## 1.0 Introduction

Researchers at The Hospital for Sick Children (the Hospital) are engaged in studies, which, directly or indirectly can have a profound effect on the health of the public. The Hospital expects its Researchers to follow generally accepted standards for proposing, conducting and reporting research, and to adhere to the highest standards of responsible conduct in every aspect of research. Research integrity best practice is exemplified when Researchers conduct research honestly, accountably, openly and fairly in the search for and in the dissemination of knowledge. The purpose of this policy is to support and promote a positive research environment, in which high standards are ubiquitous. This policy sets out responsibilities and procedures to ensure credibility and integrity of research performed at the Hospital, and to maintain public trust in the organization. This policy outlines measures to ensure Researchers follow Responsible Conduct of Research (RCR) requirements of Hospital policies and professional or disciplinary standards and comply with applicable laws and regulations.

The Hospital is committed to promoting research integrity and Responsible Conduct of Research (RCR) in alignment with the Government of Canada Tri-Agency Framework: Responsible Conduct of Research document (2016). Where relevant, excerpts from the Tri-Agency Framework: Responsible Conduct of Research are incorporated verbatim into this policy with permission from the Government of Canada Secretariat for Responsible Conduct of Research (SRCR).

This policy aligns with provincial acts (Ontario Personal Health Information Protection Act; Freedom of Information and Protection of Privacy Act) and the University of Toronto's (the University) policy on "Ethical Conduct in Research"; "Code of Behaviour on Academic Matters"; Framework to Address Allegations of Research Misconduct" (Addendum here) and the University Faculty of Medicine's "Principles and Responsibilities Regarding Conduct of Research". Research conducted under the auspices of the Hospital follows policies related to Respect in the Workplace, Code of Conduct, Prevention of Workplace Violence & Harassment, Relationship Disclosure and Management (Conflict of Interest), Records Retention and Destruction and Privacy & Confidentiality of Information. A full list of all supporting Acts and policies can be found in section 5.

### 1.1 Definitions

**Research**:

- Is a systematic study to establish facts, principles or knowledge.
- Uses scientific methods and standardized protocols. However, some studies of individual participants, and some clinical innovations, may also be defined as research.
- Includes that which is grant-supported, not grant-supported, contracted, and funded or not funded.
- May involve participants through their physical participation and/or through collection or use of personal health information, tissue, biological fluids, embryos, foetuses, human remains, and cadavers.

**Researcher:** A researcher is defined as any individual who conducts research at or under the

auspices of the Hospital. Examples include, but are not limited to:

- Individuals with scientific appointments in the Research Institute, including (Senior) Scientists, (Senior) Associate Scientists, (Associate) Scientist-Track Investigators, Project Investigators, Senior (Associate) Scientist Emeritus, Adjunct Scientists, and Visiting Scientists.
- (Senior) Research Associates.
- Research Assistants.
- Research Nurses.
- Technologists.
- Trainees (including undergraduate and graduate students, post-doctoral fellows, clinical fellows, as well as house staff and other students as defined in The Hospital for Sick Children By-laws, Part II, Article 12).
- Volunteers.

**RCR**: "RCR" refers to Responsible Conduct of Research.

**Breach:** A breach is the failure to comply with any RCR policy throughout the life cycle of a research study – from application for funding, to the conduct of the research and the dissemination of research results.

**Responsible Allegation:** A responsible allegation of a breach must be based on facts. All relevant facts known to the Complainant should be stated precisely and clearly and, where possible, supported by relevant documentation. Allegations of a general nature, with no supporting documentation to substantiate the allegation, are not considered responsible. For an allegation to be considered responsible, it must be novel and never previously investigated.

**Complainant:** The person who makes an allegation of a breach in the RCR policy. The Complainant may be (but is not limited to): anyone involved in the research activity, anyone who has information about the research in question, and/or a research subject or family member of a research subject.

**Respondent:** The person against whom an allegation is made of a breach in the RCR policy.

**Chief:** Chief of Research.

**RIA:** Research Integrity Advisor.

**Supervisor:** The individual to whom a researcher formally reports at the Hospital. The following reporting relationships are acknowledged for the purposes of this policy:

- The President & Chief Executive Officer (CEO) reports to the Board of Trustees of the Hospital.
- The Chief reports to the President & CEO.
- The RIA reports to the Chief.
- Research Program Heads report to the Chief.
- Individuals with scientific appointments in the Research Institute report to the Research Program Head of the research program in which they are a member. Additionally, scientific

staff who have a primary Hospital appointment within a Clinical Division/Department are also accountable to their Clinical Division Chief.
- Individuals without scientific appointments in the Research Institute or who are Project Investigators report to the relevant member of the medical, dental, nursing or professional staff of the Hospital.
- Trainees and research staff report to an individual with a scientific appointment in the Research Institute or to a member of the medical, dental, nursing or professional staff of the Hospital.

