

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 Study Sponsor’s Reimbursement for Services

POLICY

Standard of care and *non-standard of care services* for *research studies* are determined for appropriate reimbursement purposes.

Receiving reimbursement for standard of care services from both the research study *Sponsor* and *New Brunswick Medicare (NB Medicare)*, directly or indirectly, is a breach of the Medical Services Payment Act and Regulations.

Neither the Horizon Health Network (Horizon), nor the *Principal Investigator* will obtain reimbursement from NB Medicare for amounts paid by, or on behalf of, the Sponsor, nor for any materials including study drugs that were provided by, or on behalf of, the Sponsor at no cost to Horizon and/or the Principal Investigator/delegate. To do so could be a material breach of the agreement between Horizon, the Principal Investigator and the Sponsor, and could result in termination of the agreement by any of the Parties to the Agreement, and repayment to NB Medicare by the Principal Investigator.

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. Upon review of the study protocol, the distinction between standard of care and non-standard of care services, as well as the frequency of those services to be completed during the course of the study, is determined by the Principal Investigator.
2. The Principal Investigator communicates these distinctions to the Sponsor and ensures the negotiated budget reflects the appropriate standard of care services covered by NB Medicare (not reimbursed by the Sponsor), and non-standard of care services reimbursed by the Sponsor.
3. If the Sponsor is reimbursing for a study service, the Principal Investigator ensures that the study Sponsor, and not NB Medicare, compensates the affected department for the service provided. [See [Financial Management of Research Accounts](#) (HHN-RS-005)].
4. The Principal Investigator ensures that the research budgets cover all of the services that are over and above standard of care and seeks reimbursement accordingly (see [Table below](#)).

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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Examples of Sponsor's reimbursement responsibility for Standard of Care and Non-Standard of Care Services:

Conditions	Standard of Care Services	Research Protocol Requirements	Sponsor's Responsibility
Condition A	None	Yearly MRI	Reimburse for cost of the MRI.
Condition B	Yearly Chest x-ray (Covered by NB Medicare)	Yearly Chest x-ray (Read & reported locally, but data included in Case Report Form)	No reimbursement required.
Condition C	Yearly Chest x-ray (Covered by NB Medicare)	Yearly Chest x-ray (Read & reported locally) -Sponsor would like the Chest x-ray archived & forwarded to them	Reimburse for the additional work & time required to archive & forward the x-rays.
Condition D	Yearly Chest x-ray (Covered by NB Medicare)	Yearly Chest x-ray - Chest X-ray is performed specific to the study protocol procedures/technique, which differ from standard practice	Reimburse for the yearly Chest x-ray.
Condition E	Yearly Chest x-ray (Covered by NB Medicare)	Chest x-ray every 3 months (4 Chest x-rays a year) (Read & reported locally)	Reimburse for 3 Chest x-rays a year.

DEFINITIONS

New Brunswick Medicare - Under the terms of the Canada Health Act, all "insured persons" (legal residents of Canada, including permanent residents) are entitled to receive "insured services" without co-payment. Such services are defined as medically necessary services if provided in hospital, or by 'practitioners' (usually physicians). New Brunswick Medicare is the payer of standard of care services in NB.

Non-standard of care service - those services that are being carried out for the purpose of the study and are not part of standard of care.

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.

Standard of care - a medical or psychological treatment guideline indicating appropriate treatment based on scientific evidence and collaboration between medical and/or psychological professionals involved in the treatment of a given condition. In a research context, standard of care services are generally understood to be those services that are medically necessary independent of the study and as such payment for those services are generally reimbursed by New Brunswick Medicare.

RELATED DOCUMENTS

[Administrative Oversight of Research Studies](#) (HHN-RS-004)
[Financial Management of Research Accounts](#) (HHN-RS-005)
[Research Agreements \(Contract and Grant\)](#) (HHN-RS-006)
[Research Overhead Fees](#) (HHN-RS-007)

REFERENCES

Health Canada. Medicare. <http://www.hc-sc.gc.ca/hcs-sss/medi-assur/index-eng.php> accessed August 15, 2011

Province of NB. Medical Services Payment Act and Regulations
<http://laws.gnb.ca/en/showpdf/cs/M-7.pdf> accessed September 11, 2012

Wikipedia. Standard of Care definition. http://en.wikipedia.org/wiki/Standard_of_care accessed August 15, 2011