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CORPORATE POLICY, STANDARDS and PROCEDURE

POLICY TITLE **RESEARCH INTEGRITY**		**NUMBER** TBA
AUTHORIZATION Vice President, Medicine	**DATE APPROVED** January 2007	**CURRENT VERSION DATE** January 2014

DATE(S) REVISED / REVIEWED SUMMARY [1]

Version	Date	Comments / Changes
1.0	January 2007	Initial Policy
2.0	August 2007	Procedure 4.2.2 d) - Addition of clarification regarding recused Research Integrity and Investigation Committee members.
2.0	August 2007	Procedure 4.5.2 a) - Addition of clarification regarding potential respondents who are the subject of the allegation.
3.0	January 2014	Format; updated links
3.0	January 2014	Policy Article 3.2 g) - Clarification added regarding adherence to the FHA corporate Conflict of Interest Policy.

INTENT / PURPOSE

The purpose of this policy is to:

1) describe the Fraser Health Authority's [FHA[2]]commitment to foster an environment which promotes and fosters integrity in Research and scholarship;
2) describe FHA Researcher obligations to conduct themselves with the utmost integrity as they are involved in research-related activities [including research training];
3) proscribe those activities which breach generally accepted standards, policies and laws relevant to the ethical conduct of research;
4) describe an impartial and accountable risk management process for dealing promptly with allegations or evidence of research-related misconduct and which supports good faith Complainants.

POLICY

FHA has a commitment to foster new ideas and innovation, to be open to evidence-based research findings and to be focused on outcomes. To these ends, FHA supports research activities carried out by FHA Researchers in the belief that research can improve the quality of care provided to the FHA community[3]. The ability of research and its related activities to

[1] © Fraser Health Authority
[2] FHA, FH or Fraser Health may be used throughout this policy and denotes the Fraser Health Authority
[3] Fraser Health's Strategic Plan, October 2003, p. 2 and 37.

enable improvements in health and health care is dependent on developing and sustaining the public's trust in both the benefits of research and in the integrity with which the research is carried out.

FHA believes that trust is earned and integrity sustained when the organization and its research personnel adhere to the values of transparency and accountability, honesty, fairness and respect for others. Adherence to these values drives the ethical conduct of research which must be in the public's interest and which must be held to the highest scientific, legal and fiduciary standards.

The commitment to promote an environment which is built on the bedrock of integrity is demonstrated by FHA's obligation to bear primary responsibility for the education about, and for the prevention and detection of research-related misconduct, in addition to the inquiry, investigation, and adjudication of research-related misconduct alleged to have occurred in association with FHA in a forthright and open reportable manner.

3.1 Scope

This policy applies to all research activities carried out by any individual who is carrying out research in their FHA capacity as defined below:

i. the research is under the direction of, conducted by or involves any FHA employee or physician with privileges at FHA using any FHA property or facility, or;
ii. the research is under the direction of, conducted by, or involves any FHA employee or physician with privileges in connection with his or her FHA responsibilities, such that the research may also be conducted outside of the FHA jurisdiction, or;
iii. the research is directed or conducted by non-FHA employees/physicians at any FHA facility who have Affiliated Researcher status with FHA [e.g. faculty with an academic appointment at a FHA 'affiliated' post-secondary education institution] or who are listed as co-investigators;
iv. a portion of the research [i.e. a particular research procedure] is being carried out by a FHA principal investigator as a service to another non-FHA researcher.

3.2 Promoting Integrity in Research

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a. The maintenance of integrity in planning and designing research, in executing the approved research plan, collecting data and generating research records, analysing and publicizing research-related activities requires FHA personnel to comply with this and related FHA policies concerning research FHAResearchPolicies.

FHA researchers shall conduct themselves honestly, exercise fairness and respect towards others, demonstrate competence in carrying out research-related activities and in the stewardship of resources used for the purpose of the research and be transparent and accountable for their research-related activities.

b. Promoting integrity in research and an understanding of the consequences of research-related misconduct amongst FHA personnel shall be undertaken by the FHA Research Office. Opportunities for ongoing education regarding research integrity shall be provided on a regular basis to FHA research personnel. See the FHA Policy "The Ethical Conduct of Research and Other Studies Involving Human Subjects" for details regarding the obligations of the FHAREB with respect to the ethical requirements of research.

c. Promoting integrity in research shall also be a responsibility of all FHA staff and privileged physicians engaged in research-related activities. The principal investigator is responsible for clearly documenting the roles and responsibilities and research requirements for all involved in a research team before members are engaged.

d. The retention of accurately recorded and retrievable results from research activities is required for all research activities. A verifiable research record of all primary data in complete, original and chronological form and the results from analysis of all secondary data including documentation of its source shall be retained for a period of five years for research upon completion of research studies that are not regulated by Health Canada. The retention period for all clinical trial research which is regulated by Health Canada is twenty-five years following close-out at the FHA site. See "FHA Research Policy" 4.1.3 a.

e. All FHA researchers shall have unrestricted access to all data and products of their collaborative research. This also applies to the administrative supervisor of the Principal Investigator(s).

f. Entitlement to ownership of primary data and other products of research can vary according to the circumstances under which research is conducted. FHA researchers shall reach a written, mutual understanding about ownership of the research results with the research collaborators regardless of the source of funding, before research is undertaken. See "FHA Research Policy" 4.1.3 d.

g. All FHA researchers, listed as authors shall be expected to have been involved in the research, to have made a significant intellectual or practical contribution, to understand the significance of the research conclusions and to share responsibility for the content and reliability of the reported information. For further detail, refer to the "FHA Research Policy 4.1.3 d."

h. All FHA researchers shall ensure that any conflict of interest, financial or otherwise, amongst the research team members is disclosed prior to obtaining ethical approval to conduct the research and shall ensure that any conflict of interest that arises during the conduct of the study is also disclosed. See "FHA Research Policy" 4.1.3 a. and the FHA Corporate "Conflict of Interest" Policy.

i. All researchers shall disclose any potential intellectual property arising from their research. See "FHA Research Policy" 4.1.3 d.

3.3 Proscription of Research-related Misconduct

Research misconduct may involve breaches of the acceptable standards and policies related to the preservation of scientific integrity, the conduct of studies which involve human subjects [directly or indirectly through secondary data collection] and the execution of fiduciary responsibilities when research is being proposed, executed, reviewed, or when research results are reported. It also includes complicity in the misconduct of others.

Principal investigators and co-investigators who have failed to exercise reasonable care in directing and supervising researchers and anyone involved in carrying out research-related activities who have committed research misconduct are culpable and shall be disciplined accordingly.

Research misconduct does not include honest error, conflicting data, and valid differences in experimental design or in interpretation or judgment of information or differences of opinion.

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It is recognized that the borderline between research incompetence, carelessness and negligence and that of intentional misconduct may be very narrow. While errors of negligence or incompetence that occur infrequently and randomly may not constitute a breach of this policy, an ongoing pattern of incompetence and negligence is deemed to fall within the scope of this policy.

The following is a list of some examples of failure to respect the principles of integrity in research. Behaviours such as these are proscribed for all FHA personnel and FHA affiliated researchers who engage in research-related activities at FHA.

a. Scientific and Scholarly Misconduct

Scientific and scholarly misconduct includes fabrication, falsification and plagiarism as explained below.

i) Fabrication is defined as the making up of data or results or the qualifications of the research team and recording or reporting them. This also includes giving authorship to anyone who has not made a material contribution to the research.

ii) Falsification is defined as the manipulation of research materials, equipment, or processes, or the alteration or omission of data or results such that the research is not accurately represented in the research record, and also includes the falsification of the qualifications of the research team.

iii) Plagiarism is defined as the appropriation of another person's ideas, processes, results, or words. This includes failure to recognize and acknowledge adequately the contribution of a co-researcher, or other person who has collaborated on the research without giving appropriate credit and failure to obtain permission from another researcher before using that person's data, concepts, new information and/or unpublished work.

b. Misconduct Related to the Conduct of the Study

Research-related misconduct related to the conduct of the study as described below includes failure to obtain the applicable approvals prior to and during the conduct of research, lack of administrative record keeping and reporting to commercial sponsors, regulatory authorities and ethics boards, coercion of staff or subjects, fabrication or falsification of administrative, regulatory records including subject consent forms, breach of privacy and confidentiality law

and standards, inappropriate conduct with a research subject and failure to disclose any conflict of interest that may bias the research team.

i) Failure to obtain the applicable approvals in order to conduct research includes failure to obtain ethics approval from the FHA Research Ethics Board and other REBs as applicable, and failure to obtain regulatory and other institutional approvals according to FHA research policies and any other relevant federal, provincial legislation or international legislation, as applicable.

