

This document applies to	<input checked="" type="checkbox"/> All Horizon	<input type="checkbox"/> Fredericton Area	<input type="checkbox"/> Miramichi Area
	<input type="checkbox"/> Moncton Area	<input type="checkbox"/> Saint John Area	<input type="checkbox"/> Upper River Valley Area

**Horizon Health Network  
Policy & Procedure Manual  
Administrative Oversight of Research Studies**

**POLICY**

Any *research study* conducted within Horizon Health Network (Horizon), or accessing the patients/clients of Horizon or using Horizon services, resources and/or departments, are administratively overseen by the Office of Research Services to ensure that all legal, financial, ethical and infrastructure requirements are met.

**DIRECTLY AFFECTED**

**Horizon**

Office of Research Services employees, *Principal Investigators*/delegate(s), and Executive Management Team members/delegate(s)

**Contractors**

*Sponsors*, granting agencies and/or contractual parties associated with research activity within Horizon

**PROCEDURE**

1. The Principal investigator notifies the Office of Research Services of her/his intent to participate in a research study **prior** to engaging in any research activities at Horizon, by submitting the study protocol.
2. The Office of Research Services reviews the list of the research studies submitted for Horizon’s Research Ethics Board (REB) approval to confirm that the appropriate steps have been initiated to address the legal, financial, ethical and infrastructure requirements of the research activity, ensuring, but not limited to, the following:
  - Legal - acceptable agreement terms and conditions, appropriate parties to the agreement, review of liability under the agreement
  - Financial - initial review of financial feasibility, allotment for *overhead fees* (if applicable), payment terms
  - Ethical - submission to Horizon’s REB, approval status
  - Infrastructure - space, education/training, Horizon resources and/or departmental impact and feasibility
3. The Office of Research Services contacts the Principal Investigator if additional information or clarification is required.

**DEFINITIONS**

**Overhead Fees** - also referred to as indirect costs, are expenses incurred by Horizon Health Network for supporting the conduct of research, and which are not readily identified as direct expenses. Examples of overhead fees include the provision of research space and utilities (security, maintenance, custodial and heating), department of Financial Services (payroll, purchasing, accounting), generalized support services (computer services, library, human resources) and research support services.

**NOTE:** This is a **CONTROLLED** document. Any document appearing in paper form is not controlled and should **ALWAYS** be checked against the electronic version prior to use. Printed on: 08/08/2017

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**Principal Investigator (PI)** - the person responsible for the conduct of a research study at Horizon Health Network.

**Research Study** - any study that has been approved by the Horizon Health Network's Research Ethics Board.

**Sponsor** - an individual, company, institution, or organization that initiates, manages, has regulatory responsibility for (if applicable), and may fund (in whole or in part) a research study.

## RELATED DOCUMENTS

[Financial Management of Research Accounts](#) (HHN-RS-005)

[Research Agreements \(Contract and Grant\)](#) (HHN-RS-006)

[Research Overhead Fees](#) (HHN-RS-007)

[Research Study Sponsor's Reimbursement for Services](#) (HHN-RS-008)

## REFERENCES

Cassidy, Jane. (2002). Data and Data Management in Clinical Trials. In Gallin J, Principles and Practice of Clinical Research (p 69). California: Academic Press.

Horizon Health Research Ethics Board <http://en.horizonnb.ca/home/research.aspx>