supporting evidence, if available. Unless brought forward anonymously, the complaint should identify and be signed and dated by the complainant and provide appropriate contact information. Allegations must be made in good faith and declare any conflict of interest.

What will happen if I lodge a concern about research integrity?

The University's Framework to Address Allegations of Research Misconduct (the "Framework") ensures a standardized approach to addressing complaints of research misconduct. The initial step is to determine if the hospital or University should take the lead (e.g., where did the alleged research misconduct take place? By whom?). The Dean is also informed about the complaint and the individual about whom the complaint was is made is notified, usually within 7 days of receipt of the complaint. An initial assessment is conducted to determine if a full investigation is warranted and, if yes, the process of investigation is launched. The timeline and specifics of the Framework is provided in Appendix C.

Are there educational resources available regarding ethical research conduct?

Yes. N2 (Network of Networks) provides online modules on Responsible Conduct of Research. These are written at a general level, suitable to researchers in all disciplines, and provide a solid foundation relating to the norms, principles and rules governing responsible research practice in Canada. The University of Toronto is a member of N2. Any faculty member can access N2 modules by registering as a user on the CITI site: **https://www.citiprogram.org/** . Just click on the "Register" button under "Create an account". As long as you have a UTOR email address, you should be able to create an account and access the modules. Tri-Agency tutorials are also available online.

If I have a concern about research misconduct, who do I speak to? Does it matter if it is a trainee (UG, PG, graduate), faculty member (physician, PhD scientist), hospital staff member, other?

If there is an actual allegation that research misconduct has occurred, this needs to brought this forward to research.integrity@utoronto.ca.

Complainant	Concern is about….								
	UGME trainee	PGME trainee	Clinical or Research Fellow	Graduate Student	Clinical faculty member (full time, part time/adjunct)	Nursing staff	Allied Health staff	Research staff	Other
UGME trainee	Academy Director	Residency Program Director or Departmental Lead	Supervisor or Vice President, Research (research fellows) or Fellowship Director or Departmental Lead	Supervisor or Director of the Graduate Program or Vice Dean, Graduate Studies	Chief of the hospital department or Hospital division head or University division head or Department Chair	Hospital director of nursing or HR	Hospital director of allied health or HR	Vice President, Research or Director of the Research Institute/ Group	If in doubt, submit concern to research.integrity@utoronto.ca
PGME trainee									
Clinical or research fellow									
Graduate student									
Clinical faculty (full time, part time/adjunct)									
Nursing staff									
Allied health staff									
Research staff, e.g. research coordinator									