ii) Lack of record keeping and reporting to commercial sponsors, regulatory authorities and ethics boards occurs when documentation concerning serious adverse events, protocol deviations, changes to the protocol or consent form or any other applicable research-related document is not submitted to the appropriate body as required by law, policy or contract.

iii) Coercion occurs when a prospective research subject feels compelled to participate in a research study because the researcher either directly or implicitly suggests that appropriate care will be withheld. Coercion of a research team member occurs when that individual feels compelled to conduct a research-related procedure, including the consenting procedure, against their better judgement.

iv) Fabrication occurs when research documentation [i.e. including consent forms, approval letters, etc.] is artificially constructed for the purposes of submission to commercial sponsors, regulatory authorities and ethics boards.

v) Falsification occurs when research subject signatures or FHA approval signatures are falsified.

vi) Breach of privacy can occur when health records are used to contact individuals to recruit them to be active participants in FHA REB approved research studies, unless this is approved by FHA Privacy.

vii) Breach of confidentiality can occur when identifiable personal information is released without the consent of the individual to whom it belongs.

viii) Inappropriate conduct with a research subject includes any situation throughout the conduct of the research during which the research subject is mistreated by research personnel.

ix) Conflict of interest occurs when there is a failure to reveal a conflict of interest that might influence FHA's or an external parties' decision on whether one should be asked to review or conduct research work. In addition, conflict of interest arises when any measure is taken to intentionally oppose or block the work of another researcher for the purpose of benefiting oneself directly or indirectly.

c. Financial Misconduct

Financial misconduct includes fabrication, falsification and the misuse of funds:

i) Fabrication is making up a research proposal which is awarded funds from a granting agency but which is never carried out;

ii) Falsification is the misrepresentation of information pertaining to conflict of interest with respect to commercially funded studies and the misrepresentation of the expenditures for funded studies;

iii) Misuse of funds is the use of funds for purposes not specified in the funded research proposal or the acquisition of items under the pretence of research in order to benefit personally.

3.4 Responsibilities of the Responsible Institutional Official

a. The Vice President (VP) Medicine shall have primary responsibility for implementation of the **Procedures** set forth in this document.

b. The VP shall appoint members of the Research Inquiry and Investigation Committee [the RIIC] as specified under Procedures Section 4.2.

c. The VP shall receive and review all allegations to determine whether the allegation falls within the scope of this Policy and is in the appropriate form.

d. The VP may consider allegations sent from anonymous sources or via a third party, but only if all relevant facts are publicly available or otherwise independently verifiable.

e. The VP shall refer the individual or allegation to other offices or officials with responsibility for resolving the problem if the circumstances described by the Complainant do not meet the definition of research misconduct.

f. The VP shall authorize an Inquiry into the allegation by the RIIC if the allegation falls within the scope of this Policy and is in the appropriate form. Upon receipt of the report of the Inquiry and a finding that there is evidence of research misconduct to warrant an Investigation, the VP shall authorize the Investigation.

The associated actions of Inquiry and Investigation shall normally be taken when an allegation of possible misconduct is received. Particular circumstances in an individual case may dictate variation from the normal procedure if deemed in the best interests of FHA.

g. The VP shall receive the final Investigation Report, accept the conclusion of the RIIC as to a finding or otherwise of research misconduct, determine the appropriateness of the recommended sanction(s)/administrative actions, determine whether to impose them, and specify a follow up process to ensure implementation of the sanction(s).

h. The VP shall inform the parties involved, including funding bodies, regulatory bodies, and authorities as applicable, of the decision reached by the RIIC and of any sanctions or corrective actions to be imposed.

i. The VP shall provide an opportunity for appeal if misconduct is concluded.

3.5 Responsibilities of the Research Inquiry and Investigation Committee (RIIC)

a. The RIIC shall conduct its proceedings according to the procedures detailed under Procedures – Sections 4.8 and 4.11.

b. The RIIC shall have the authority to decide whether, upon inquiry, the allegation of misconduct meets the criteria for investigation and that decision is binding.

c. Upon investigation, the RICC shall have the authority to decide on the misconduct and that decision is binding.

d. The RICC shall recommend sanctions in the final report of the Investigation.

e. The RIIC shall report directly to the VP upon finalization of the written report for either inquiry or investigation.

3.6 Responsibility to Report Research-related Misconduct

a. Allegations should be made in good faith.

b. All FHA personnel shall report observed, suspected, or apparent research-related misconduct directly to the VP. See Procedures Section - 3.3.4 The Complainant and Informants.

c. All FHA personnel shall report any alleged or apparent retaliation against the Complainant arising from the allegation made by the Complainant.

d. At any time, FHA personnel may have informal confidential discussions and consultations about concerns of possible research-related misconduct or to clarify whether a suspected incident falls within the definition of research-related misconduct with the VP and shall be informed about appropriate procedures for reporting allegations.

3.7 Conflict of Interest in Research Misconduct Proceedings

a. Individuals involved in carrying out any part of the research misconduct proceedings shall declare any unresolved personal, professional, or financial conflicts of interest with the Complainant(s), Respondent, or Informant(s).

3.8 Privacy and Confidentiality in Research Misconduct Proceedings

a. Disclosure of the identity of Complainants/Informants and Respondents in research-related misconduct proceedings is limited, to the extent possible, to those who need to know, consistent with a thorough, competent, objective and fair research misconduct proceeding, and as allowed by law with the exception that the identity of Complainants/Informants and Respondents may be disclosed to granting agencies/sponsors in compliance with any memoranda of understanding and/or contract.

b. Except as may otherwise be prescribed by applicable law, confidentiality shall be maintained for any records or evidence from which research subjects might be identified. Disclosure is limited to those who have a need to know to carry out research misconduct proceedings.

3.9 Notification to and Cooperation with Funders and Regulatory Bodies

a. FHA shall notify the funder(s) and/or applicable regulatory body(ies) for regulated research of an allegation of research misconduct if:

i) the allegation involves funded research or an application for funding or involves a regulated clinical trial and it meets the definition of research misconduct given above, and;
ii) FHA's inquiry into the allegation determines there is sufficient evidence to proceed to an investigation.

b. When an investigation is complete, FHA shall provide a copy of the final Investigation report and its recommendations to the funder and/or applicable regulatory body(ies) within 30 days.

c. At any time during an inquiry or investigation, the funder and/or applicable regulatory body(ies) shall be notified if public health or safety is at risk; if the funder's resources or interests are threatened; if research activities should be suspended; if there is reasonable indication of possible violations of civil or criminal law; if federal action is required to protect the interests of those involved in the investigation; if FHA believes that the inquiry or investigation may be made public prematurely so that appropriate steps can be taken to safeguard evidence and protect the rights of those involved; or if the research community or public should be informed.

d. FHA shall provide full and continuing cooperation with any funder or regulatory body(ies) during the conduct of any investigation undertaken on the request of the funder or regulatory body. This includes providing all research records and evidence under FHA's control, custody, or possession and access to all persons within its authority necessary to develop a complete record of relevant evidence.

3.10 Protecting Funds Related to Research Under Inquiry

a. The VP shall take interim administrative actions, as appropriate, to ensure that the administration of funds held by FHA and related to the research under inquiry and investigation are protected.

3.11 Protecting Complainants and Informants

a. The privacy of those who report misconduct in good faith shall be protected to the maximum extent possible.

b. The Complainant(s) and Informant(s) shall be protected from retaliation arising from their allegation and/or participation in an inquiry/investigation with respect to the terms and conditions of their employment, reputation or other status at FHA.

c. Instances of alleged retaliation shall be reviewed by the VP and appropriate action taken.

3.12 Protecting Respondents

a. Inquiries and investigations shall be conducted in a manner that shall ensure fair treatment to the Respondent(s) during the Inquiry or Investigation such that the Procedures described under Section 4 are implemented appropriately.

b. The filing of an allegation of research misconduct against the Respondent shall not be sufficient to bring the Respondent's research to a halt or be the basis for other disciplinary or adverse action absent other compelling reasons.

3.13 Responsibility to Co-operate with Inquiries and Investigations

a. FHA personnel shall cooperate in the review of the allegations and with the RIIC in the conduct of inquiries and investigations and shall provide any relevant evidence upon request.

3.14 Finding Research Misconduct

a. A finding of research misconduct shall require that:

i) there be a significant departure from accepted practices of the relevant research community, and that,

ii) the misconduct be committed intentionally, or knowingly, or recklessly, and that,

iii) the allegation be proven by a preponderance of evidence.

