Saskatchewan Health Authority

Operational Approval Requirements for REB-Exempt Projects

Guidance for researchers, investigators, and study teams

Key message

An REB Letter of Exemption confirms the ethics-review pathway. It does not authorize access to SHA patient PHI, administrative data, patients, clients, residents, staff, facilities, services, systems, recruitment pathways, or other operational resources. Operational Approval is required when SHA resources are used or impacted.

Purpose and scope

A Research Ethics Board (REB) Letter of Exemption confirms that a project does not require full REB review. REB exemption does not automatically waive the requirement for Saskatchewan Health Authority (SHA) Operational Approval (OA).

OA is required when a project involves: SHA patient personal health information (PHI), SHA administrative data, patients, clients, residents, staff, facilities, equipment, services, clinical systems, recruitment through SHA, or other SHA operational resources. This includes quality improvement, quality assurance, program evaluation, chart review, audit, case reports, and case series when they require SHA information, record access, or support from an SHA department.

The OA process confirms the applicable authority, privacy requirements, data-stewardship approvals, operational capacity, and departmental support. As required, the OA team coordinates review with impacted operational leaders, Privacy, data stewards, Health Information Management Services, Advanced Analytics, Digital Health, and other relevant departments before issuing a Letter of Authorization.

Required pathway

1. Obtain the ethics determination

If an activity is quality improvement, quality assurance, program evaluation, or otherwise believed to be exempt from REB review, obtain a formal exemption determination from the Research Ethics Office before proceeding. See the separate guidance below for case reports and case series.

2. Assess SHA involvement

After the exemption determination is issued, determine whether the project involves SHA PHI, administrative data, patients, clients, residents, staff, facilities, equipment, services, systems, recruitment pathways, or other operational resources.

3. Submit for Operational Approval

When SHA data or operational resources are involved or affected, submit an OA application. Do not access records, recruit participants, use SHA systems, or begin activities requiring SHA support until the required authorization is in place.

4. Reassess changes

If the project scope changes after the exemption determination or OA is issued, contact the OA team before implementing the change. An OA amendment may be required.

Apply for Operational Approval: Open the OA application

When OA may not be required

An OA application may not be required when an REB-exempt project involves no SHA PHI or administrative data and no SHA patients, clients, residents, staff, facilities, equipment, services, systems, recruitment pathways, or other operational resources. Document the rationale and contact the OA team if the scope changes.

Decision guide

Project situation	Is OA needed?	Direction
Research involves SHA PHI, administrative data, people, facilities, services, equipment, or systems	**Yes**	Submit an OA application. OA is required when SHA resources are used or affected.
An REB-exempt project uses SHA PHI, administrative data, staff time, facilities, services, systems, or operational support	**Yes**	Submit an OA application so operational, privacy, data-stewardship, and departmental reviews can be completed.
Quality improvement, quality assurance, or program evaluation may involve SHA information, people, staff, facilities, or resources	**Yes, when involved**	First obtain an exemption determination. Submit an OA application when SHA data or resources are involved.
Audit, chart review, or evaluation uses SHA records, administrative data, or data-extraction support	**Yes**	Submit an OA application to confirm authority, privacy, data stewardship, and departmental approvals.
Recruitment occurs through SHA patients, clients, residents, clinics, programs, services, or staff	**Yes**	Submit an OA application because SHA recruitment pathways and operational areas are involved.

Project situation	Is OA needed?	Direction
SHA staff will collect, extract, validate, prepare, disclose, or transfer data	**Yes**	Submit an OA application. The impacted department must authorize the requested staff time or service.
Access is required to SHA systems, databases, registries, dashboards, or reports	**Yes**	Submit an OA application. System and data access require operational, privacy, and data-stewardship review.
Support is required from HIMS, Privacy, Digital Health, Advanced Analytics, Pharmacy, Laboratory, Medical Imaging, or another department	**Yes**	Submit an OA application so the OA team can coordinate the required departmental review.
A data-sharing, data-transfer, material-transfer, research, or other project agreement is required	**Usually yes**	Consult the OA team before initiating agreement or contract review. Ethics and OA documentation may be required.
The project has no SHA PHI, administrative data, people, staff, facilities, services, systems, recruitment pathways, or operational support	**Usually no**	OA may not be required. Document the rationale and contact the OA team if the scope changes.
An internal activity uses existing SHA resources, with no secondary use of PHI or administrative data and no additional support	**May not be required**	Obtain an exemption determination if the activity may be research, QI, QA, or program evaluation. Consult OA if documentation is needed or impact is unclear.
A project with OA changes activities, data sources, staff access, departments, facilities, team members, systems, or timelines	**Amendment may be required**	Submit an OA amendment or consult the OA team before implementing the change.
A previously approving department has no new work under a later amendment	**No new approval unless impact changes**	The department may still be copied on the amended Letter of Authorization for transparency and continuity.
The study team is unsure whether OA is required	**Consult OA**	Contact the OA team before proceeding.

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Case reports and case series

A case report generally describes one patient, while a case series describes a small group of patients. A descriptive case report or small case series that is not intended to contribute to generalizable knowledge may not require full REB review. Obtain guidance or a formal determination from the Research Ethics Office before proceeding, particularly when more than one case is involved or when there is uncertainty about whether the activity is research.

REB Exemption Determination Application: Download the application

Operational Approval is required when a case report or case series requires access to SHA health records, PHI, staff, facilities, services, systems, or other operational resources. This applies whether the records are physical or electronic. Required OA and privacy reviews must be completed before records are accessed or information is used, disclosed, submitted, presented, or published.

Consent and privacy requirements

Written patient consent for publication or presentation is generally required, including when information has been de-identified, because complete anonymity cannot always be guaranteed. If the patient cannot provide consent, the authority and appropriateness of consent from a legally authorized substitute decision-maker must be assessed through applicable SHA privacy and operational processes.

Case reports and case series often contain detailed clinical narratives and small patient numbers, increasing re-identification risk. Collect, use, and disclose only the minimum information necessary. Do not include names, initials, health card numbers, exact dates, specific locations, rare diagnoses, unique clinical circumstances, photographs, diagnostic images, or other potentially identifying details unless necessary and appropriately authorized.

A journal or publisher consent form may be required, but it does not replace SHA privacy review, record-access authorization, or OA requirements. Consent materials, de-identification practices, and the proposed publication or presentation must be reviewed through the applicable SHA process before work proceeds.

Checklist

- Obtain guidance or a formal exemption determination from the Research Ethics Office.
- Submit an OA application when SHA records, PHI, staff, facilities, services, systems, or other operational resources are involved.
- Do not access records or use patient information until the required authorization is in place.
- Use only the minimum necessary information and address re-identification risks.
- Obtain and document the required patient or substitute decision-maker consent.
- Contact Privacy through the OA process regarding consent, de-identification, record access, and disclosure.

Questions

For questions about whether an activity is research or qualifies for an exemption, contact the Research Ethics Office. For questions about privacy, consent, de-identification, access to patient records, or

disclosure, contact Privacy and address the matter through the OA process before information is accessed or used.

Contacts and applications

Research Inquires: ResearchInfo@saskhealthauthority.ca

Research Ethics Office: ResearchEthics@saskhealthauthority.ca

Privacy Intake: Privacy@saskhealthauthority.ca

Operational Approval Office: researchapprovalregina@saskhealthauthority.ca
researchapproval.saskatoon@saskhealthauthority.ca

Operational Approval application: Open the online application