February 18, 2003

To: Clinical investigators of McMaster University Faculty of Health Sciences, Hamilton Health Sciences, St. Joseph’s Healthcare Hamilton

From: John G. Kelton, Dean and Vice-President, Dean and Vice-President, McMaster University Faculty of Health Sciences

Murray T. Martin, President and CEO, Hamilton Health Sciences

Kevin Smith, President and CEO, St. Joseph’s Healthcare Hamilton

Essential changes in the way indirect research costs are funded at our institutions will be put into effect April 1, 2003.

The indirect cost, or overhead rate, will be 30 per cent of the overall research budget on all private sector funded clinical trials signed on or after April 1, 2003.

This change will affect any new or renewed clinical trial contracts being conducted through the auspices of McMaster University Faculty of Health Sciences, Hamilton Health Sciences and St. Joseph’s Healthcare Hamilton. This change will not affect clinical trials funded by peer-review sponsors (CIHR, NCIC, HSFO, etc). As well, clinical trials managed through the Hamilton Regional Cancer Centre are not affected at this time.
The costs of conducting clinical research have been rising steadily, particularly where new drugs or devices are being tested. Our overhead rate has been the lowest in the country and has not changed since 1995. The new rate will be at the median of the rates charged by our peer hospitals and universities.

The overhead rate assists our institutions in providing the research facilities, research office space, equipment, resources, libraries and administrative services essential to support research. In addition to essential infrastructure, our institutions pay for, or subsidize, ethics reviews, grant application processes, budget setting, account management, purchasing, audit, financial reporting, human resource counsel, payroll, risk management, and computer systems networking.

The overhead rate will be distributed as follows:

- Principal Investigator: 3%
- Hospital: 17%
- Faculty of Health Sciences: 10%
- TOTAL: 30%

If you have questions concerning this issue or would like some assistance in notifying your sponsor, please contact the research administrator at the institution administering your research accounts.

**Hamilton Health Sciences**
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Thank you for your co-operation and your ongoing support of our research mandate.
Frequently Asked Questions (FAQ) about Indirect Costs

Q: What is the definition of “clinical trials”?  
A: Clinical trials include the development, conduct or evaluation of clinical trials including early development trials (Phase I and Phase II) as well as pre-marketing and post-marketing trials (Phase III and Phase IV) for assessment of the pharmaceutical, biologic and other clinical interventions, such as the development of equipment, prostheses, biomedical devices, etc. A Research Ethics Board (REB) review must be completed for all clinical trials.

Q: How can I tell if my current research project is affected?  
A: This change affects agreements signed by the Institution (i.e., Hamilton Health Sciences, St. Joseph’s Healthcare Hamilton or McMaster University) on or after April 1, 2003. It is not our intention to disrupt current negotiations or the relationship between the researcher and the sponsor.

Q: What types of contracts are included?  
A: This policy applies to funds received from the private sector to support the conduct of clinical trials research. It does not apply to research funded by the major peer-review agencies (CIHR, NCIC, HSFO, etc.); grants that prohibit such a surcharge by policy and contracts with government agencies in which there are agreed upon overhead rates. Contracts that currently have a 40 per cent overhead rate will not change.

Q: How will the overhead contribution funds be distributed?  
A: Each institution has a different formula for the distribution of these funds. All funds will be used to support research activities.

Q: Why are these additional funds required?  
A: The University, Hamilton Health Sciences and St. Joseph’s Healthcare Hamilton all share a mandate to foster excellent research, but are also accountable for a balanced budget. The new rate will be at the median of the rates charged by our peer universities and hospitals that conduct clinical research.