3.15 Consequences of Breaches of Research Integrity

a. Upon conclusion of the Investigation and a finding of research misconduct as detailed in the Investigation Report, appropriate sanctions shall be imposed by the VP depending on the circumstances of each individual case. Refer to **Administrative Actions**

3.16 Appeals

a. A Respondent may contest FHA findings of research misconduct including any debarment or suspension action, by requesting a hearing within 30 calendar days of receipt of the written notice of the finding of misconduct.
b. The appeal process shall be separate from that of the RIIC.

c. The appeal process shall be completed within a period of 120 calendar days from its initiation.

3.17 Accountability

a. Upon completion of an investigation, The VP shall bring the report of the RIIC to the FHA Executive and FHA Board, and if applicable file it with the appropriate bodies, including regulatory authorities and funders, and make the findings of the report public.

b. An annual report of the RIIC shall be filed as part of the Research Annual Report.

c. All reasonable and practical efforts, if requested and as appropriate, shall be undertaken to protect or restore the reputation of persons alleged to have engaged in research misconduct but against whom no finding of research misconduct is made.

d. All reasonable and practical efforts shall be undertaken to protect or restore the position and reputation of any Complainant or Informant and to counter potential or actual retaliation against these Complainants or Informants and RIIC members.

3.18 Timeliness

a. The Inquiry and report shall be completed within 60 calendar days of the initiation of the Inquiry unless circumstances clearly warrant a longer period.

b. The Investigation and report to the VP shall be completed within 120 calendar days.

c. The final Investigation Report shall be distributed to all parties involved and concerned within 7 calendar days of receipt by the VP.

d. Where research misconduct is found to have occurred, the final Investigation report shall be forwarded within 30 days to any funders that provided funds for the research at issue and/or to the applicable regulatory bodies.

3.19 Records Retention and Release

a. All records related to allegations, inquiry or investigation of research misconduct shall be maintained in a secure and confidential manner for a period of 10 years once an inquiry/investigation is completed as per the information retention and release requirements of the Statute of Limitations.

b. The release of any records related to allegations, inquiry or investigation of research misconduct shall be released by FHA under the terms of the British Columbia Freedom of Information and Protection of Privacy Act.

DEFINITIONS

Accountability
Obligation or willingness to accept responsibility.

Administrative Action
Administrative Action means any decision taken by the VP with respect to levying sanctions against the individual found to have committed research misconduct.

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Affiliated Researcher
An affiliated researcher is an individual who does not have a direct relationship with FHA by virtue of employment or being engaged as a privileged physician but who has met specific requirements for applying for this status and who has been granted this status by the VP.

Allegation
Allegation means a disclosure of possible research misconduct.

A good faith allegation is made with the honest belief that research misconduct may have occurred. An allegation is not in good faith if it is made with reckless disregard for or wilful ignorance of facts that would disprove the allegation. See Good Faith.

Bias
An inclination that influences judgment.

Complainant
Complainant means a person who makes an allegation of research misconduct.

Conflict of Interest
A person has a conflict of interest when the person is in a position of trust which requires them to exercise judgment on behalf of others (people, institutions, etc.) and also has interests or obligations of the sort that might interfere with the exercise of their judgment, and which the person is morally required to either avoid or openly acknowledge.

Debarment or suspension
Debarment or suspension means the Government wide exclusion, whether temporary or for a set term, of a person from eligibility for U.S. federal grants, contracts, and cooperative agreements under the Department of Health and Human Services regulations at 45 CFR part 76 and 48 CFR subparts 9.4 and 309.4 and also includes the withdrawal of licensing by the applicable regulatory body for that individual's activities.

Ethical
A set of standards of conduct that guide decisions and actions based on duties derived from core values. (From "The Ethics of Non-profit Management," Stephen D. Potts)

Fundamental principles and basic concepts of what is considered morally good and bad, right and wrong in human conduct.

Evidence
Evidence means any document, tangible item, or testimony offered or obtained during a research misconduct proceeding that tends to prove or disprove the existence of an alleged fact.

Fairness
Consistent with rules, logic, or ethics.

Funders
Funders include granting agencies that fund research through unrestricted grants and industry or government sponsors that typically fund research under the terms of a contract between the institution, i.e. FHA, the FHA principal investigator, and the sponsor.

Good faith
Good faith as applied to a Complainant or Informant/Witness, means having a belief in the truth of one's allegation or testimony that a reasonable person in the Complainant's or Witness's position could have based on the information known to the Complainant or Informant/Witness at the time. An allegation or cooperation with a research misconduct proceeding is not in good faith if made with knowing or reckless disregard for information that would negate the allegation or testimony. Good faith as applied to a RIIC member means cooperating with the research misconduct proceeding by carrying out the duties assigned impartially for the purpose of helping an institution meet its responsibilities under this policy. A RIIC member does not act in good faith if his/her acts or omissions on the committee are dishonest or influenced by personal, professional, or financial conflicts of interest with those involved in the research misconduct proceeding.

Honesty
Fairness and straightforwardness of conduct.

Informant
Informant means an individual who is required to or who voluntarily brings forward evidence/testimony during an inquiry and/or investigation.

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Inquiry
Inquiry means preliminary information-gathering and preliminary fact-finding to determine whether an allegation that falls within the scope of the definition of research misconduct in this policy warrants an investigation.

Investigation
Investigation means the formal development of a factual record and the examination of that record leading to a decision not to make a finding of research misconduct or to a recommendation for a finding of research misconduct and the person(s) responsible, which may include a recommendation for other appropriate actions, including administrative actions.

Institutional Counsel
Institutional counsel does not represent the Respondent, the Complainant, or any other person participating during the Inquiry or Investigation, other than the VP and FHA Research office responsible for managing the administration of the inquiry and investigation processes.

Integrity
Strict adherence to moral values and principles. Making choices that are consistent with each other and with the stated and operative values one espouses. Striving for ethical congruence in one's decisions.

Notice
Notice means a written communication served in person, sent by mail or its equivalent to the last known street address, facsimile number or e-mail address of the addressee.

Obligation
Something that one ought to do or not do for moral reasons such as keeping just laws, promises, or respecting the rights of others.

Preponderance of the evidence
Preponderance of the evidence means proof by information that, compared with that opposing it, leads to the conclusion that the fact at issue is more probably true than not.

Principal Investigator
The principal investigator is the researcher who is deemed to have overall accountability for the research conducted at a FHA site, despite who is the awardee of a grant for grant funded studies. The principal investigator is always considered the supervisor of the research team.

Research Involving Human Subjects
Research involving human subjects is defined as any systematic investigation (including pilot studies, exploratory studies, and academic course work assignments) designed to contribute to generalizable knowledge. Generalizable knowledge consists of facts, theories, principles or relationships, or the accumulation of information on which they are based, that can be corroborated by accepted scientific methods of observation and inference. Research includes:

- obtaining data about a living individual through intervention (e.g. a medical procedure) or interaction (e.g. an interview) with the individual, or the obtaining of private personal information about the individual;
- secondary use of data (e.g. information, such as medical records, collected for purposes other than the proposed research) that contains identifying information about a living individual, or data linkage through which living individuals may become identifiable;
- naturalistic observation, except the observation of individuals in contexts in which it can be expected that the participants are seeking public visibility;
- the use of human remains, cadavers, tissues, biological fluids, embryos or foetuses.

Research Record
Research record means the record of data or results that embody the facts resulting from scientific inquiry, including but not limited to, research proposals/grant applications, laboratory records, both physical and electronic, progress reports, subject consent forms, research notes, abstracts, theses, oral presentations, internal reports, publications, equipment use logs, videos, photographs, medical records, contracts and any related documents and materials pertaining to the conduct of the research provided to an institutional official by a Respondent in the course of the research misconduct proceeding.

Respect
Polite attitude shown toward someone or something.

Respondent
Respondent means the person against whom an allegation of research misconduct is directed or who is the subject of research misconduct proceedings. There can be more than one Respondent for a particular research study at issue.

Retaliation
Retaliation for the purpose of this part means an adverse action taken against a Complainant, Informant/Witness, or RIIC member by an institution or one of its members in response to:
(a) A good faith allegation of research misconduct; or
(b) Good faith cooperation with a research misconduct proceeding.
This may include but is not restricted to retaliation that affects that person's employment or status within FHA.

Stewardship
The careful conducting, supervising, or managing of something

Subject
A subject is a person about who a research investigation is being conducted for a purpose other than the sole purpose of benefiting the subject as an individual, specifically that of the discovery of new knowledge. If a person, such as a family member or employer is asked to provide information about another individual, then both individuals are considered to be subjects. Donors of organs, tissues, and body fluids for research purposes and individuals, whose records are used for research, are considered to be subjects.

Transparency
Sharing information and acting in an open manner.

Trust
Is confident reliance in that an individual may confidently rely on events, circumstances or people and/or beliefs.

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PROCEDURE

4.1 Accountability and Obligations

To ensure that the obligations of FHA are discharged in such a way that research integrity is preserved, the following institutional and individual responsibilities are established and recognized.

