

LUDWIG INSTITUTE FOR CANCER RESEARCH LTD

SCIENTIFIC INTEGRITY POLICY

Statement of Policy and Procedure (SPP) 203

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Statement of Policy

Scientific staff of the Ludwig Institute for Cancer Research Ltd shall execute their work in accordance with scientific standards of objectivity, accountability and professionalism.

Research integrity is fundamental to the ethical conduct of the scientific process and to the credibility and reputation of the Institute. Research findings are to be reported accurately, results are not to be fabricated or falsified and plagiarism in written documents is unacceptable. Timely, accurate, complete, authentic and reliable records of research data are to be maintained in line with the Institute's Maintenance of Laboratory Notebooks and Records Policy.

Research misconduct is defined as fabrication or plagiarism of performed or proposed research or reports, falsification of data or credentials, or misuse of research resources and is not tolerated. Any case of suspected or alleged research misconduct or misuse of research funds shall be investigated thoroughly and where applicable, disciplinary measures, including possible termination of employment, shall be applied. Research misconduct in the context of this Policy does not include authorship or collaboration disputes.

Responsibility and Action

All individuals affiliated with the Institute have an ethical responsibility to report the suspicion or occurrence of research misconduct. The report may consist of an oral or written notification to the Branch Director, Scientific Director, or any other person identified in Section 2.2 of the Institute's Whistleblower Policy.

The procedures for making, managing and responding to allegations of research misconduct are set out below.

Making, Managing and Responding to Allegations of Research Misconduct

Identifying, managing and resolving instances of suspected research misconduct is everyone's responsibility and requires unbiased detailed procedures.

1. Description

1.1. Research misconduct is

1.1.1. Fabrication, falsification or plagiarism in proposing, performing, or reviewing research or in reporting research results.

1.2. Research misconduct is not:

1.2.1. Honest error or differences of opinion.

1.3. Limitations

1.3.1. Unless, it is determined that the alleged misconduct, if it actually occurred, could possibly have a substantial adverse effect on the health or safety of the public, only allegations of suspected research misconduct that have occurred within six years prior to the date of the allegation may be pursued using this procedure.

2. Parties

2.1. Research Integrity Officer (RIO)

2.1.1. Responsible Person

- The Scientific Director or in the case of a conflict of interest, the President shall appoint the RIO on a case-by-case basis.

2.1.2. Primary responsibility

- Implementing the Institute's research misconduct policies and procedures.
- Evaluating, managing, processing and resolving allegations of suspected research misconduct.

2.2. Decision Officer (DO)

2.2.1. Responsible Person

- The Scientific Director or, if the Scientific Director is serving as RIO or has a conflict of interest, the President, serves as the DO.

2.2.2. Primary responsibility

- Consults with the RIO and other institutional officials to determine whether an investigation is warranted based upon an inquiry report.

2.3. Complainant

2.3.1. A person who alleges suspected research misconduct.

2.4. Respondent

2.4.1. A person against whom an allegation of suspected research misconduct is made.

3. Suspected Research Misconduct

3.1. When research misconduct is suspected the Complainant, confidentially if desired, shall:

3.1.1. Notify orally or in writing the Branch Director, Scientific Director, or any other contact person identified in Section 2.2 of the Institute's Whistleblower Policy ("recipients") of suspected research misconduct.

3.1.2. The name of a Complainant will not be revealed if requested by the Complainant unless required to carry out a thorough and fair investigation or because of legal requirements. Complainant will be advised before their name is revealed so that they may waive the claim to confidentiality or withdraw the allegation.

3.2. Anonymous Complainants

3.2.1. Allegations of research misconduct by anonymous Complainants will not be investigated.

3.3. Recipients of an allegation of research misconduct will determine whether the allegation is:

3.3.1. Groundless

Allegations determined by the recipient to be clearly groundless will be described by the recipient in a written document retained in a file separate from the Respondent's Personnel Review File. The Complainant will be notified in writing of the outcome of the assessment. The Respondent need not be informed of the allegation.