### 1.2 Retention of research records

The Hospital's Records Retention and Destruction policy defines a "research record" as a record containing information related to research (a systematic investigation to establish facts, principles or generalizable knowledge) or having commercial value to the Hospital, such as: raw data, analyzed data, lab notes, protocols, manuscripts, patents, trademarks, copyrights and any supporting documentation. A "record" is any record of information in any form or in any medium, whether in written, printed, photographic, film, by electronic means or otherwise can be in paper, photograph, microfilm or electronic format. All research records are owned by the Hospital.

The minimum retention period for research records obtained as part of non-regulated research (not registered with Health Canada) is 7 years, per Appendix A: Minimum Retention Periods for Hospital Records Schedule in the SickKids Records Retention and Destruction policy.

The minimum retention period for research records obtained as part of a clinical regulated trial (i.e. registered with Health Canada) is 25 years from the creation of the record, per Health Canada Food and Drug Regulations: Division 5.

## 2.0 Responsibilities of Researchers

Researchers must ensure that the research performed under their direction and by them meets the highest possible standards of research integrity and RCR. At a minimum, researchers are responsible for the following:

a. *Rigour*: Scholarly and scientific rigour in proposing and performing research; in recording, analyzing, and interpreting data; and in reporting and publishing data and findings.

b. *Record keeping and data sharing*: Keeping complete and accurate records of data, methodologies and findings, including graphs and images, in accordance with the applicable funding agreement(s), institutional policies, laws, regulations, and professional or disciplinary standards in a manner that will allow verification or replication of the work by others, and sharing of published research materials or data in field-specific repositories (Tri-Agency Open Access Policy on Publications).

c. *Accurate referencing*: Referencing and, where applicable, obtaining permission for the use of all published and unpublished work, including theories, concepts, data, source material, methodologies,

findings, graphs and images.

d. *Authorship or Inventorship*: Following accepted standards of Authorship as described in the Vancouver Guidelines (International Committee of Medical Journal Editors). Including as authors, with their consent, all those and only those who have made a substantial contribution to, and who accept responsibility for, the contents of the publication or document. The substantial contribution may be conceptual or material. Including as inventors all those that have made a substantial conceptual contribution to intellectual property.

e. *Acknowledgement*: Acknowledging appropriately in scientific presentations and publications all those and only those who have contributed to research, including core facilities, funders and sponsors.

f. *Responsible dissemination and confidential review of research.* Publishing manuscripts in peer-reviewed open access journals that are listed in the Directory of Open Access Journals (DOAJ),or making their contents available on preprint servers or post-publication in PubMed Central as required by the Tri-Agency Open Access Policy on Publications. Fairly and confidentially reviewing manuscripts and grant applications and assessing researcher performance using the principles of the Declaration on Research Assessment (DORA).

g. *Conflict of interest management*: Appropriately identifying and addressing any real, potential or perceived conflict of interest, in accordance with the institution's policy on conflict of interest in research, and conforming with conflict of interest policies in reviewing manuscripts, grant applications and assessing researcher performance.

h. *Applying for grants or other funding.* Providing true, complete and accurate information in applications and related documents and represent themselves, their research and their accomplishments in a manner consistent with the norms of the relevant field. Applying only when eligible and not under investigation anywhere for reasons of breach of RCR policies such as ethics, integrity or financial management policies. Ensuring others listed on the application have agreed to be included.

i. *Research approvals and certifications.* Familiarizing themselves with national, provincial, funding agency and Hospital policies and guidelines and legislation relevant to their research (see Section 6.0 for related documents). Complying with all applicable requirements and legislation for the conduct of research, including, but not limited to:

- 2nd edition of Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans (TCPS 2);
- Canadian Council on Animal Care Policies and Guidelines;
- Agency policies related to the Canadian Environmental Assessment Act;
- Licenses for research in the field;
- Laboratory Biosafety Guidelines;
- Controlled Goods Program;
- Canadian Nuclear Safety Commission (CNSC) Regulations; and
- Canada's Food and Drugs Act.

j. *Reporting policy breaches.* Report breaches to the Chief (or RIA) or an allegation of a breach of research integrity arising from a researcher's submitted or published manuscript, scientific presentation

or grant application (see Section 4.4.3). Suspected or observed breaches in research integrity and RCR may occur within the researcher's team or in another team in the Hospital or University, in the scientific literature or elsewhere (see Section 4.2).

k. *Rectifying a breach.* Researchers in breach of a policy are expected to be proactive in rectifying a breach, for example, by correcting the research record, amending research approvals and certifications, providing a letter of apology to those impacted by the breach, and/or repaying funds.

**2.1 Responsibilities of the Chief of Research**
The Chief is responsible for creating a culture that promotes research integrity and RCR in all types of research in the Hospital. The Chief provides a mechanism to deal with alleged breaches in research integrity and RCR. In most cases, the RIA will be the primary designate for supporting this environment and managing alleged breaches. The Chief may also handle allegations of breaches directly or assign another designate if appropriate.