4.1.1. The FHA Researcher

Adherence to the values of research integrity by FHA Researchers is demonstrated by, but not limited to:

i) recognizing the substantive contributions of collaborators;
ii) using unpublished work of other researchers and scholars only with permission and with due acknowledgement;
iii) using archival material in accordance with the rules of the archival source;
iv) obtaining the permission of the author before using new information, concepts or data originally obtained through access to confidential manuscripts or applications for funds for research or training that may have been seen as a result of processes such as peer review;
v) using scholarly and scientific rigour and integrity in obtaining, recording and analysing data, and in reporting and publishing results;
vi) carrying out the study according to the highest ethical standards and norms as articulated in research-related international, national and provincial legislation, policy and guidelines as applicable and in FHA research-related policies and guidelines;
vii) ensuring that authorship of published work includes all those who have materially contributed to, and share responsibility for, the contents of the publication, and only those people;
viii) revealing any material conflict of interest, financial or otherwise, to FHA, external funders, affiliated academic institutions and publishers that might influence their decision on whether the individual should be asked to review manuscripts or applications, test products or be permitted to undertake work sponsored by outside sources;
ix) ensuring that the use of awarded or contracted funds meets the terms of the award or contract, and;
x) ensuring that research team members or anyone involved in carrying out research-related procedures is aware of this and related FHA research policies.

4.1.2 Fraser Health Authority

a. FHA shall ensure that FHA personnel involved in carrying out research-related activities and affiliated researchers receive appropriate training in the skills necessary for the ethical conduct of such research, oversight of the use of funds awarded from granting agencies or from commercial sponsors, and are made aware of this policy and other relevant standards (e.g. legal, professional, and institutional) and policies pertinent to the conduct of research in FHA.

b. The FHA Research Office shall institute a regular program of education to fulfill these requirements.

4.2 Appointment Process for The Research Inquiry and Investigation Committee

a. The VP shall appoint three standing members and the Committee Chair who shall be typically drawn from the disciplines of law, finance, bio-ethics and from academic research. One of the standing members shall be appointed from an institution that has no direct connection with FHA. Each standing member shall designate an alternate in the event that they are not able to attend the meeting
b. Expert ad hoc members shall be appointed as necessary by the standing committee members, who have expertise appropriate to the type of complaint and circumstances of the case and who have the necessary expertise to evaluate the evidence and issues related to the allegation and interview the parties involved and key Informants. Expert members provide a strictly advisory function to the committee and do not vote, although they may interview witnesses, if deemed necessary by the standing committee members.
c. The standing committee members may elect to appoint different expert ad hoc members for the Inquiry and for the Investigation, as appropriate.
d. If the Complainant or Respondent is a member of a bargaining unit, one ad hoc member may be appointed up to a maximum of 1 for each relevant bargaining unit.
e. Only the standing members shall vote.

4.2.1 Notification to and Objection by the Respondent

a. The Respondent shall be notified of the RIIC membership for the Inquiry and any subsequent Investigation within 10 days of its constitution.

b. The Respondent may submit a written objection to any appointed member of the RIIC or expert ad hoc member based on bias or conflict of interest within 5 days of notification.
c. The VP shall determine whether to replace the challenged member or expert with a qualified substitute.
d. Any of the RIIC members found to be in real or apparent conflict of interest shall be recused from participation in any further proceedings.

4.2.2 Conflict of Interest

a. RIIC members shall complete a conflict of interest declaration form prior to the start of an inquiry and also prior to the start of an investigation to attest to the lack of bias, personal or professional conflict of interest with the Respondent, Complainant, the case in question.

b. The determination of bias or conflict of interest shall be made based upon any facts that indicate that the member (or any members of his or her immediate family) has:
   i) had any financial involvement with the Respondent or Complainant;
   ii) been a coauthor on a publication with the Respondent or Complainant;
   iii) been a co-investigator or collaborator with the Respondent or Complainant;
   iv) been a party to a scientific controversy with the Respondent or Complainant;
   v) had a supervisory or mentor relationship with the Respondent or Complainant;
   vi) had a special relationship, such as a close personal friendship, kinship, or a physician/patient relationship with the Respondent or Complainant; or
   vii) been party to any other circumstance that might appear to compromise the individual's objectivity in reviewing the allegations.

c. Any of the RIIC members found to be in real or apparent conflict of interest shall be recused from participation in any further proceedings.

d. A recused standing member of the RIIC would be replaced with an alternative for the standing member to ensure sufficient votes

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4.2.3 Confidentiality

a. RIIC committee members including ad hoc members shall agree in writing to observe the confidentiality of the Inquiry and Investigation proceedings and any information or documents reviewed as part of the Inquiry and/or Investigation.

b. Outside of proceedings, members are not allowed to discuss proceedings with the Respondent, Complainant, Informants or anyone not authorized by the VP to have knowledge of the Inquiry or Investigation.

4.3 Receipt of Allegation

a. All allegations must be received in writing for review and a decision as to the necessity of an Inquiry by the VP.

b. The allegation must clearly identify the person who is the subject of the allegation (the Respondent), the nature of the alleged misconduct, and be accompanied by all available documentation and refer to any evidence that may support the allegation.

c. Allegations sent from anonymous sources or via a third party may be considered by the VP, but only if all relevant facts are publicly available or otherwise independently verifiable.

d. An acknowledgement of receipt of the written allegation shall be issued to the source of the allegation within 3 business days of receipt.

e. The source of the allegation shall be contacted to obtain any further details required prior to referring the allegation to the RIIC.

f. Written notice of the allegation including details of the allegations shall be issued to the Respondent within 5 business days of receipt.

g. If the Inquiry subsequently identifies additional respondents, the latter shall be notified immediately of the Inquiry.

4.4 Criteria Warranting An Inquiry

a. An inquiry is warranted if the allegation:
   i) falls within the definition of what constitutes research misconduct under this Policy, and;
   ii) is sufficiently credible and specific so that potential evidence of research misconduct might be identified.

b. An inquiry shall not be conducted when the allegation is impossible to pursue without further information which cannot be obtained either because the source is anonymous and the facts are not publicly available nor otherwise independently verifiable, or because the source refuses, or is unable, to provide such further information.

4.5 Notification of the Respondent

4.5.1 Specific Respondents

a. The VP shall notify the Respondent in writing of the opening of the Inquiry.

b. The notice/notification shall include the following:
   i) identification of the research project in question and the specific allegations,
   ii) definition of research misconduct as per this Policy,
   iii) identification of any funding source(s),
   iv) the names of the Inquiry Committee including external experts,
   v) an explanation of the Respondent's opportunity to challenge the appointment of a committee member or expert for bias or conflict of interest,
   vi) an explanation of the Respondent's right to be assisted by his or her legal counsel to be interviewed, present evidence to the committee and to committee on the Inquiry Report,
   vii) a statement that explains the Respondent's obligation as a FHA employee to cooperate,
   viii) a statement that describes the Research Integrity Policy regarding protection of the Complainant against retaliation and the need to maintain the Complainant's confidentiality during the Inquiry and any subsequent proceedings,
   ix) a statement that describes the Research Integrity Policy regarding protection of the Respondent.

4.5.2 Potential Respondents

If no specific respondent has been identified at this stage of the process, the VP shall notify the Principal Investigator for the study that an Inquiry will be undertaken .

4.6 Custody of Research-related Records and Relevant Material

a. Whenever possible, all reasonable and practical steps shall be taken by the FHA Research Office to locate, collect and secure custody of the original copies of the research-related records and evidence to conduct the inquiry and/or investigation (copies may be secured if originals cannot be found). The sequestration of research-related records is required to prevent loss, alteration or fraudulent creation of records. The sequestration shall take place:
   i) Before or at the time the Respondent is notified of the allegation, and;
   ii) Whenever additional items become known or relevant to the inquiry and/or investigation.
   iii) The Respondent should not be notified in advance of sequestration of research records to prevent questions being raised later regarding missing documents or materials and to prevent accusations against the respondent of tampering with or fabricating data or materials after the notification.

b. The Respondent may assist with the location and identification of the research-related records; in addition, assistance for this purpose may be obtained from the researcher's administrative supervisor.

c. Sequestration may occur in the absence of the Respondent, if this is necessary.

d. In addition to securing those records under the control of the Respondent, the records of other individuals, such as co-investigators and Complainants, may also need to be sequestered.

e. An inventory of the research-related records and evidence shall be kept.

f. A dated receipt shall be signed by the sequestering official and the individual from whom an item is collected.

g. A copy of the receipt shall be given to the individual from whom the record is taken.

h. A list of the complete inventory shall be prepared as soon as possible and a copy given to the person from whom the items were collected.

i. As soon as is practical, a copy of each sequestered research record shall be provided to the individual from whom the record is taken if requested.

j. Should it not be practical to copy a particular record, e.g. X-rays, the person from whom the item was collected may have access to his or her original items under direct and continuous supervision of a FHA official.

k. The research-records and evidences shall be kept under lock in a secure place.

l. An exception to the procedure to secure research-related records may occur when the research records or evidence encompass scientific instruments shared by a number of users. Under these circumstances, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments.

m. Where appropriate, the Respondent shall be given copies of, or reasonable, supervised access to the research-related records and evidence.

n. The research records and evidence shall be maintained as required for the duration of the inquiry and investigation and thereafter for a period of 7 years in a secure manner.