3.3.2. Not research misconduct as defined herein

Allegations involving disputes about research practices, authorship or other topics determined to not be research misconduct shall be resolved informally, through mediation, or via other applicable policies, at the discretion of the Scientific Director of the Institute.

3.3.3. Within the purview of this Policy

- Allegations considered by the recipient to be within the purview of this policy will be referred to the Scientific Director for assessment and consideration by the RIO.
- The RIO shall determine after discussion with the Respondent, if deemed appropriate, whether an inquiry is warranted.
- If an inquiry is warranted, the date of the decision will be documented by the RIO and retained in the inquiry file.

4. Respondents with Dual Academic Appointments.

4.1. Coordination with Host Institution

If the RIO determines that an inquiry is warranted and, in addition to an Institute appointment, a Respondent also holds an academic appointment from the institution hosting the Branch, the Scientific Director shall advise the appropriate host institution faculty committee of the allegation. The Institute shall coordinate with the host institution to avoid parallel or duplicative inquiries and investigations where possible. Such coordination may consist of conducting a joint inquiry/investigation, one organization taking the lead and investigating the matter, sharing its results and findings with the other, with such other organization adopting the results and findings as presented or undertaking further inquiry/investigation as deemed necessary and issuing its own findings and conclusions.

5. Inquiry Establishment

5.1. Inquiry committee

An inquiry committee must be established within approximately 14 calendar days of the decision to conduct an inquiry.

5.1.1. Purpose

- To determine whether the allegation warrants an investigation

5.1.2. Membership

- Members are appointed by the RIO

Members may include:

- The RIO if appropriate
- One or more senior scientists of the Institute
- Representatives from the Scientific Advisory Committee (SAC) of the Institute
- Scientists unaffiliated with the Institute with relevant expertise and no conflict of interest

5.2. Notification

5.2.1. The RIO shall prepare a written notification immediately after the establishment of the inquiry committee that includes

- The nature of the allegation
- The names of the individuals appointed as members of the inquiry committee

5.2.2. The RIO shall provide the written notification to the:

- Branch Director
- Scientific Director
- Complainant
- Respondent
- Other interested parties

5.2.3. The RIO shall notify the funding sources of all relevant grants supporting research that is the subject of the allegation that an inquiry is being undertaken if:

- Required by the funding agency law, contract, agreement or,
- If judged to be necessary by the RIO.

6. Inquiry Process

The inquiry process should be completed if reasonably possible within 30 calendar days after notification as outlined in Section 4.2.

Documentation of meetings of the inquiry committee such as a summary or minutes should be generated and retained in the record.

6.1. Research records and materials

All relevant research records including the original data, notebooks and critical research materials will be examined.

6.2. Inquiry

Interviews should be conducted if considered by the committee to be appropriate or necessary.

6.2.1. Complainant

- A summary, or, if produced, transcript or recording, of any interview between the inquiry committee and the Complainant will be provided to the Complainant for corrections.
- The Complainant may submit a detailed written response to a query from the RIO in lieu of an interview if appropriate.

6.2.2. Respondent

Opportunities will be provided for the Respondent to respond to the allegation either verbally or in writing.

6.2.3. Key staff relevant to the allegation

6.3. Report

The inquiry committee shall submit an inquiry report to the RIO.

6.3.1. The inquiry report shall include:

- The name and title of each committee member
- The name and title of each expert consulted by the committee if any
- The name of the Complainant
- The name of the Respondent
- The allegation in its entirety
- Funding sources for the research under scrutiny
- A detailed description of the steps taken by the committee
- A list of the research records reviewed
- Summaries of any interviews
- Comments and responses of the Respondent
- Findings categorized as one of the following:
 - The allegation is without substance and is or is not an allegation made in bad faith or,
 - The allegation involves questionable research practices but they do not meet the definition of research misconduct or,
 - There is probable cause as to all or part of the allegation that research misconduct may have occurred.

6.3.2. Report Review

The RIO will review the inquiry report to insure:

- The inquiry committee has completed its charge
- The report provides sufficient information to justify the committee's findings
- The report is in proper form
- The report does not include information that is inappropriate

6.3.3. Inadequate Report

- The RIO will request that the inquiry committee modify an incomplete report and a report that is not in the required form, or does not contain the required information.
- If the inquiry committee fails to modify an inadequate report as requested by the RIO, the RIO shall have the option of either accepting the original report as final or not accepting the original report and re-initiating the inquiry process by establishing a new inquiry committee.