**2.2 Responsibilities of the Research Integrity Advisor**
The RIA fosters RCR in the Hospital through providing ongoing educational opportunities and resources for researchers and their teams; maintaining relevant policies and procedures for RCR in the Hospital; acting as the main contact to help the Hospital's research community resolve questions or concerns related to research integrity; liaising between the Hospital and the Secretariat for Responsible Conduct of Research (SRCR), the University of Toronto, and other institutions; and managing alleged breaches of research integrity as directed by the Chief. Further details about the RIA's role can be found here.

## 3.0 Breaches in the Responsible Conduct of Research

The Hospital is committed to investigating allegations of breaches in research integrity and RCR and is aligned with the recommendations and guidelines of the Tri-Agency Framework as outlined below. In determining whether an individual has breached a policy, it is not relevant to consider whether a breach was intentional or a result of honest error. However, intent is a consideration in deciding on the severity of the recourse that may be imposed. Breaches include the following:

**3.1 Breaches of research integrity and RCR**

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 and which results in inaccurate findings or conclusions.

c. *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 and/or laws, regulations and professional or disciplinary standards.

d. *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.

e. *Redundant publication or self-plagiarism*: The re-publication of one's own previously published work or part thereof, including data, in any language, without adequate acknowledgment of the source, or justification.

f. *Invalid authorship or inventorship*: Inaccurate attribution of authorship, including attribution of authorship to persons other than those who have made a substantial contribution to, and who accept responsibility for, the contents of a publication or document. Denial of legitimate inventorship, as outlined in the Hospital's Intellectual Property policy.

g. *Inadequate acknowledgement*: Failure to appropriately recognize contributors. Failure to identify correctly the source of research funds.

h. *Mismanagement of conflict of interest*: Failure to appropriately identify and address any real, potential or perceived conflict of interest, in accordance with the institution's policy on conflict of interest in research.

**3.2 Misrepresentation in a grant application or related document**

a. 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 a contract.

b. Applying for and/or holding an award when deemed ineligible by any other research funding organization world-wide for reasons of breach of RCR policies such as ethics, integrity or financial management policies.

c. Listing of co-applicants, collaborators or partners without their agreement.

**3.3 Mismanagement of grants, award funds or contracts**

Using grant or award funds for purposes inconsistent with the policies of the funding agency and the Hospital; misappropriating grants and award funds; contravening financial policies; or providing incomplete, inaccurate or false information on documentation for expenditures from grant or award accounts. Offering or accepting finders' fees, as outlined in the Hospital policy on Prohibited Fees in the Recruitment of Research Subjects. Misusing resources, facilities or equipment of the Hospital.

**3.4 Breach of policies or requirements for certain types of research**

Failing to meet policy requirements of the funding agency or the Hospital or, to comply with relevant policies, laws or regulations, for the conduct of certain types of research activities; failing to obtain appropriate approvals, permits or certifications before conducting these activities.

### 3.5 Breach of review processes and confidentiality

a. Non-compliance with the Hospital Relationship Disclosure and Management (Conflict of Interest) and Privacy & Confidentiality of Information policy.

b. Participating in review processes while under investigation.

c. Breach of confidentiality in an inquiry/investigation of research integrity and RCR.

## 4.0 Procedures for managing allegations of breaches in research integrity and RCR

The procedures outlined in this document apply to all Researchers at the Hospital, with the exception of graduate students at the University of Toronto. Cases that involve one or more graduate students, or University of Toronto campus-based faculty cross-appointed at the Hospital, as the Respondents of a breach of research conduct are referred immediately to the Associate Vice President, Research Oversight and Compliance at the University of Toronto. The University of Toronto decides which institution has jurisdiction and informs the RIA of the progress of the inquiry/investigation and, if appropriate, may conduct its inquiry/investigation in conjunction with the Hospital.

### 4.1 Reporting breaches

All privacy breaches are to be reported to the SickKids Compliance, Privacy, and Risk Management Department and will be dealt with in accordance with established Hospital practices. All research ethics breaches on the conduct of human research are to be reported to the SickKids Research Ethics Board (REB) and will be dealt with in accordance with established Hospital practices. Cases that involve one or more research subjects or their family members will be referred immediately to the REB for decision on most appropriate follow up and who needs to be involved.

### 4.2 Principles

The principles listed below are followed in handling allegations of breaches in RCR:

- The process used to resolve allegations of a breach must not damage the scientific process by inhibiting creativity and innovation.
- All researchers are obligated to report breaches in RCR whenever observed or thought to have occurred. If a breach is observed in an informal context within a research team and where intent to deceive is not apparent, it may be appropriate in such circumstances that the researcher attempts to resolve the concern with the perceived offending party, possibly with the intervention of the offending party's supervisor. Because the role of a Supervisor is to mentor and to teach RCR to team members, the Supervisor will provide guidance and instruction to avoid this breach in the future. If this action does not lead to a satisfactory resolution, or the Supervisor suspects a willful intent to deceive, the researcher and/or supervisor must report the breach to RIA.