4.7 Retention and Release of Research-related Records

a. The retention of records related to the research misconduct proceedings is required for the following:
   i) the records that FHA secured for the proceedings to the extent that FHA subsequently determines and documents that those records are not relevant to the proceeding or that the records duplicate other records that are being retained;
   ii) the documentation of the determination of irrelevant or duplicate records;

iii) the Inquiry Report and final documents (not drafts) produced in the course of preparing that report, including the documentation of any decision not to investigate.
iv) the Investigation Report and all records (other than drafts of the report) in support of that report, including the recordings or transcriptions of each interview conducted, and
v) the complete record of any institutional appeal.

b. FHA shall maintain records of research misconduct proceedings in a secure manner for seven years after completion of the proceeding.

c. All requests for access to the records shall be handled in accordance with the requirements of the B.C. Freedom of Information and Protection of Privacy Act and FHA Information Management policies. Funders and regulatory bodies shall have access to the records for their audit purposes.

4.8 Inquiry and Investigation

a. The associated actions of Inquiry and Investigation shall normally be taken when an allegation of possible misconduct is received. Particular circumstances in an individual case may dictate variation from the normal procedure if deemed in the best interests of FHA.

b. The Inquiry shall make a preliminary evaluation of the available evidence and testimony of the Complainant(s), Respondent(s) and key Informants to determine whether there is sufficient evidence of possible scientific misconduct to warrant an investigation. The purpose of the Inquiry is not to reach a final conclusion about whether misconduct definitely occurred or who was responsible. The findings of the Inquiry shall be set forth in an Inquiry report made to the VP upon conclusion.

c. The Investigation shall develop a factual record and examine that record to determine if there should be a dismissal of the case or a recommendation for a finding of research misconduct. The Complainant(s)/Informant(s) and Respondent shall be interviewed during the investigative process.

d. The Investigation shall allow the Respondent and Complainant(s)/Informant(s) due process and full opportunity to respond to/comment on the allegations throughout the Investigation through mechanisms consistent with due process and natural justice.

e. The Investigation shall determine the actions to be taken as a result of conclusions reached, including: any sanctions or corrective actions imposed; any actions taken to protect or restore the reputation(s) or credibility of any person(s) wrongly accused of, or implicated in, misconduct in research, including procedures to ensure that if the allegations have been dismissed, copies of documents and related files provided to third parties have been destroyed; and any actions taken to protect the Complainant(s) deemed to have made a responsible accusation;

f. The findings of the Investigation shall be set forth in an Investigation report made to the VP upon conclusion.

4.9 Conducting the Inquiry

4.9.1 Charge to the Inquiry Committee

a. The VP shall prepare a charge for the Inquiry Committee that describes the allegations and any related issues identified during the allegation assessment. The charge shall include the following:
   i) a statement that the purpose of the Inquiry is to let each Respondent, Complainant and key Informant tell their own story and to make a preliminary evaluation of the evidence and testimony presented in order to determine whether there is sufficient evidence of possible research misconduct to warrant an investigation.
   ii) The purpose of an Inquiry is to conduct an initial review of the evidence to determine whether to conduct an investigation. Therefore, an inquiry does not require a full review of all the evidence or the conduct of exhaustive interviews and analyses related to the allegation.

b. The prescribed standards and procedures as detailed in this policy shall be provided to the RIIC by the Research office.

c. Prior to conducting the Inquiry, the RIIC shall formulate a plan that in general should follow the steps outlined below under b. General Steps.

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4.9.2 General Steps

a. The RIIC shall normally interview the Complainant, the Respondent and key Informants, as well as examine relevant research-related records and materials.

b. The interviews shall be conducted in the order of the Complainant, key Informants, and the Respondent, if at all possible.

c. Informants shall be asked to provide, in advance if possible, any relevant evidence that was not sequestered previously and relevant to the allegation.

d. The interview should determine the Complainant's view of the significance and impact of the alleged misconduct. It is not the Complainant's responsibility to prove his or her allegations.

e. The Respondent should be asked to provide his or her own response to the allegations, including any analysis of primary data, should this be relevant. If the Respondent claims that an honest error difference of scientific judgement occurred, he or she should provide any evidence to support that claim. The Respondent may make a closing statement at the end of the interview, upon their request.

f. Before an interview, the RIIC shall provide each interviewee with a summary of the matters or issues intended to be covered in the interview. If the committee raises additional matters, the interviewee shall be given an opportunity to supplement the record in writing or in another interview. The interviewee shall be informed that his or her cooperation and truthful answers are expected and that absolute confidentiality is required other than with their legal counsel or advisor.

g. Interviewees may be accompanied and advised by their legal counsel or by a non-legal advisor who is not otherwise associated with the case. The counsel/advisor may only advise the interviewee and may not participate in the interview directly; the interviewee must respond to questions directly.

h. A conflict in testimony should not be disputed at this stage; clarifying questions only should be asked.

i. Ad hoc expert members may be used to prepare questions for the committee, to interview individuals involved, and to read transcripts or summaries of the meeting(s).

j. All interviews shall be tape-recorded and transcribed. A transcript or summary of the interview shall be provided to each interviewee for review and correction of factual errors only. Additional information may be added if deemed to be of a factual nature.

k. The RIIC shall evaluate the evidence and testimony obtained during the Inquiry.

l. After consultation with Institutional Counsel, the RIIC shall decide whether there is sufficient evidence of possible research misconduct to recommend further investigation.

m. The RIIC shall ensure that all necessary steps are taken to avoid bias or conflict of interest between any of the individuals involved as the proceedings are undertaken.

n. Committee deliberations shall never be held in the presence of the interviewee; nor should committee members engage in debate amongst themselves or interviewees regarding possible interpretations.

4.9.3 Admissions of Misconduct

a. If the Respondent admits to the misconduct as a consequence of the Inquiry, the Respondent shall be asked to immediately sign a statement attesting to the occurrence and extent of the misconduct, acknowledging that the statement is voluntary and stating that the Respondent was advised of his or her right to seek the advice of legal counsel.

b. An admission is a sufficient basis to proceed directly to an Investigation.

c. The admission is not a sufficient basis for closing a case.

4.9.4 The Inquiry Report

a. A written Inquiry Report shall be prepared that includes the following information:
   i) name and title of appointed members, and of experts, if any;
   ii) the allegations;
   iii) funding support, if any;

iv) summary of the inquiry process used;
v) list of research-related records and materials reviewed;
vi) summaries of any interviews;
vii) description of the evidence in sufficient detail to demonstrate whether an investigation is warranted or not;
viii) RIIC's determination as to whether an investigation is recommended and whether any other actions should be taken if an investigation is not recommended;
ix) documentation of decision not to investigate in order to provide sufficient detail to permit a later assessment by funders of the reasons why a decision not to proceed with an investigation was taken by the RIIC, and;
x) any comments on the draft report received from the Complainant or Respondent.

b. Institutional counsel shall review the report for legal sufficiency.

c. The Inquiry Report shall include documentation of the reasons for exceeding the 60-day period should it take longer than that to complete.

4.9.5 Opportunity to Comment on the Draft Inquiry Report

a. The Respondent shall be provided with a copy of the draft Inquiry Report for comment and rebuttal. The Respondent's legal counsel may review the draft Inquiry Report.

b. The Complainant(s) shall be provided with portions of the draft Inquiry Report that address the Complainant's role and opinions in the Inquiry.

c. The review of the draft Inquiry Report shall be conducted under the supervision of a FHA institutional official.

d. The Respondent and Complainant(s) may provide written comments to the draft Inquiry Report within 14 calendar days of receipt of the draft Inquiry Report.

e. Comments received from the Complainant(s) and/or Respondent shall become part of the final Inquiry Report and record.

f. The RIIC may revise the Inquiry Report based on any received comments as deemed to be appropriate.

