IWK Research Ethics
Standard Operating Procedures

Document # **RE 8.803**	Title: **Delegation of Responsibilities**	Effective Date: **November 19, 2024**
Pages**: 4**	Responsibility of: **Research & Innovation Advancement**	Date Approved: **November 19, 2024**

PURPOSE

The purpose of this standard operation procedure (SOP) is to outline the procedures for the delegation of responsibilities for individuals involved in conducting any human research where key responsibilities are delegated by the Principal Investigator (PI).

DEFINITIONS

Refer to the Glossary of Terms.

RESPONSIBILITY

This SOP applies to the IWK research community, including employees, investigators, physicians, management, consultants, students, volunteers, and other personnel involved in conducting research with human subjects.

RATIONALE

Review of delegation logs by the REB can be helpful in validating or better understanding the nature of and distribution of research project roles, responsibilities, and accountabilities as articulated in the protocol.

PROCEDURES

Delegation of Authority Process:

1. Determination of Delegation Log Requirements:
    - A delegation log **is** required to be submitted to the Research Ethics Board (REB) for studies with three or more study personnel.
    - A delegation log is not required to be submitted to the REB for studies that exclusively involve health records or database reviews without participant contact.
    - For sponsored trials, the delegation log can be submitted after REB approval and prior to study start as an acknowledgement request.

- For all other studies, the delegation log must be submitted with the original REB application. A revised delegation log must be submitted whenever there is a personnel change affecting the original log and signed by the new/changing study team members.

2. Delegation Log Completion:
    - Before beginning research-specific tasks, the PI, with the study team's assistance, will complete and maintain a current study specific delegation log. An example of a delegation log is attached to the IWK application forms.
    - The PI will review the protocol documents to identify any protocol-specific tasks that will be delegated to study team members.
    - Each protocol requires a separate delegation log. The original log will be filed with the study's site files. Studies may use a combination of hard copy and electronic logs if needed.
3. Clinical Trials Compliance:
    - According to the International Conference on Harmonization Good Clinical Practice (ICH GCP), a delegation log must be used for all prospective clinical trials (e.g., device, biologic, behavioral, drug).
    - For sponsored trials, the sponsor will typically provide the delegation log. If the Sponsor does not provide a delegation log the study team will be responsible for ensuring one is created and maintained throughout the duration of the study.
4. Significant Study-Related Duties:
    - The delegation log will list each study team member assigned significant research-specific tasks, as determined by the PI. These duties are generally those that impact subject safety, protocol compliance, and data quality/integrity (e.g., obtaining informed consent, performing study-specific procedures, collecting data, regulatory compliance, assessing primary endpoints, attributing adverse events, and dispensing investigational products).
5. Exclusion of Routine Personnel:
    - Personnel performing administrative tasks or routine procedures (e.g., standard care assessments) are not considered key personnel and will not be listed on the delegation log unless they make a direct and significant contribution to the research. This includes inpatient or clinic nurses, radiologists, pathologists, technicians, residents, fellows, and administrative staff, unless specified by the PI.
6. Education and Training:
    - All staff delegated significant study-related duties must complete appropriate education and training as directed by the study sponsor and/or institution. Documentation of such training must be maintained and filed with the study's site files.
7. Qualifications Documentation:
    - At a minimum, Curriculum Vitae (CV) and TCPS2 – 2022 certifications must be on file with the Research Office for all team members listed on the delegation log.

- For clinical trials, Good Clinical Practice (GCP) certification must be on file with the Research Office for all team members listed on the delegation log.
- For studies involving Indigenous peoples, Ownership, Control, Access & Possession (OCAP) certification must be on file with the Research Office for the local PI.

8. Acknowledgement of Duties:
    - Each study staff member will acknowledge their delegated duties by signing, dating, and initialing the delegation log.
9. Documentation of Tasks and Responsibilities:
    - The delegation log must document the research-specific tasks for each person, including start and end dates of their involvement with the protocol.
10. Maintenance and Review:
    - The PI, with the study team, must ensure the delegation log is maintained, reviewed, and signed off in a timely manner for all active studies.
11. Regulatory Compliance:
    - The delegation log is a required regulatory document and will be requested during audits and inspections.

Note: US regulations will be applied as applicable.

DEFINITIONS

Delegation Log – A comprehensive list of study staff members and the duties that have been delegated to them by the Principal Investigator.

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)

IWK REB SOP 801 Responsibilities of Investigators, Investigator Qualifications and Responsibilities

Revision History:

Revision	Date	Description of changes
0.0		Initial Release