- The reputation of the Hospital and its researchers require that any breach in RCR be promptly detected and effectively dealt with. To this end, allegations of breaches are taken seriously, and vigorous leadership is exercised in their investigation and resolution.
- All persons involved in an investigation of an RCR breach, Complainants or Respondents, and those who assist in the investigation -- are all treated with respect, fairness and due sensitivity to their scientific, professional and personal reputations. Actions of all involved persons are governed and protected under the Hospital's Code of Conduct policy.

**4.3 Two-step approach**

There are two steps in the procedures to address and manage a breach: (1) an *inquiry* step to determine if an investigation of an allegation is warranted; and (2) an *investigation* step to determine if the suspected breach has been committed.

Once a formal written allegation of breach has been made and an inquiry or investigation has been initiated, all persons involved in the inquiry or investigation are required to maintain confidentiality by not discussing matters related to the allegation, inquiry or investigation with anyone other than those directly involved in the inquiry or investigation. Failure to maintain confidentiality is considered a breach of this policy and will be investigated in alignment with this policy. The RIA and members of the investigating committee maintain confidentiality by discussing the allegation only with individuals who are being asked to provide information for the inquiry or investigation or with individuals or groups who are considered to have a need to know (as outlined in the procedures section below).

In addition, the Research Integrity Office maintains records of who receives copies of documentation pertaining to the inquiry or investigation and ensures that, upon completion of the inquiry or investigation, all copies are returned to the Office to be shredded (see Section 4.5.9). Electronic mail can be used to transmit correspondence regarding the inquiry and/or investigation, provided that the subject line reads "Privileged & Confidential Information" and the first line of the body of the email indicates that the message not be forwarded or shared. The Hospital will keep reports confidential to the maximum extent possible, subject to the need to conduct an effective investigation and the law.

In the investigation of allegations, conflicts of interest are avoided wherever possible and are openly declared when they cannot be avoided.

- All proceedings related to the investigation of alleged breaches are conducted in a timely manner.
- All stages of the proceedings are appropriately documented.
- Once the proceedings are complete, appropriate recourse is taken.

See section 6.0 for further detail on procedures in cases where the investigation involves a study funded through a federal regulated body or the U.S. Public Health Service agency requirement in the event of an investigation.

### 4.4 Inquiry

#### 4.4.1 Purpose of inquiry

In the inquiry stage, facts and information are gathered and expeditiously reviewed to determine if an investigation of the allegation is warranted. The inquiry is designed to separate responsible allegations that require further investigation from frivolous, unjustified or clearly mistaken allegations.

#### 4.4.2 Initiation of inquiry

The Complainant is encouraged to discuss the allegation with the Respondent's supervisor and the RIA before filing a written allegation. If the Complainant subsequently wishes to proceed with the allegation, the Complainant must communicate the allegation in writing to the RIA, preferably by submitting the Allegation Intake Form found on the Research Integrity Office website. The Complainant will be protected under the Code of Conduct policy. This approach to dealing with allegations is strongly encouraged in the Hospital, to support a clear and transparent process of inquiry.

Should an individual prefer to file an anonymous complaint, it is strongly recommended to use the Hospital's Safety Reporting System. An alternative to this would be the use of a third party. The third party would act as a representative of the Complainant (i.e. a proxy) and present the information to the RIA. An anonymous complaint from outside the Hospital can be received by the RIA or Chief.

Any person who makes an anonymous allegation will be encouraged to identify themself properly and to express their concerns in good faith. If a person wishes to remain anonymous, reasonable efforts will be made to gather relevant facts relating to the concerns and to protect their confidentiality to the extent permitted.

At the point of a written allegation to the RIA, the RIA will conduct the inquiry, unless another designate is identified. The RIA will inform the Chief of the allegation. If the written allegation involves the Chief, the case is reported to the President & CEO.

Where the allegation is related to conduct that occurred at another institution (whether as an employee, a student or in some other capacity), the institution that receives the allegation will contact the other institution and determine with that institution's designated point of contact which institution is best placed to conduct the inquiry and investigation, if warranted. The institution that received the allegation will communicate to the Complainant which institution will be the point of contact for the allegation.

#### 4.4.3 Conduct of inquiry

When a written allegation is made, the RIA notifies the Chief and contacts the Respondent to discuss the allegation. The identity of the Complainant, or that the Complainant is anonymous, must be made known to the Respondent. All involved parties are informed that they will be required to

cooperate with the inquiry in a timely manner. This includes provision of information to conduct the inquiry. Failure to cooperate may result in disciplinary action being taken by the Chief.

Should an allegation have implications to a study on human subjects, the REB will be notified.