4.9.6 Inquiry Decision and Notification

a. The final Inquiry Report shall be transmitted to the VP by the RIIC Chair no more than 60 calendar days following its first meeting, unless an extension has been approved by the VP.

b. The VP shall notify the Respondent in writing of the allegations within 7 calendar days of receipt of the Inquiry Report determining that an investigation is warranted.

c. The notice shall include:
   i) a copy of the final Inquiry Report,
   ii) the specific allegations, sources of funding, if applicable,
   iii) the definition of research misconduct,
   iv) a description of the investigation procedures,
   v) the membership of the Investigation Committee including experts,
   vi) the opportunity of the respondent to be interviewed,
   vii) his or her obligation to provide information and his or her right to be assisted by independent legal counsel, to challenge the membership of the committee and experts based on bias or conflict of interest and to comment on the draft report,
   viii) a copy of or refer to this part and the FHA policies and procedures as applicable.

d. The VP shall notify the Complainant whether the Inquiry found that an investigation is warranted and may provide relevant portions of the report to the Complainant within 7 calendar days of the receipt of the Inquiry Report.

e. The VP shall notify the Respondent and Complainant in writing immediately upon receipt of the Inquiry Report which states that an investigation is not warranted.

f. The VP shall notify FHA institutional officials of the decision of the RIIC's Inquiry.

4.10 Notification of Funding Agencies and Regulatory Authorities

a. Upon a positive recommendation from the RIIC to open an investigation, the VP shall issue written notice to the funders and/or applicable regulatory authorities involved on or before the date on which the Investigation begins and shall provide a copy of the Inquiry Report and procedures for conducting investigations under this Policy.

b. Should the RIIC decide not to proceed to an investigation and the Inquiry was begun at the request of an external funding agency or sponsor, the RIIC shall provide a copy of the final Inquiry report as notice to the funding agency or sponsor.

4.11 Conducting the Investigation

4.11.1 Purpose

a. The purpose of the investigation is to explore in detail the allegations, to examine the evidence in depth, and to determine specifically whether misconduct has been committed, by whom, and to what extent, and in addition why there was a serious deviation from accepted practices at the time the actions were committed.

b. The investigation shall also determine whether there are any additional instances of possible misconduct that would justify broadening the scope beyond the initial allegations.

4.11.2 Custody of the Research-related Records and Relevant Material

a. The FHA Research Office shall immediately sequester any additional pertinent research-related records and material that were not previously sequestered during the Inquiry.

b. This sequestration shall occur before or at the time that the Respondent is notified that the Investigation has begun.

c. Sequestration of records may include those that were identified during the inquiry process and that had not been previously secured or those related to additional allegations not considered during the inquiry stage.

d. The procedures to be followed for sequestration during the investigation are identical to those that apply during the Inquiry.

4.11.3 Investigation Procedures

a. The Investigation shall begin within 30 days after the conduct of the Inquiry by the RIIC determines that an Investigation is warranted.

b. The Respondent shall be notified in writing of any new allegations of research misconduct within a reasonable amount of time of deciding to pursue allegations not addressed during the Inquiry or in the initial notice of Investigation.

c. Based upon the findings of the Inquiry report, the VP shall define the subject matter of the Investigation in a written letter to the RIIC that describes the allegations and related issues identified during the Inquiry, defines scientific misconduct, and names the Respondent. The letter shall state that the RIIC is to evaluate the evidence and testimony of the Respondent, Complainant and key Informants to determine whether, based on a preponderance of the evidence, scientific misconduct occurred and, if so, to what extent, who was responsible, and its seriousness.

d. If during the course of the Investigation, additional Respondents are identified, the RIIC shall provide written notice to these additional Respondents in the same form as to the original Respondent.

e. An investigation plan shall be established by the RIIC for each investigation and completed as reasonably as possible. The investigation plan shall include:
   i) an inventory of all previously secured evidence and testimony;
   ii) a determination of whether additional evidence needs to be secured;
   iii) who needs to be interviewed, including the Respondent, Complainant and other key Informants ;
   iv) a proposed schedule of meetings;
   v) briefing of expert ad hoc members;
   vi) anticipated analyses of evidence;
   vii) and a plan for the investigation report.

f. The Investigation shall be sufficiently documented and include examination of all research-related records and evidence relevant to reaching a decision on the merits of the allegations. Review of documentation shall normally involve examination of all documentation including, but not necessarily limited to, relevant research records, computer files, proposals, manuscripts, publications, regulatory and ethics documents, correspondence, memoranda, and notes of telephone calls.

g. The interviews shall be conducted as previously described under Procedures Section 4.9.2 of this Policy, except that the interviews at this stage should be in depth and all significant witnesses should be interviewed. Each witness shall have the opportunity to respond to inconsistencies between his or her testimony and the evidence or other testimony, subject to the need to take reasonable steps to maintain the confidentiality of the testimony of the respondent and other witnesses.

h. The RIIC shall prepare carefully for each interview by reviewing all relevant documents and research data in advance and preparing specific questions or issues in advance of the interviews.

i. The RIIC shall appoint one individual to take the lead on each interview.

j. The RIIC shall take a recess to discuss any significant questions or issues that arise during the interview that require committee deliberation and not conduct any deliberations in the presence of the interviewee.

k. The RIIC shall interview each Respondent, Complainant, and any other available person who has been reasonably identified as having information regarding any relevant aspects of the Investigation, Informant(s), including witnesses identified by the Respondent, and tape record and transcribe each interview, provide the transcript to the interviewee for correction, and include the recording and transcript in the record of the investigation. Changes to the transcript shall only be made to correct factual errors.

l. The RIIC shall pursue diligently all significant issues and leads discovered that are determined relevant to the Investigation, including any evidence of additional instances of possible research misconduct, and continue the Investigation to completion.

m. The RIIC shall conduct all interviews in a professional and objective manner, without implying guilt or innocence on the part of the individual.

n. No party, legal counsel, or other party representative may communicate outside of the formal proceeding [i.e. ex parte] on any matter at issue in a case, unless both parties have notice and an opportunity to participate in the communication. However, a party, legal counsel or other party representative may communicate with FHA research staff about administrative or procedural matters.

o. If an ex parte communication should occur, it shall be disclosed to the other party and made part of the record after the other party has an opportunity to comment.

4.11.4 Evidentiary standards

a. The following evidentiary standards apply to findings made under this Policy:

i) Standard of proof: Institutional research misconduct and who committed it must be proved by a preponderance of the evidence.

ii) Burden of proof: FHA has the burden of proof for making a finding of research misconduct. Research misconduct must be established by a preponderance of evidence in that it is more likely than not that the Respondent committed research misconduct.

- The destruction, absence of, or Respondent's failure to provide research records adequately documenting the questioned research is evidence of research misconduct where FHA establishes by a preponderance of the evidence that the Respondent intentionally, knowingly, or recklessly had research records and destroyed them, had the opportunity to maintain the records but did not do so, or maintained the records and failed to produce them in a timely manner and that the Respondent's conduct constitutes a significant departure from accepted practices of the relevant research community.

iii) The Respondent has the burden of going forward with and the burden of proving, by a preponderance of the evidence, any and all affirmative defences raised. In determining if FHA has carried the burden of proof imposed by this part, the RIIC shall give due consideration to admissible, credible evidence of honest error or difference of opinion presented by the Respondent.

iv) The Respondent has the burden of going forward with and proving by a preponderance of the evidence any mitigating factors that are relevant to a decision to impose administrative actions following a research misconduct proceeding.

4.11.5 Admissions of Research Misconduct

a. If the Respondent admits to the misconduct as a consequence of the Investigation, the Respondent shall be asked to immediately sign a statement attesting to the occurrence and extent of the misconduct, acknowledging that the statement is voluntary and stating that the Respondent was advised of his or her right to seek the advice of legal counsel.

b. The admission may not be used as a basis for closing the investigation unless the RIIC has adequately determined the extent and significance of the misconduct and all procedural steps for completion of the investigation have been met.

c. The investigation shall not be closed unless the Respondent has been appropriately notified and given an opportunity to comment on the Investigative Report.

4.11.6 Criteria for Making a Final Finding of Research Misconduct

a. The criteria for making a decision regarding an administrative action must include the seriousness of the misconduct and also includes, but is not limited to the following factors:
   i) Knowing, intentional, or reckless: Were the Respondent's actions knowing or intentional or was the conduct reckless?
   ii) Pattern. Was the research misconduct an isolated event or part of a continuing or prior pattern of dishonest conduct?
   iii) Impact: Did the misconduct have significant impact on the proposed or reported research record, research subjects, other researchers, institutions, or the public health or welfare the public?
   iv) Acceptance of responsibility: Has the Respondent accepted responsibility for the misconduct by:
      (1) admitting the conduct;
      (2) cooperating with the research misconduct proceedings;
      (3) demonstrating remorse and awareness of the significance and seriousness of the research misconduct; and

(4) taking steps to correct or prevent the recurrence of the research misconduct.

v) Failure to accept responsibility: Does the Respondent blame others rather than accept responsibility for their actions?
vi) Retaliation: Did the Respondent retaliate against Complainants, Informants, RIIC members or other persons?
vii) Present responsibility: Is the Respondent presently responsible enough to conduct research?
viii) Other factors: Other factors appropriate to the circumstances of a particular case.

