IWK Research Ethics
Standard Operating Procedures

Document # **RE 4.407**	Title: **Non-compliance and Ethical Impropriety**	Effective Date: **November 19, 2024**
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POLICY STATEMENT

The IWK promotes and upholds the highest ethical standards in the conduct of human research and expects IWK investigators to comply with generally accepted national and international guidelines and regulations and any specific additional requirements imposed by the REB. Investigators and others in the IWK who become aware of any deviation from these standards occurring must promptly inform the REB.

DEFINITIONS

See Glossary of Terms

RESPONSIBILITY

This SOP applies to Investigators, REB Chair, Manager and REB members and Research Ethics Office (REO) staff.

PROCEDURES

Reporting Concerns

Reports of non-compliance in human research may come from many sources including but not limited to: An investigator (as a self- report), a study monitor, IWK based compliance and review offices; a sponsor; a research participant; a department chair; a member of the research team; or a person not directly involved in the research.

Persons raising such concerns are encouraged to submit them in writing. However, verbal concerns will be received and recorded by the REO staff, for onward passage to the Chair.

Malicious complaints will be referred to IWK Management, to the IWK MDSS, or to Dalhousie University, as appropriate.

Compliance Review

1. Directed Reviews: The Chair may initiate a directed review of any approved research in progress to ascertain compliance with ethical standards. Triggers for review may include:
   - REB concerns
   - A complaint from an external source
   - An internally initiated complaint or concern
   - An investigator with a history or poor adherence to IWK policies and procedures

2. Routine Reviews: Routine compliance reviews are conducted from time to time on active or recently active projects chosen by random selection, with a bias towards a greater proportion of above minimal risk studies. Routine compliance reviews may include but are not limited to the following:
   - Examination of the entire research project
   - Review limited to advertisements and other recruiting materials
   - Review to determine if unapproved changes have been incorporated into the study
   - Comparison of data on case report forms to the original source documents

Allegations of non-compliance

When an allegation of non-compliance is referred to the REB, the Chair will assess the allegation to determine its validity. The Chair may then select any of the following methods to gather the required information:

- Conduct an initial review alone
- Convene a subcommittee of the REB to conduct a review
- Seek guidance from IWK counsel
- Request that the Research Review Committee conduct a directed review

In most instances, if the REB Chair has confirmed the validity of the complaint, he/she will request that the Research Review Committee conduct a directed review.

Research Review Committee will conduct a review and produce a written report of the findings and evidence, and include an opinion on the significance of any findings of non-compliance.

- The final report of the review committee will be sent to the PI, the REB Chair, and the VP Research
- Where there have been no findings of non-compliance, or where the non-compliance is deemed to be not serious or not continuing and the investigator has taken appropriate corrective measures, no further action will be taken
- If the review results in findings of significant non-compliance, the REB Chair will determine an appropriate course of action
  - For less serious infractions, the Chair may offer advice to the investigator on how best to overcome the difficulties
  - If the non-compliance is serious and/or continuing, the Chair will inform the investigators Head of Department or discipline chief, and the VP Research

    - The Chair may also inform any involved Sponsor, Funding Agency, or Regulatory Agency, particularly in matters involving patient safety
- Any evident malfeasance on the part of the investigator will be referred to the VP Research to be dealt with in accordance with the IWK Research Integrity Policy
- If in the course of the review it emerges that the initiating complaint may have been made maliciously, the VP research will take up the matter with the appropriate Health Centre or University authority

Actions that the REB May Consider in Responding to Serious or Continuing Non-compliance
The actions the REB may take in response to serious or continuing non-compliance include, but are not limited to, the following:

- Seeking more information pending a final decision
- Referral
- Request modifications to the research protocol
- Request modification of the information disclosed during the consent process
- Request additional information be provided to past participants
- Requiring notification of current participants (required when such information may relate to participants' willingness to continue to take part in the research)
- Requiring current participants re-consent to participation
- Request modification of the continuing review schedule
- Initiate or increase monitoring of the research
- Request that the consent process be monitored
- Suspend the research
- Terminate the research
- Referral to the VP Research when institutional action is deemed appropriate

Notifications
The REB will notify the investigator in writing of the results of the investigation and of any remedial actions required by the REB. Depending on circumstances, the Chair may send a copy of this letter to the investigator's Department/Division Head and the Vice-President, Research. The letter will include a request for the investigator to respond in writing. A record of the nature of the event, the findings, actions taken, and plans for continued investigation or action if required, will be added to the REB project file.

Unapproved Research
Any unapproved research coming to the attention of the REB or REO Staff will be immediately referred to the VP Research, who may or may not involve the REB in the further management of the problem.

Note: US regulations will be applied as applicable.

REFERENCES

1. Tri-Council Policy Statement: Ethical conduct for Research Involving Humans, 2018: (short name: TCPS 2), Article 2.8 and 6.12;
2. The International Conference on Harmonization Good Clinical Practices, Sections 3, 4.4, 4.5, 4.10, 4.11, 4.12;
3. US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.109, 46.111, 46.113, 46.115;
4. OHRP Guidance on Continuing Review;
5. US Food and Drug Administration (FDA) CFR Title 21 Part 56.108, 56.109, 56.110, 56.111, 56.115;

Forms/Records:

Form #	Form/Record Name
SOP 407	Non-compliance and Ethical Impropriety

Revision History:

Revision	Date	Description of changes
0.0	April 1, 2017	Initial Release
1.0	September 9, 2022	Additions to comply with TCPS2-2018
1.1	February 1, 2023	Updated logo
1.2	November 19, 2024	Added note regarding compliance with US regulations where applicable & update to responsibility (RIA)