If an allegation involves suspected misuse of Agency funds, the Research Institute may take immediate action to protect the administration of Agency funds, including freezing grant accounts or requiring a second authorized signature from an institutional representative on all expenses charged to the researcher's grants accounts, or other measures, as appropriate.

If the allegation concerns one or more Respondents who hold faculty cross-appointments at the University, the RIA also notifies the University of Toronto's Associate Vice-President, Research Oversight & Compliance that an inquiry is being initiated**.**

The RIA consults confidentially with anyone who is thought to have facts or information that might be relevant and examines relevant documents and data. The RIA may seek assistance in conducting the inquiry to gain appropriate expertise to carry out a thorough evaluation of the relevant information. The RIA will reach a decision based on the facts and information obtained, irrespective of whether individuals choose to cooperate with the inquiry.

If an allegation is made by a researcher from another institution, the RIA may invite a member from that institution to assist with the inquiry.

If an allegation is made by a journal editor, reviewer, grant agency etc. the Respondent is obliged to notify the RIA. The same two-step approach applies.

In the initial inquiry, the RIA is vigilant not to permit personal conflicts between colleagues to obscure the facts and divert attention from the substance of the allegation. The RIA pursues all allegations to resolution, as appropriate. If it becomes apparent during the inquiry that the RIA has a real or apparent conflict of interest, the case is referred to the Chief who may request that another senior official of the Hospital undertake the inquiry.

#### 4.4.4 Timing of inquiry

Every effort is made to ensure that an inquiry is completed within 2 months of the reporting of an allegation. If it is necessary to extend this timeline, all parties will be notified.

#### 4.4.5 Outcome of inquiry

Every effort will be made to inform all parties of the outcome of an inquiry. If an allegation can be resolved to the satisfaction of all parties, the RIA formally documents the outcome of the inquiry in a letter, which will be co-signed by all parties (the Complainant, the Respondent and the Supervisor) in addition to the RIA's signature.

If the RIA is convinced that the allegation is frivolous, unjustified or mistaken, this is stated in writing to the Complainant, the Respondent and the Supervisor. The RIA may propose alternative forms of mediation, if appropriate, such as the Hospital's Employee Relations services.

If the allegations are found to have been maliciously motivated, the Chief may take disciplinary action against those responsible, consistent with Hospital practice and in consultation with SickKids Human Resources.

If the Respondent admits to having breached the policy, the RIA finds that the allegation was responsible and informs the Complainant, the Respondent and the Supervisor in writing concluding that the inquiry is closed and a breached occurred.

If the allegation is found to be responsible (responsible allegation) and further investigation is warranted, the RIA informs the Complainant, the Respondent and the Supervisor in writing advising that an investigation will be initiated. If no further facts are likely to be uncovered by an investigation, the RIA may, at the inquiry step, make a determination that a breach occurred.

If the allegation concerns one or more Respondents who hold faculty cross-appointments at the University of Toronto, the RIA also notifies the University of Toronto's Associate Vice-President, Research Oversight & Compliance, outlining the nature of the allegation, all action taken to date and the outcome of the inquiry.

If the allegation involves Tri-Agency funded research conducted by one or more Respondents or the Complainant, the RIA informs the SRCR outlining the nature of the allegation, all action taken to date and the outcome of the inquiry.

The RIA will communicate the results of the inquiry to the Chief. The Chief will communicate the findings of the inquiry to other appropriate individuals, including Research Program Heads, Clinical Division Heads or other members of the Hospital Executive. If the inquiry finds that an investigation is required, the Chief will communicate the results of the inquiry to the SickKids President & CEO.

Detailed documentation pertaining to the inquiry is kept in a confidential and secure manner in the Research Integrity Office for a period of at least seven years. The documentation outlines the actions taken during the inquiry and the reasons for determining that an investigation is or is not warranted.

### 4.5 Investigation

#### 4.5.1 Purpose of investigation

The purpose of the investigation is to further explore the allegations and determine whether the alleged breach has been committed.

### 4.5.2 Involvement of University

If the allegation concerns one or more Respondents who hold faculty cross-appointments at the University of Toronto, the RIA informs the University of Toronto Associate Vice-President, Research Oversight & Compliance of all aspects of the investigation as described below (sections 4.5.4 - 4.5.11).

### 4.5.3 Initiation of investigation

The RIA recommends a committee to perform the investigation according to the process described below. The RIA in consultation with the Chief establishes terms of reference for the investigating committee, which define the scope of the investigation and the authority delegated to the committee. The scope of the investigation may be defined in terms of: research activities, circumstances, time period, or particular sources of information. The terms of reference will specifically authorize the investigating committee to review such records or equipment as it deems relevant, including paper or electronic documents, files or databases.

