

News Release

NORTH AMERICA'S FIRST CLINICAL TRIAL OF PRESCRIBED HEROIN BEGINS THURSDAY

For immediate release

VANCOUVER, BRITISH COLUMBIA (February 8, 2005)—Enrolment begins here Thursday (Feb.10) in North America's first clinical trial of prescribed heroin for people with chronic heroin addiction who have not been helped by available treatment options.

The North American Opiate Medication Initiative (NAOMI) is a carefully controlled medical study (clinical trial) that will test whether medically prescribed heroin can successfully attract and retain street-heroin users who have not benefited from previous repeated attempts at methadone maintenance and abstinence programs.

The NAOMI study will enrol 470 participants at three sites in Vancouver, Montreal and Toronto. The Toronto and Montreal sites are expected to begin recruitment this spring.

Recruitment information for the study will be posted in Vancouver, Wednesday afternoon (Feb.9).

Each site will enroll about 157 participants. About half of these volunteers will be assigned to receive pharmaceutical-grade heroin (the experimental group) and half will receive methadone (the control group). The prescribed heroin will be self-administered under careful medical supervision within a specially designed clinic. Those in the heroin group will be treated for 12 months then transitioned, over three months, into either methadone-maintenance therapy or another treatment program. The researchers expect a 6-9 month recruitment period, so that the total time to complete the study will be 21 to 24 months.

Methadone, an oral medicine that blocks heroin craving and prevents heroin withdrawal symptoms, can be an effective treatment for some people with heroin addiction. However, a substantial proportion of people with heroin addiction do not benefit from methadone maintenance therapy. These individuals may represent just 10-20% of the heroin-addicted population, but they account for a disproportionately large percentage of the drug-related problems undermining public health, the criminal justice system and public order.

In 1973 the federal Commission of Inquiry into the Non-Medical Use of Drugs recommended that heroin-assisted therapy be tested in clinical trials. More recently, large studies in Switzerland and the Netherlands have indicated that heroin-assisted therapy is useful in helping some chronic users to stabilize their addictions, reduce criminal activity and lead more healthy and productive lives.

The Canadian Institutes of Health Research (CIHR) is providing \$8.1 million toward NAOMI and the study is approved by Health Canada. The principal investigator is Dr. Martin Schechter of the University of British Columbia Faculty of Medicine.

Ethical review boards at each of NAOMI's three sponsoring institutions—the University of British Columbia, Toronto's Centre for Addictions and Mental Health and Université de Montréal—have approved the study.

“Results from the European studies suggest that medically prescribed heroin could greatly help our most troubled heroin addicts—those for whom we have no effective treatments,” said Dr. Schechter. “But we won't know whether the same results hold true in the Canadian setting until we complete this carefully designed scientific study.”

“Heroin addiction afflicts an estimated 60 to 90,000 Canadians and the costs associated with it—in terms of human misery, public health, social problems and crime—are staggering,” said Dr. Alan Bernstein, President of CIHR. “Canada, and many other countries, therefore, need studies such as NAOMI to investigate new approaches to reducing the harm caused by heroin addiction.”

The Canadian Institutes of Health Research is the Government of Canada's agency for health research. Its objective is to excel, according to internationally accepted standards of scientific excellence, in the creation of new knowledge and its translation into improved health for Canadians, more effective health services and products and a strengthened Canadian health care system. Composed of 13 Institutes, CIHR provides leadership and support to more than 9,000 researchers and research teams in every province of Canada. www.cihr-irsc.gc.ca

-30-

To view a short video, interviews and key documents about the NAOMI clinical trial, please go to <http://www.naomistudy.ca/>