4.11.7 Administrative Actions

a. Administrative actions that may be recommended by the RIIC include, but are not limited to:
   i) appropriate steps to clarify, correct or retract the research record;
   ii) withdrawal or correction of all pending or published abstracts and papers emanating from the research where scientific misconduct was found;
   iii) removal of the responsible person from the particular project;
   iv) probation;
   v) suspension;
   vi) initiation of steps leading to possible rank reduction or termination of employment/privileges;
   vii) letters of reprimand;
   viii) imposition of special certification or assurance requirements to ensure compliance with applicable regulations or terms of grants, contracts, or cooperative agreements;
   ix) suspension or termination of a grant, contract, or cooperative agreement, and;
   x) restriction on specific activities or expenditures under an active grant, contract, or cooperative agreement;
   xi) special review of all requests for future funding;
   xii) imposition of supervision requirements on future research;
   xiii) certification of attribution or authenticity in all future requests for funding support;
   xiv) no participation in any advisory capacity to funders;
   xv) suspension or debarment under Canadian licensing legislation, and;
   xvi) recovery by FHA of FHA funds spent in support of the activities that involved research misconduct;

xvii) In the event of suspension or debarment the information shall be made publicly available through the applicable authority.

b. If FHA believes that criminal or civil fraud violations may have occurred, FHA shall promptly refer the matter to the appropriate authority.

4.11.8 No Settlement or Finding of Research Misconduct

a. When the RIIC Investigation does not result in a settlement or finding of research misconduct, FHA shall:
   i) provide written notice to the Respondent, the Complainant, and the funder if applicable.
   ii) take any other actions authorized by law.

4.11.9 Opportunity to Review and Comment on the Draft Investigation Report

a. The Respondent shall be given a copy of the draft Investigation Report and, concurrently, a copy of, or supervised access to, the evidence on which the report is based. The comments of the Respondent on the draft report, if any, must be submitted within 30 days of the date on which the Respondent received the draft Investigation Report.

b. At the discretion of the RIIC, the Complainant, if he or she is identifiable, may be provided a copy of the draft Investigation report or relevant portions of that report. The comments of the Complainant, if any, must be submitted within 30 days of the date on which the Complainant received the draft Investigation Report or relevant portions of it.

c. The Respondent and Complainant shall sign a confidentiality statement prior to review of the draft Investigation Report and shall review the Report in the office of the VP and/or designate.

d. The RIIC shall consider, address and attach any comments received to the draft Investigation Report before issuing the final report.

e. Institutional counsel shall review the draft Investigation Report for its legal sufficiency. Comments shall be incorporated into the report as appropriate.

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4.11.10 The Final Investigation Report

a. The final RIIC Investigation Report shall be in writing and include the following sections.

i) Background: Include sufficient background information to ensure a full understanding of the issues as they relate to the definition of research misconduct. This section should detail the facts leading to the Inquiry, the research at issue, the persons involved in the alleged misconduct and the role of the Complainant.

ii) Allegations: Describe the nature of the allegations of research misconduct. The source and basis for each allegation should be cited except to the extent that the confidentiality of a Complainant requesting anonymity is compromised or where the identity of the source if irrelevant or unnecessary.

iii) Funding support, if applicable: Describe and document the funding support as applicable, including, for example, agency, any grant numbers, grant applications, contracts, and publications listing the support of the funding agency.

iv) Policies and procedures: If not already included with the Inquiry Report, include the institutional policies and procedures under which the Investigation was conducted.

v) Research records and evidence: List and summarize the research records and evidence reviewed, and identify any evidence taken into custody but not reviewed, and identify the measures taken to ensure its security.

vi) Interviews: List the persons interviewed and provide the actual text or an accurate summary of the parties interviewed.

vii) Analysis: For each separate allegation of research misconduct identified during the Investigation, describe the particular matter in which the alleged misconduct occurred and why and how the issue came to be under investigation; cite the source of all relevant statements and claims; cite the use of expert analysis, summarize or quote relevant statements, including rebuttals, made by the witnesses and reference/cite the appropriate sources; describe the commonly accepted practice of the relevant scientific community at the time that the misconduct occurred and indicate the extent of any deviation from that; summarize each argument that the Respondent raised in his or her defence against the allegation and cite the source of each argument [any inconsistencies among the Respondent's various arguments should be noted]. The analysis should describe the relative weight given to the various witnesses and pieces of evidence, noting inconsistencies, credibility, and persuasiveness; describe any evidence that the Respondent knowingly engaged in the allegation or other research misconduct and any

evidence that supports the possibility that honest error or differences of scientific opinion occurred with respect to the issue.

viii) Comments: Include and consider any comments made by the Respondent and Complainant on the draft Investigation Report.

ix) Findings: For each allegation and/or issue, provide a finding as to whether research misconduct did or did not occur, and if so: identify the type of research misconduct for each issue, the extent and seriousness of the research misconduct and if it was intentional, knowing, or in reckless disregard and if it met any of the other prohibitions under Section 3.3 of this policy.
   a) Identify whether any publications need correction or retraction;
   b) Identify the person(s) responsible for the misconduct;
   c) List any current support or known applications or proposals for support that the Respondent has pending with any funding agencies and/or commercial sponsors;

x) Recommended Institutional Actions: Based upon its findings, recommended administrative actions should be described that the RIIC believes that FHA should take consistent with its own policies and procedures.

xi) Attachments: Append copies of all significant documentary evidence that is referenced in the report and include a 'list of attachments'. Allegedly false statements, misrepresentation in figures, areas of plagiarism, may be identified on a copy of the page or section of the questioned document and a side by side comparison with the actual data or material may be made.

4.11.11 Transmittal of the Final Investigation Report

a. After comments have been received and the necessary changes have been made to the draft report, the RIIC shall transmit the final report and attachments to the VP.

b. The final Investigation Report shall be distributed to all parties involved and concerned within 7 calendar days of receipt by the VP.

c. Where research misconduct is found to have occurred, the final Investigation report shall be forwarded within 30 days to any funders that provided funds for the research at issue and/or to the applicable regulatory bodies.

4.12 Notification of Administrative Actions Taken by FHA

a. The VP shall provide final written notification of any research misconduct findings of the RIIC and the recommended administrative actions to be taken by FHA to the Respondent, the Complainant(s), and to any funder and/or regulatory body, as applicable, and within the timelines stipulated by the funder and/or regulatory body.

b. FHA shall take steps to ensure that any published research reports or other sources of scientific information (such as data bases) are retracted or corrected as necessary.

4.13 Contest of Findings and Appeal

a. The Respondent may contest RIIC findings of research misconduct including any debarment or suspension action, by requesting a hearing within 30 days of receipt of the written notice.

b. The Respondent's request for a hearing must be:
   i) in writing;
   ii) signed by the Respondent or by the Respondent's lawyer, and;
   iii) sent by certified mail, or other equivalent (i.e., with a verified method of delivery), to the VP.

c. The request for a hearing must:
   i) admit or deny each finding of research misconduct and each factual assertion made in support of the finding;
   ii) accept or challenge each proposed FHA administrative action;
   iii) provide detailed, substantive reasons for each denial or challenge;
   iv) identify any legal issues or defences that the Respondent intends to raise during the proceeding, and;
   v) identify any mitigating factors that the Respondent intends to prove.

d. The appeal must be completed within 120 days of its filing.

e. The funder or other agency must be informed of the appeal upon receipt, if applicable.

f. Upon completion of the appeal, the following documents shall be provided to the funder and other agency as applicable:
   i) Investigation Report: Include a copy of the report, all attachments, and any appeals.
   ii) Final institutional action: State whether research misconduct was found, and if so, who committed the misconduct.
   iii) Findings. State whether FHA accepts the appeal's findings.
   iv) Institutional administrative actions: Describe any pending or completed administrative actions against the Respondent.
   v) Provide written notice to the Respondent, FHA Executive and Board, and to any funders, as applicable.

4.14 Notification of Other Bodies

a. The VP/designate shall take steps to ensure that the appropriate official bodies are informed as per the findings of the Investigation Report. These may include professional societies, professional licensing boards, editors of journals in which falsified reports may have been published, collaborators of the Respondent in the research under question, law enforcement agencies, or other relevant parties.