### 4.5.4 Composition of investigating committee

The composition of the investigating committee is determined by the RIA, in consultation with the Chief. The committee includes a minimum of three members, one of whom will serve as Chair. Membership will include at least one member from the Hospital, at least one member from the University of Toronto or other University-affiliated institutions, and one external member. Administrative support for the function of the investigating committee is assigned by the RIA, and in most cases is either the Coordinator or Senior Manager of the Research Integrity Office.

The Chair and members of the investigating committee should have no real or apparent conflicts of interest, should be and be seen to be unbiased, and jointly should have appropriate scientific and administrative expertise to carry out a thorough and authoritative evaluation of the relevant evidence.

The Respondent and Complainant are advised of the membership of the investigating committee and given an opportunity to comment on the membership. The RIA gives due consideration to the Respondent's and Complainant's comments but is not obligated to take any action based on the comments.

Conflicts of interest must be declared by committee members. If a conflict of interest becomes apparent at any time during the course of the investigation, the case is referred back to the Chief, who may change the structure of the committee.

Committee members must ensure that all documentation and information that the Hospital entrusts to them is kept confidential at all times, and is used only for the purpose for which it was originally collected. Committee members must sign a Confirmation of Conflict of Interest agreement and a Confirmation of Confidentiality agreement.

### 4.5.5 Notification of investigation

The RIA notifies the Respondent and the Complainant of the process that has been established for the particular investigation. The RIA will notify the Chief that an investigation has been initiated. The Chief informs the President & CEO (and other any other appropriate member of the Hospital Executive) that an investigation has been initiated.

The RIA may initiate contact with the Hospital's legal counsel on behalf of the Hospital to determine what involvement counsel should have in the conduct of the investigation, if any, as well as to assist in determining the scope and process of the investigation.

The RIA may inform other appropriate parties considered to have a need to know that an investigation has been initiated. This may include the SRCR or relevant funding agencies, regulatory agencies, scientific journals and other professional bodies.

### 4.5.6 Timing of investigation

If an investigation is warranted, it must begin within 1 month of the completion of the inquiry. Every effort is made to ensure that the investigating committee convenes within 10 working days of its formation.

Every effort is made to ensure that the investigation is completed within 5 months of the completion of the inquiry. This includes conducting the investigation, preparing the report of the findings, making that report available for comment by the subjects of the investigation and submitting the report to the Chief.

If these time frames cannot be met, a report citing the reasons for the delay and the progress to date is submitted to the Chief, the Respondent, the Complainant and any other parties that the Chief considers having a need to know.

### 4.5.7 Conduct of investigation

The Respondent has the following rights:

- The identity of the Complainant must be made known to the Respondent or that they are anonymous.
- The Respondent has an opportunity to present their case to the investigating committee at the initial and subsequent meetings, if any.
- The investigating committee provides access to supporting documents regarding the investigation to the Respondent.
- In the course of the investigation, additional information may emerge that broadens the scope of the investigation beyond that of the inquiry. The Respondent is informed by the RIA if the scope of the investigation is changed.

All involved parties are informed that they will be required to cooperate with the proceedings of the

investigation in a timely manner. This includes the provision of information to conduct the investigation. Failure to cooperate may result in the decision to recommend that the Chief take disciplinary recourse as appropriate. The committee reaches a decision based on the facts and information it is able to obtain, irrespective of whether individuals choose to cooperate with the inquiry.

If, during the course of the investigation, the Respondent resigns from the Hospital, the investigation will nevertheless be continued to its full conclusion.

If the Complainant decides not to proceed with the allegations after the investigation has been initiated, the investigating committee may decide to proceed with the investigation even without the further participation of the Complainant.

The investigating committee:

- Has the authority to interview persons whose evidence is thought to be helpful, to examine relevant documents and data records and to consult with experts both within and outside the Hospital, as required;
- Consults confidentially with anyone who comes forward with information regarding the allegation;
- Maintains confidentiality during the entire course of the investigation in order to protect the rights of all parties involved;
- Is vigilant not to permit personal conflicts between colleagues to obscure the facts and divert attention from the substance of the allegation;
- Maintains appropriate documentation of the investigation, including summaries of interviews and all original written submissions and correspondence.

#### 4.5.8 Interim measures

The investigating committee notifies the Chief of any interim findings that require immediate action. The Chief will take appropriate action if the research breach may have an impact on the health and safety of patients or interests of staff, faculty colleagues or the reputation of the Hospital. This may include the partial or complete suspension of the activities and responsibilities of the Respondent pending the results of the investigation and notification of the relevant parties.

#### 4.5.9 Report of investigation

The RIA ensures that all allegations are pursued to resolution, as appropriate. The RIA submits a written report to the Chief, summarizing the process and timeline, the evidence that was reviewed, findings and conclusions and any relevant recommendations of the investigation. The investigation must result in either a finding of a breach and or a finding that no breach was committed. The report will also state whether the committee found evidence of honest error or a willful intent to deceive and take this, and any prior findings of a breach by the Respondent, into account when recommending an appropriate recourse.

