



IWK Health

**IWK Research Ethics
Standard Operating Procedures**

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PURPOSE

The purpose of this standard operating procedure (SOP) is to outline when the Research Ethics Board (REB) requires a letter of support and the signature page.

DEFINITIONS

See Glossary of Terms

RESPONSIBILITY

This SOP applies to the IWK research community (including employees, investigators, physicians, management, consultants, students, volunteers or other personnel) involved in the conduct of research involving human subjects.

PROCEDURES

What is meant by “letter of support”?

A letter of support serves to inform the REB that individuals, divisions, or departments potentially impacted by the research endorse the study. This ensures there is no research fatigue within a division and/or a study population and that similar studies are not being duplicated. Confirms no other issues were identified i.e. Would opening a study negatively impact recruitment to other studies within the division, does the division head agree this is an appropriate study that they support, etc. does the PI have the capacity to take on another study, etc.

When is a letter of support needed?

A letter of support is required from the Principal Investigator's (PI) supervisor, or division head, and must be included with the initial application. If the division head is listed on the application, the letter of support needs to be signed by the department head. Additional letters of support

are necessary if the research activities are conducted outside the PI's division or clinic; in such cases, support from the applicable clinic manager is required.

Furthermore, a letter of support is required from each division/department whose resources are impacted by the research, such as pharmacy, laboratory, diagnostic imaging, etc. This is separate and independent of the costing form.

In certain situations, a letter of support may be needed from those responsible for a specific population or community. For example, if involved, approval is required from following; the Reproductive Care Program (RCP), Joint Data Access Committee (JDAC), Halifax Regional Centre for Education (HRCE), Mi'kmaw Ethics Watch.

GUIDANCE

- The letter must be from an individual who has the authority to commit on behalf of the location or population they are representing. (e.g. school board approval, lab/clinic manager/head of division).
- For IWK departmental support, either the REB provided template, or an email can be used.
- For support from outside of the IWK, letterhead with signature or email from the individual's official email address that can be confirmed by the REB, is needed. In some cases, external REB approval letters may be acceptable.
- For support outside the IWK, the letter does not need to include final approval to conduct the research. For example, the HRCE follows a formal process to review and approve research, which may involve a review of the REB-approved protocol. While the individual or organization may still need to review the final IWK REB approval, the letter can indicate their support for the research and confirm that the study's conduct is feasible pending additional review.
- Must include the name of the study or project, and a clear indication that this support is specific to the study or project being proposed in the REB application.
- The department, clinic, or business providing the letter of support is not responsible for guaranteeing the success of the study. For instance, a school principal is not required to ensure that parents agree to participate in the study.
- The individual providing the letter of support must show they are informed about the study's aims, the resources requested, they are able and willing to provide those resources in support of the study.
- The letter can either be provided on the template, IWK letterhead or email.

Note: US regulations will be applied as applicable.

DEFINITIONS

Principal Investigator (PI) - The person responsible for the conduct of a research study at IWK Health

Researchers - Anyone who conducts research activities falling under the jurisdiction of the IWK Research Ethics Board.

REFERENCES

TCPS2 [Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS 2 \(2022\) – Glossary \(ethics.gc.ca\)](#)

Revision History:

Revision	Date	Description of changes
0.0		Initial Release
1.0		