6.3.4. Final Report

The final inquiry report should be completed within 60 calendar days after the committee appointments are made.

- An original unmodified report, if acceptable to the RIO, or an original report modified by the inquiry committee as requested by the RIO, will become the final report.
- The final report will be dated and signed by a designated member of the inquiry committee.

After consultation with the DO and within seven days of receiving the signed final report the RIO will determine whether the allegation warrants an investigation.

- All interested parties shall be notified by the RIO when the outcome of an inquiry has been accepted by the RIO.

7. Inquiry Outcomes and Action

7.1. Allegations determined to be without substance

7.1.1. The RIO in consultation with the Respondent shall make reasonable efforts to notify the appropriate individuals and organizations of the outcome for the purpose of restoring the Respondent's reputation.

7.1.2. Any written responses to these notifications shall be placed in the Inquiry record.

7.2. Allegations determined unlikely to be research misconduct but commonly accepted research standards or Institute policies may have been violated

7.2.1. Findings will be summarized in a memorandum by the RIO.

7.2.2 The memorandum is submitted to the Scientific Director of the Institute for disciplinary action if appropriate.

7.3. Allegations determined to have probable cause for research misconduct

7.3.1. The Inquiry and resultant inquiry report, as determined by the RIO, can serve in place of an investigation or,

7.3.2. An investigation is warranted and will proceed.

8. Inquiry Appeal

An inquiry finding of an allegation without substance or unlikely research misconduct may be challenged by any interested party.

8.1. Basis for appeals

- 8.1.1. Substantial new evidence has been identified.
- 8.1.2. Appropriate procedures were not followed.
- 8.1.3. A conflict of interest existed within the inquiry committee.

8.2. Appeal Process

- 8.2.1. Any interested party may appeal to the Scientific Director within 30 calendar days of the RIO's notification of the outcome of an inquiry.
- 8.2.2. Appeals upheld by the Scientific Director shall be remanded back to the RIO for further inquiry proceedings or implementation of an investigation.
- 8.2.3. The Respondent, Complainant and appellant will be notified in writing if a formal investigation is to be initiated.

9. Inquiry reports that substitute as an investigation

The RIO may determine that an inquiry may substitute for an investigation if all the following conditions are met.

9.1. Conditions

- 9.1.1. Inquiry concludes by a preponderance of the evidence that research misconduct occurred.
- 9.1.2. The inquiry committee has examined all relevant documentation, interviewed the Complainant, Respondent and other key individuals, secured appropriate expertise and evaluated the evidence thoroughly and it is unlikely that an investigation would uncover significant new information.
- 9.1.3. There is concurrence between Institute Counsel and appropriate external agencies that the inquiry may serve in place of an investigation.

10. Investigation Establishment

The investigation committee shall be established as soon as possible after the RIO determines an investigation is warranted subject to Section 4.1.

10.1. Investigation Committee

10.1.1. Membership

- Members are appointed by the RIO
- Members may include:
- The RIO if appropriate
 - Members from the inquiry committee if appropriate

- Three or more Institute senior scientists
- Scientific Advisory Committee members
- Scientists unaffiliated with the Institute but with relevant scientific expertise
- Members appointed to the investigation committee must disclose and document conflicts of interest.
- The RIO shall notify the Respondent of the appointments and unless the RIO receives a written objection from the Respondent within seven calendar days, the Respondent shall be deemed to have accepted the appointments.
- A Respondent's objection to any appointment must be made in writing to the RIO within seven calendar days.
- The RIO may replace appointments to which the Respondent objects.

10.2. Notification

10.2.1. The details of the investigational process shall be provided in writing to the investigational committee by the RIO.