At the end of the investigation, a complete record of the proceedings and findings is filed in a confidential and secure manner in the Research Integrity Office. The investigating committee collects copies of all documents circulated to its members and to anyone else involved in the investigation and returns this documentation to the Research Integrity Office for secure disposal. Electronic mail can be used to circulate information during or at the conclusion of the investigation provided that the subject line reads “Privileged & Confidential Information” and the first line of the body of the email indicates that the message not be forwarded or shared. At the end of the investigation, the investigating committee deletes their copies of all electronic mail or documents.

The Respondent and the Complainant receive a full report of the investigation. If the Respondent or Complainant comments on the report within one month of receiving it, these comments may be made part of the record. If the investigation takes longer than 5 months to complete, the record of the investigation includes documentation of the reasons for exceeding the 5-month period. If the breach under investigation concerns Tri-Agency funded research conducted by one or more Respondents or the Complainant, the RIA provides the full report of the investigation to the SRCR.

**4.5.10 Outcome of Investigation**

Every effort will be made to inform all parties of the outcome of an investigation. The Chief informs the President & CEO (and any other appropriate member of the Hospital Executive) of the outcome of the investigation.

When the Chief is advised that an investigation has determined that there has been a breach, they consider the recommended recourse and if appropriate consults with:

- The Respondent’s Supervisor, Research Program Head, and/or Clinical Department/Division Chief/Head,
- SickKids Human Resources,
- Appropriate members of the Hospital Executive and the Associate Chief, Clinical Research,
- The Hospital's legal counsel,
- The police (if the law appears to have been broken),

To determine the appropriate disciplinary recourse. If a breach has occurred, the response of the Hospital will depend on any finding of honest error, the severity and intent of the breach, and take into consideration any prior breach by the Respondent. The recourse may include:

- Letter of awareness or reprimand added to employee’s file;
- Auditing of data and manuscripts from the Respondent for a period of time;
- Loss of appointment in the Research Institute;
- Suspension or termination of employment with the organization.

Funding agencies may impose their own disciplinary recourse.

If a breach has been committed, the RIA will inform each of the following, if applicable:

- Associate Vice-President, Research Oversight and Compliance of the University of Toronto;

- The SRCR for Tri-Agency funded research, regulatory agencies, funding sources;
- Co-authors, co-investigators, collaborators;
- Other institutions involved in the research conducted by the Respondent;
- Editors of journals in which fraudulent research was published;
- Professional licensing boards;
- Editors of journals or other publications, other institutions, sponsoring agencies and funding sources with which the individual has been affiliated in the past;
- Professional societies.

When the Chief is advised that an investigation has determined that no breach has been committed, the Chief ensures that a letter confirming full exoneration is sent to the Respondent, with a copy to the Complainant and to any other persons or agencies known to have knowledge of the accusation.

The investigation may disclose evidence that requires further action, even in those cases where no breach is found. This could include retraction of published findings.

The Chief takes no disciplinary measures against the Complainant if the allegations are found to have been made in good faith; moreover, every effort will be made to ensure that no retaliatory action is taken against the Complainant by anyone.

If the allegations are found to have been maliciously motivated, the Chief may take disciplinary recourse against those responsible, consistent with Hospital practice and in consultation with SickKids Human Resources. Similar appropriate disciplinary recourse, consistent with Hospital practice and in consultation with SickKids Human Resources, may be taken against individuals who engage in acts of retaliation or intimidation against Complainants and/or accused persons.

#### 4.5.11 Appeal by Respondent

The Respondent may only make an appeal of the outcome of the investigation on the basis of procedural issues. In order to initiate an appeal, the Respondent must send a letter to the Chief outlining the basis for the appeal within one month of receiving the inquiry/investigation report. The Chief refers the appeal to the President & CEO of the Hospital, who ensures that the investigation was conducted in accordance with this policy. The President & CEO does not conduct a re-examination of the evidence.

If the President & CEO determines that the investigation was not properly conducted, they appoint a new investigating committee to: review the evidence collected by the original committee; collect any additional information required to address any procedural oversights; compile a report outlining the process followed and the findings of the committee.

The investigation must result in either a finding of a breach, or a finding that no breach was committed.

The results of the appeal, if different from the original finding, will be communicated as outlined in

sections 4.5.9 and 4.5.10 above.

