

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 Research Agreements (Contract and Grant)

### POLICY

An executed [research agreement](#) is required before engaging in any research activities at Horizon Health Network (Horizon). Research agreements incorporate legal terms and legally bind all parties to the obligations set forth in the agreement.

The [Principal Investigator](#) is a party to the Research Agreement and signs on his/her own behalf. Principal Investigator signatures do not bind Horizon. [Institutional signatures](#) legally bind Horizon and the Principal Investigator to the obligations set forth in the agreement.

All research agreements are centrally reviewed by the Horizon Regional Contract and Grant Administrator in the Office of Research Services. The types of agreements that are reviewed include, but are not limited to:

- [clinical trial](#) agreements
- confidentiality agreements
- material transfer agreements
- consulting agreements
- [research grant](#) agreements
- [research contract](#) agreements
- collaboration agreements
- memorandum of understanding

The review process ensures that the agreement is:

- in the interest of Horizon, including staff, physicians, patients and clients.
- fiscally responsible and includes the appropriate budget considerations.
- consistent with standards and regulations governing research.
- approved as required by law and the policies and practices of Horizon.
- circulated appropriately for additional internal consultations, if required.
- identifying potential issues of indemnification and insurance, giving attention to mitigation and management of risk.
- addressing concerns of publication rights, intellectual property considerations, patient safety, potential conflict of interest scenarios, among others.

### 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

**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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## PROCEDURE

To achieve an executed agreement:

1. **Submission:** Principal Investigator/delegate submits the agreement, protocol and budget to the local manager of Research Services. The submitted documents are forwarded to the Regional Contract and Grant Administrator in the Office of Research Services.

*Note: Submitting the Research Agreement for Institutional review and approval is separate from submitting to the Research Ethics Board (REB) for review and approval; however, both submissions can occur simultaneously. REB approval is not required prior to the agreement review.*

2. **Acknowledgement of Receipt:** The Regional Contract and Grant Administrator sends acknowledgement of receipt of the submission to the Principal Investigator/delegate.
3. **Negotiation:** The Regional Contract and Grant Administrator negotiates the agreement with the identified parties and communicates with the Principal Investigator/delegate.
4. **Signature and Approval: Institutional signing authority**
  - 4.1 The Principal Investigator receives the final copy of the agreement for review and signature and forwards to the local Research Office. The Principal Investigator is responsible for meeting her/his obligations under the research agreement.
  - 4.2 The local Research Office then forwards the signed agreement to the Regional Contract and Grant Administrator who obtains Institutional signatory approval.
  - 4.3 All research agreements are presented to the President and Chief Executive Officer of Horizon, or delegate, for the final execution and signature approval.
  - 4.4 The Regional Contract and Grant Administrator then forwards the signed agreement to the Sponsor for final execution.
  - 4.5 The Sponsor signs the agreement and returns two of the three signed originals to the Regional Contract and Grant Administrator who then forwards one of the signed original agreements to the Principal Investigator to be maintained in their files.
  - 4.6 Signed agreements are maintained in this priority:
    - Sponsor
    - Regional Contract and Grant Administrator
    - Principal Investigator
    - One copy is sent to the applicable local Research Office by the Regional Contract and Grant Administrator

## DEFINITIONS

**Clinical Trial** - a research study conducted in humans and designed to answer specific questions using scientifically controlled conditions, with specified methodologies and endpoints.

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

**Research Agreement** - a legally binding written document (e.g. Research Contract or Research Grant) between Horizon and one or more parties for the purposes of conducting research at Horizon.

**Research Contract** - a legally binding agreement between a researcher, Horizon Health Network and a Sponsor (e.g. a private corporation) that guarantees financial support to an Investigator to conduct research under conditions defined by the Sponsor within a Horizon facility and in accordance with agreed upon deliverables.

**Research Grant** - an agreement under which a public or private organization provides funding to pay for all or part of the costs of a research study. A research grant does not typically require the researcher to deliver a pre-determined set of research outcomes.

**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**

[Administrative Oversight of Research Studies](#) (HHN-RS-004)

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

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

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