10.2.2. Written notification of the investigation shall be prepared by the RIO and must include:

- The nature of the allegation
- The names of the individuals appointed as members of the investigation committee

10.2.3. The RIO shall provide the written notification to:

- Respondent
- Complainant
- Branch Director of the Respondent
- Scientific Director
- Other involved parties

10.2.4. The RIO shall notify the funding sources of all relevant grants supporting research that is the subject of the allegation and the Office of Research Integrity of the Health and Human Services, if appropriate, that an investigation is being undertaken if:

- Required by the funding agency law, contract, agreement or,
- If judged to be necessary by the RIO.

11. Investigation Process

The investigation process including the preparation of the report should be completed within 75 calendar days after the committee appointments are made. The process shall include:

11.1. Research records and material

All relevant research records including the original data, notebooks and critical research material will be examined.

11.2. Interview Complainant, Respondent, and other witnesses

11.2.1. Generate written documents for all interviews

11.2.2. Include receipt of written documentation from the Respondent

11.3. Report

A report shall be submitted to the RIO by the investigation committee.

11.3.1. The report shall include:

- The name and title of each committee member
- The name and title of each expert consulted by the committee if any
- The name of the complainant
- The name of the respondent
- The allegation in its entirety
- Funding sources for the research under scrutiny
- A detailed description of the steps taken by the committee
- A list of the research records reviewed
- Summaries of any interviews
- Comments and responses of the Respondent
- Findings categorized as one of the following and based on the preponderance of evidence:
 - Research misconduct occurred.
 - A violation other than research misconduct has occurred.
 - The allegation is not supported by the evidence.
 - A discussion on the documentation, physical evidence, testimony, and reasoning that supports the finding.

11.3.2. Review of the report by the RIO shall confirm that:

- The investigation committee has completed its charge
- The report provides sufficient information to justify the committee's findings
- The report is in proper form
- The report does not include information that is not inappropriate

11.3.3. Inadequate report

- The RIO will request that the investigation committee modify a report deemed inadequate.

- The investigation committee shall rapidly modify and revise the report to the satisfaction of the RIO and re-submit a signed report to the RIO.

11.3.4. Final Report

- The RIO shall submit a copy of the final report to the Respondent.
- The Respondent must submit any comments or suggested revisions in writing to the RIO within 14 days of receipt.
- The Respondent's suggested changes shall be immediately submitted back to the investigation committee where they will become a permanent part of the investigation committee record. The investigation committee may or may not revise the report.
- The final report, signed by the investigation committee shall be submitted to the RIO within seven calendar days of receipt of the Respondent's response unless additional time is requested and granted by the RIO.
- In consultation with the Scientific Director and Institute Counsel and quickly after receiving the final report, the RIO shall determine whether a preponderance of the evidence in the report supports a finding of research misconduct.
- The RIO shall provide the Respondent with a copy of the report and a statement on the results of the investigation.
- The RIO shall promptly notify, and at the RIO's discretion provide a written summary of the investigation committee's findings and the RIO's determination in the case to, those notified of the investigation, the Complainant, witnesses, and all other interested parties.
- Typically within seven calendar days after the RIO's final determination of the findings of the investigation and in compliance with regulations or contractual agreements, the RIO shall provide a copy of the report, including the actual text or an accurate summary of the Respondent's response and a description of any sanctions taken against the Respondent, to the appropriate funding agencies and affiliated institutions.

12. Investigation Outcomes and Action

12.1. Allegations not supported by the investigation

- A diligent effort will be made by the RIO and the Respondent to make known the outcome of the investigation to appropriate individuals and organizations identified by the RIO with the intention of restoring the Respondents reputation if it is deemed to have been affected by the allegation.

12.2. Allegations determined unlikely to be research misconduct but commonly accepted research standards or Institute policies may have been violated

- Findings will be summarized by the RIO in a memorandum.
- The memorandum is submitted to the Scientific Director of the Institute for disciplinary action.

12.3. Allegations determined to be research misconduct

- After complying with Institute and funding agency notification requirements, the RIO shall initiate disciplinary action
- In consultation with the Scientific Director of the Institute and Institute counsel, the RIO shall implement corrective action including correction of the published record.

13. Appeals

The findings of the investigation committee and the RIO's final determination as to whether research misconduct occurred shall not be subject to appeal by any party.