## 5.0 National Guidelines and Related Documents

Canada's Food and Drugs Act
Canadian Council on Animal Care Policies and Guidelines
Canadian Environmental Assessment Act
Canadian Nuclear Safety Commission (CNSC) Regulations
Code of Conduct
Conflict of Interest
Controlled Goods Program
Disclosure of Personal Health Information
Dishonest or Fraudulent Activities
Free and Informed Consent in Research
Freedom of Information and Protection of Privacy Act
Information Security
International Committee of Medical Journal Editors
Laboratory Biosafety Guidelines
Management of Patient Safety Events
Minimum Retention Periods for Hospital Records
Participation in Public Meetings or Fora
Privacy and Confidentiality of Information
Prohibited Fees in the Recruitment of Research Subjects
Records Retention and Destruction
Release of Information to the Media and General Public
Research Agreements: Eligibility, Review and Approval
Research Integrity Advisor Position Description
Research Involving Human Subjects
Research Using Animals
Respect in the Workplace
Safety Reporting
Tri-Agency Framework: Responsible Conduct of Research
Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2010 (TCPS2)

## 6.0 Further procedures in cases where the investigation involves other agencies

### 6.1 Tri-Council

All Researchers should be familiar with the "Tri-Agency Framework: Responsible Conduct of

Research" the principles of which are embedded in this policy. The Framework describes Agency policies and requirements related to applying for and managing Agency funds, performing research, and disseminating results, and the processes that Institutions and Agencies follow in the event of an allegation of a breach of an Agency policy. In accordance with requirements set out in the Framework, the Hospital will send reports to the SRCR as needed.

**6.2 U.S. Public Health Service (PHS)**

The following additional notes apply to any research supported by funding from the U.S. Public Health Service (PHS), as described in 42 CFR Parts 50 and 93, "Public Health Service Policies on Research Misconduct," available from the Office of Research Integrity (ORI) on its website https://ori.hhs.gov/

The ORI oversees and directs the U.S. Public Health Service (PHS) research integrity effort with the exception of the research regulatory activities of the Food and Drug Administration. If the RIA ascertains at any stage of the inquiry/investigation that any of the following conditions exist under s. 93.318 of 42 CFR Part 93, the ORI is notified immediately when:

- Health or safety of the public is at risk, including an immediate need to protect human or animal subjects.
- U.S. Department of Health and Human Services ("HHS") resources or interests are threatened.
- Research activities should be suspended.
- Reasonable indication of possible violations of civil or criminal law exist.
- Federal action is required to protect the interests of those involved in the research misconduct proceeding.
- The research institution believes the research misconduct proceeding may be made public prematurely so that HHS may take appropriate steps to safeguard evidence and protect the rights of those involved.
- The research community or public should be informed.

The Director of the ORI, is notified if the RIA determines, on the basis of the initial inquiry, that an investigation is warranted. This notification occurs on or before the date the investigation begins. The notification process shall be in accordance with s. 93.309 of CFR Part 93.

The RIA may take interim administrative actions, as appropriate, to protect federal funds and ensure that the purpose of the federal financial assistance is carried out. During the course of the investigation, the RIA keeps the ORI apprised of any developments which disclose facts that may affect current or potential Department of Health and Human Services funding for the individual(s) under investigation or that the PHS needs to know to ensure appropriate use of federal funds and otherwise protect the public interest.

The Hospital shall conduct the research misconduct investigations consistent with this policy and s. 93.310 of CFR Part 93. Notice to ORI of the Hospital's findings and actions shall be in accordance with s. 93.315 of CFR Part 93.

ORI expects the Hospital to carry inquiries and investigations through to completion and to pursue diligently all significant issues. If the Hospital plans to terminate an inquiry or investigation, the Hospital must comply with s. 93.316 of CFR Part 93.

### 6.3 Office for Human Research Protections (OHRP)

The following additional notes apply to any research supported by the United States Department of Health and Human services (HHS) or conducted under the SickKids Federal Wide Assurance (FWA).

The OHRP provides leadership in the protection of the rights, welfare, and wellbeing of subjects involved in research conducted or supported by the U.S. Department of Health and Human Services (HHS). The Hospital shall conduct the research misconduct investigation consistent with the OHRP document "Guidance on Reporting Incidents to OHRP 2011)" https://www.hhs.gov/ohrp/sites/default/files/Guidance-on-Reporting-Incidents-to-OHRP.pdf. This obligation includes promptly reporting:

- Any unanticipated problems involving risks to subjects or others;
- Any serious or continuing noncompliance with the above noted OHRP guidance, or the requirements or determinations of the REB and
- Any suspension or termination of REB approval.

Notice to OHRP of the Hospital's findings and actions shall also be in accordance with this guidance.

### 6.4 Health Canada

Sponsors of clinical trials regulated by Health Canada have an obligation to notify the sponsor of the trial of any premature terminations or suspensions of a trial, for any reason. If, during the course of the investigation, a trial is suspended or terminated, the Hospital will notify the sponsor of the study. If SickKids is the sponsor of the study, SickKids has the obligation to notify Health Canada, and any other sites if deemed appropriate. The RIA will notify Health Canada's Health Products and Food Branch (HPFB) Inspectorate and will notify the Inspectorate of the Hospital's findings and actions.

**Attachments:**

SickKids Process to Address Allegations of Responsbile Conduct of Research Breaches_AUG2020.docx