4.15 Termination of Institutional Employment or Resignation Prior to Completing Inquiry or Investigation

a. The termination of the Respondent's institutional employment, by resignation or otherwise, before or after an allegation of possible research misconduct has been reported, will not preclude or terminate the misconduct procedures.

b. If the Respondent refuses to participate in the process after resignation, the RIIC will use its best efforts to reach a conclusion concerning the allegations, noting in its report the Respondent's failure to cooperate and its effect on the RIIC's review of all the evidence.

4.16 Restoration of the Respondent's Reputation

a. If no misconduct is found, FHA shall undertake reasonable efforts to restore the Respondent's reputation. This could include notification of those individuals aware of or involved in the investigation of the final outcome, publicizing the final outcome in forums in

which the allegation of scientific misconduct was previously publicized, or expunging all reference to the scientific misconduct allegation from the Respondent's personnel file. Any institutional actions taken shall be approved by the VP.

4.17 Protection of the Complainant and Others

a. Regardless of whether a finding of research misconduct was made, FHA shall undertake reasonable efforts to protect Complainants who made allegation of scientific misconduct in good faith and other who cooperated in good faith with inquiries and investigations of such allegations. Upon completion of an investigation, the VP shall determine, after consulting with the Complainant, what steps, if any are needed to restore the position or reputation of the Complainant and delegate their execution to the FHA Research office.

4.18 Allegations Not Made in Good Faith

If relevant, the VP shall determine whether the Complainant's allegations of research misconduct were made in good faith. If any allegation was not made in good faith, the VP shall determine whether any administrative action should be taken against the Complainant.

4.19 Accountability Reporting

a. An annual report of the RIIC shall include:
   i) the number of allegations received by FHA in any given year and the general nature of the allegations received;
   ii) the number of allegations that were not pursued and the general reasons why;
   iii) the number that were pursued and investigated;
   iv) the number that were resolved with a brief categorization of the outcomes; and
   v) the number of allegations that remain outstanding.

b. The annual report shall be provided to the FHA Board and Executive and posted on the FHA Research website and updated on a semi-annual basis.

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5. SCHEDULE OF TIMELINES

a. Notice of Allegation

i) An acknowledgement of receipt of the written allegation shall be issued to the source of the allegation within 3 business days of receipt by the VP.
ii) Written notice of the allegation including details of the allegations shall be issued to the Respondent within 5 business days of receipt by the VP.

b. Inquiry

The Inquiry and report shall be completed within 60 calendar days of the initiation of the Inquiry unless circumstances clearly warrant a longer period.

i) The Respondent shall be notified of the RIIC membership for the Inquiry and any subsequent Investigation within 10 days of the constitution of the RIIC, including ad hoc membership.
ii) The Respondent may submit a written objection to any appointed member of the RIIC or expert ad hoc member based on bias or conflict of interest within 5 days of notification.
iii) The Respondent and Complainant may provide written comments to the draft Inquiry Report within 14 calendar days of receipt of the draft Inquiry Report.
iv) The final Inquiry Report shall be transmitted to the VP by the RIIC Chair no more than 60 calendar days following its first meeting, unless an extension has been approved by the VP.

c. Investigation

The Investigation and report to the VP shall be completed within 120 calendar days.

i) The VP shall notify the Respondent in writing of the allegations within 7 calendar days of receipt of the Inquiry Report determining that an investigation is warranted.
   a) The VP shall notify the Respondent and Complainant in writing immediately upon receipt of the Inquiry Report which states that an investigation is not warranted.
ii) The VP shall notify the Complainant whether the Inquiry found that an investigation is warranted and may provide relevant portions of the report to the Complainant within 7 calendar days of the receipt of the Inquiry Report.

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iii) The Investigation shall begin within 30 days after the conduct of the Inquiry by the RIIC determines that an Investigation is warranted.
iv) The Respondent shall be given a copy of the draft Investigation Report and, concurrently, a copy of, or supervised access to, the evidence on which the report is based. The comments of the Respondent on the draft report, if any, must be submitted within 30 days of the date on which the Respondent received the draft Investigation Report or relevant portions of it.
v) At the discretion of the RIIC, the Complainant, if he or she is identifiable, may be provided a copy of the draft Investigation report or relevant portions of that report. The comments of the Complainant, if any, must be submitted within 30 days of the date on which the Complainant received the draft Investigation Report or relevant portions of it.
vi) The final Investigation Report shall be distributed to all parties involved and concerned within 7 calendar days of receipt by the VP.
vii) Where research misconduct is found to have occurred, the final Investigation report shall be forwarded within 30 days to any funders that provided funds for the research at issue and/or to the applicable regulatory bodies.

d. Appeal

i) The Respondent may contest RIIC findings of research misconduct including any debarment or suspension action, by requesting a hearing within 30 days of receipt of the written notice.
ii) The appeal must be completed within 120 days of its filing.

e. Maintenance of Research Records

i) The research records and evidence shall be maintained as required for the duration of the inquiry and investigation and thereafter for a period of 7 years in a secure manner.

REFERENCES

1. CIHR, NSERC, SSHRC: Framework for Tri-Council Review of Institutional Policies Dealing with Integrity in Research at http://www.nserc.gc.ca/institution/framework_e.htm .

2. U.S. Department of Health and Human Services, Office of Research Integrity: Model Procedures for Responding to Allegations of Scientific Misconduct

3. Canadian Federal and Provincial Regulatory Requirements or Standards

(i) Federal Policy - TCPS

The 'Tri-council Policy Statement: Ethical Conduct for Research Involving Humans' (TSPS2) provides the Canadian framework for ethical review of research involving human subjects.
Refer to:
http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/

(ii) Health Canada Legislation

REB's that review clinical trial research AND researchers who conduct clinical trial research that is regulated by Health Canada must comply with the following regulatory requirements for research involving drugs, devices and natural health products:

Food and Drug Act: Regulations Amending The Food And Drug Regulations (1024 - Clinical Trials) For Clinical Trials For Drugs And Radiopharmaceuticals
Refer to:
http://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,_c._870/page-286.html#h-274

Food and Drug Act: Medical Device Regulations – Part 3 Medical Devices For Investigational Testing Involving Human Subjects
Refer to:
http://laws-lois.justice.gc.ca/eng/regulations/SOR-98-282/page-1.html

Food and Drug Act: Natural Health Products Regulations
Refer to:
http://laws-lois.justice.gc.ca/eng/regulations/SOR-2003-196/page-1.html

REB's who review clinical trial research and researchers who conduct clinical trial research that is regulated by Health Canada must also adhere to the International Conference on Harmonization Tripartite Guideline for Good Clinical Practice: Consolidated Guideline (1997) [ICH GCP].

Health Canada follows the ICH GCP's to determine whether or not good clinical practices are adhered to by researchers [i.e. qualified investigators] and research ethics boards during their inspections of clinical trials.

Refer to:
http://hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/ich/efficac/e6-eng.php

(iii) British Columbia Privacy Legislation

As a public body, the FHAA, and the FHAA REB and researchers under its jurisdiction are obliged to follow the regulations concerning the use of personal information for research related purposes under Bill 73 – Amendments to the Freedom of Information and Protection of Privacy Act Article 35 – Disclosure for Research or Statistical Purposes.
Refer to: http://www.bclaws.ca/EPLibraries/bclaws_new/document/ID/freeside/96165_00

4. United States Regulations

Researchers who conduct research funded either by the United States Department of Health and Human Services or other U.S. government agencies must comply with the following regulatory requirements for any of the funded research.

Department of Health and Human Services funded research regulated under 45 CFR 46.109 (e);
Refer to:
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

Other U.S. government funded research regulated under 21 CFR 56.110.

Refer to: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=56.110.

REBs that receive funds from United States government funding agency must adhere to the ethical principles contained in the 'Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research' (1979) of the National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research.
Refer to:
http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html

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5. International Standards

(i) REB's that adhere to the ICH GCP and receive funds from United States government funding agency must adhere to the ethical principles contained in the 'Declaration of Helsinki' (1964) of the World Medical Association.
Refer to:
http://www.wma.net/en/30publications/10policies/b3/17c.pdf

(ii) Association of American Medical Colleges: Principles for Protecting Integrity in the Conduct and Reporting of Clinical Trials. January 6, 2006

6. FHA CORPORATE RESEARCH-RELATED POLICIES:

- FHA Research
- The Ethical Conduct of Research and Other Studies Involving Human Subjects
- The Collection, Use and Disclosure of Personal Information for Research-related Purposes
- The Provision of Research-related Services to Non-FHA Researchers
- Intellectual Property
- Clarification of Ethical Requirements for Studies Involving Quality Assurance/Improvement, Program Evaluation, Operational Review and Product Review
- Allegations of Wrongdoing
- Confidentiality and Security of Personal Information
- Conflict of Interest