

Research St. Joseph's – Hamilton (RSJ-H)		Pages 1 of 5	Number 041-RSJ-H
Policy Title Clinician Remuneration from Industry Sponsored Research		Date 19 January 2015	
Supersedes New policy	Cross Reference 005-RSJ-H	Issuing Authority RSJ-H Board of Directors	
<input checked="" type="checkbox"/> Charlton Campus	<input checked="" type="checkbox"/> West 5th Campus	<input checked="" type="checkbox"/> King Campus	

Position responsible for developing and maintaining the policy: RSJ-H Scientific Director

1.0 BACKGROUND

Research St. Josephs – Hamilton (RSJ-H) is committed to academic freedom and excellence in research. We seek to ensure that the work conducted by their Faculty and staff meet the highest scientific and ethical standards.

Clinicians and other health care professionals may assume a number of positions and responsibilities in exercising the practice of health care and research at RSJ-H. Some of the roles and responsibilities may lead to real or perceived conflicts of interest. These include activities or situations that place an individual in a real or potential conflict between personal, institutional or other interests (including personal financial interests), and his or her duties, commitments or responsibilities to RSJ-H and St. Joseph's Healthcare Hamilton (SJHH).

In the context of treating patients in the academic setting of SJHH, clinicians are often providing the best possible health care to patients as well as in the secondary role of researcher. Both roles are often undertaken simultaneously when caring for patients in an academic setting. Given the different focus of the two roles, there is a potential for conflict of interest between them. One such conflict arising from the two roles is the remuneration of clinical activities undertaken in the conduct of research.

To maintain public trust and confidence RSJ-H and SJHH must deal with conflict in a fair, open, consistent, and practical manner. This requires that real or perceived conflict situations be identified and managed. The appearance of a conflict may be as damaging to the public trust and institutional reputation as an actual conflict. For this reason any perception of conflict must be disclosed, evaluated and managed with the same thoroughness as actual conflicts.

2.0 PURPOSE

The purpose of this policy is to clearly define the parameters of clinician remuneration amounts and the criteria that must be met in order for remuneration to occur.

3.0 POLICY

3.1 Principles

3.1.1 Compensation

Recognizing that overseeing and caring for patients in clinical trials can be a considerable amount of work (e.g. ensuring eligibility, examination of patients, oversight of care, review of records with monitors/company/Health Canada etc.) the Ontario Ministry of Health clearly indicates in the billing schedule that clinical services conducted purely for research are not eligible for payment by the Ontario Ministry of Health and Long Term Care. As such, physicians evaluating patients purely for research purposes should not be submitting billing to OHIP. Physicians and other health care providers can be compensated for their time in evaluating and managing patients in research protocols assuming (a) the patient is made aware of the payment, (b) the ethics review process and budget reflects the payment, and (c) there are sufficient funds in the research account for the payment. The payment should be commensurate with the amount of work.

3.1.2 Conflict of Interest

By accepting payment for services in a clinical trial, clinicians and other health professionals introduce a potential for significant conflict of interest in their respective roles as care provider and as health professionals being paid for working on behalf of a third party (industry or other sponsored clinical trial). The real or perceived conflict must be recognized and considered in any policy developed for compensation. All possible avenues should be sought to minimize real and perceived conflicts. This would include education of health professionals, review and approval of all fees and salaries charged by investigators, minimizing direct links between patient enrolment, consent and participation, and clinician fees. The consent process should also be adapted to minimize conflict of interest including informing potential research participants about the remuneration.

3.1.3 Rate of Remuneration

The fees disbursed to health professionals must be proportionate to the work performed. The rate of pay should not act as an inducement for clinicians to enroll patients in clinical trials. The rate of remuneration for direct patient contact should not exceed that which would be provided under the OMA fee schedule, or in the case of non-covered services at a rate of reimbursement for an equivalent service. It is appreciated that many clinicians conduct clinical research without any formal remuneration for their services. For activities where remuneration will be requested the allowable amount must be explicitly stated in each study budget. This remuneration may be disbursed to the clinician.

3.1.4 Academic Mission

All clinicians at RSJ-H must strive to support the academic mission of SJHH. Clinical investigators must uphold first their patient's trust, and second the academic

mission of the hospital beyond any potential self-interest such as fees for services rendered.

3.1.5 Disclosure

In order to mitigate the perceived and real conflict arising from accepting fees for clinical research services in clinical trials, the Research Ethics Committee must be made aware of the intention to seek remuneration. Patient consent and/or information sheets must disclose the financial arrangement in order to mitigate any perception of conflict of interest. Clinicians should also inform patients directly and ensure that the consent process is not coercive in any way.

4.0 **POLICY STATEMENT**

Clinician Remuneration from Industry sponsored research will be allowed provided that:

1. The Research Ethics Board is informed of the real or perceived conflict of interest.
2. Research participants are made aware of the financial arrangement.
3. Payments do not exceed budget line items.

5.0 **PROCEDURE**

5.1 **Pre-Recruitment**

- 5.1.1 Research Ethics Board application and patient information submitted to the Research Ethics Board to disclose any financial remuneration to clinician.

5.2 **After Study Close-out**

- 5.2.1 Research to complete and submit a cheque request and "Application for Clinician Remuneration" form to Research Administration, with study budget and patient disclosure documentation.
- 5.2.2 Request for remuneration not to exceed budgeted and disclosed amounts.

6.0 **DOCUMENTATION**

Cheque request sent via email or memo accompanied by the "Application for Clinician Remuneration" form to include study budget and patient disclosure documentation.

7.0 **REFERENCES**

Ontario Hospital Research Institute Administrative Policy – Clinician Remuneration from Industry-Based Clinical Trials

8.0 ATTACHMENTS

Application for Clinician Remuneration Form from Industry Sponsored Research

Application for Clinical Remuneration Form From Industry Sponsored Research

Study Information			
Investigator:			
Study Title:			
Account No:			
Protocol / REB ID#			
Date			
Activity		Patient Study ID	Fee Submitted
Grand Total \$			

NOTE:	Cheques will be made payable to the Physician's Clinical Practice Plan and forwarded on your behalf where applicable – otherwise, they will be directed to the clinician.
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Attachments:

- Study Budget
- Latest REB Approved Consent Form

✓ I hereby acknowledge that I have not applied for or received funding from any public or private health insurance or other third party for the clinical research related expenses that are being claimed.	Yes	<input type="checkbox"/>
	No	<input type="checkbox"/>
✓ In addition, the rate of remuneration for direct patient contact does not exceed that which would be provided under the OMA fee schedule.	Yes	<input type="checkbox"/>
	No	<input type="checkbox"/>

Certified as a True Claim	Claim Authorized
Investigator Signature	Authorized Research Administration Signature
Date	Date