

Scientific misconduct: Documents reveal faked research, ethics breaches in federally funded projects

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Byline: Margaret Munro

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More than a dozen scientists and doctors, several of them recipients of sizable federal grants, have been faking research, destroying data, plagiarizing or conducting experiments on people without necessary ethics approvals, the country's lead research agencies report.

One medical researcher, who was awarded \$1,347,445 for various projects, fabricated and falsified data and was permanently barred last year from receiving more federal money, according to documents obtained by CanWest News Service.

Another researcher altered and destroyed data and cannot apply for funding for three years. A third researcher, who engaged in "academic dishonesty in publication," has been barred from receiving more federal research money until 2007.

Officials at the Canadian Institutes of Health Research (CIHR) and Natural Sciences and Engineering Research Council (NSERC) say they cannot, under federal privacy law, identify the researchers.

But CIHR says it awarded "approximately" \$12,410,816 to projects in which researchers have been found to be violating research ethics or integrity rules since 2003. They worked at Dalhousie University, McGill University, McMaster University, Sunnybrook & Women's College Health Sciences Centre in Toronto, the University of Alberta, the University of British Columbia, Université de Montreal, and Université de Sherbrooke.

No effort has been made to recoup the funds. But the \$1.3 million awarded to the researcher permanently barred from applying for CIHR funding has been transferred to his research partners, says Dr. Mark Bisby, the agency's vice-president.

Four Vancouver research projects, part of studies that received more than \$3 million in federal grants, did not have ethics renewal certificates required under federal rules. CIHR says the "serious breach" was first discovered at UBC in June 2004, just three months after President Martha Piper apologized for earlier research ethics breaches made in 2001.

Piper said in March 2004 UBC had learned from its mistakes and had one

of the best research ethics procedures in the country.

The federal documents show audits of 41 research projects at UBC in the June and October 2004 uncovered four projects without ethics renewal certificates, which are meant to help ensure protection of people who volunteer to participate in studies. The researchers stopped enrolling patients in one trial, which was part of a multi-centre drug trial involving pediatric patients. Funding for the other projects, which UBC says were behavioural studies, was suspended until the proper certificates were in place.

Minutes of CIHR meetings show officials were concerned about UBC's "institutional weaknesses" and talked about freezing funding to all UBC researchers.

In November 2004, the agency's research integrity committee discussed drafting a letter to UBC in which "suspension of future funding (results of the September 2004 open grants competition) be added among the list of possible sanctions."

CIHR officials decided against making the threat and froze funding only for the projects without proper ethics certificates.

John Hepburn, UBC vice-president of research, said this week that cutting off all UBC funding which he likened to "the atomic-bomb threat" would have been "a grotesque over-reaction." He said it was not necessary since the university was anxious to resolve the problem. He said UBC has spent several million dollars to improve the management and effectiveness of its ethics review process and remains committed to having the the best process in the country.

CIHR closed the file in June 2005 after UBC improved its tracking system to ensure all projects have the necessary ethics certificates.

NSERC is much less forthcoming about the cases it handles. It will not name the universities involved in four cases of misconduct and plagiarism it has confirmed since 2003. But the agency has released several hundred pages of documents about allegations it has investigated, stripping them of all identifiers.

CIHR's response to an access-to information request for documents on misconduct cases was a skeletal two-page summary of the 15 cases of non-compliance it has resolved since 2003. It then provided more information on request.

CIHR and NSERC distribute almost \$1.5 billion tax dollars a year to close to 16,000 researchers and thousands more graduate students across

the country.

Council officials say their agencies are transparent and publicly accountable.

Health Canada stymies research misconduct probes, papers suggest
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Byline: Margaret Munro
Source: CanWest News Service
Summary: With photos of Eric Poehlman; committee documents.

Government secrecy and unco-operative universities are hobbling the work of a federal committee that handles allegations of misconduct and fraud by Canadian medical researchers.

Health Canada refuses to share information that can be key to misconduct cases, according to documents released by the Canadian Institutes of Health Research, the country's lead medical research agency.

``We can't function as a committee without Health Canada's input," say minutes of CIHR's research integrity committee, which addresses allegations of research misconduct relating to everything from the destruction of human embryos to academics' unauthorized use of corporate documents.

The minutes, obtained by CanWest News Service through an access to information request, lament how the federal department, which is responsible for protecting Canadians who volunteer to test new drugs and treatments, won't provide information on university research projects it shuts down.

``If Health Canada can't give CIHR information on whether an issue is resolve(d), how are we to proceed?" the CIHR committee noted in February 2005 in reference to a university trial Health Canada had shut down.

The issue was raised again last July in the most recent committee minutes available: ``Health Canada has strict confidentiality rules and does not agree to divulge information, even in response to a specific request concerning a research integrity file."

To get around the agency, CIHR bureaucrats have created a new rule that requires academics to reveal when Health Canada enforcement officers come calling on them.

``This is the only way to get the information," say the minutes of the committee.

Health Canada is bound by privacy laws and is limited in the information it can share, says Jirina Vlk, a Health Canada media officer.

But she said the department is working with the Canadian Institutes of Health Research to ``facilitate the flow of information."

CIHR and its integrity committee have also been sending missives to universities, which receive close to \$700 million in federal health research funding, stressing the need to abide by the federal ethics and integrity rules.

The documents reveal universities, in some cases, have let misconduct investigations drag on so long researchers accused of faking results or unethical conduct had moved on to new jobs or left the country.

CIHR hounded one university for close to two years making repeated requests ``every two months by mail and telephone" for updates on an investigation that in the end proved ``unsatisfactory," according to the minutes.

And in one bizarre case, an academic who engaged in misconduct was promoted and now oversees the work of the researcher who tipped authorities to the unethical conduct.

Another investigation into allegedly fraudulent studies was dropped because the researcher had left Canada.

``Since the individual is now out of the country and cannot be located and since the necessary information can not be obtained, the investigation can not be pursued any further at this stage," the CIHR committee notes in closing the file in mid-2004.

CIHR, which funds close to 9,000 academic researchers and graduate students, says it's bound by the Privacy Act and will not identify individuals who engage in misconduct. And it does not pursue researchers who leave the country.

Canada's approach stands in sharp contrast to the way the United States deals with research misconduct.

Last year, the U.S. Office of Research Integrity tracked down Dr. Eric Poehlman at the Universite de Montreal and charged him with faking research on menopausal women between 1992 and 2002.

Poehlman moved from Vermont to Montreal in 2001 and subsequently received more than \$1 million in Canadian research funds. Poehlman's job at the Universite de Montreal was terminated in January 2005. He pleaded guilty in March 2005 in what U.S. investigators called the worst case of scientific fakery in two decades.

U.S. investigators also revealed in 2003 that University of Alberta researcher Jianhua (James) Xu had been clandestinely sneaking into a lab and doctoring experiments and altering results of project funded by a U.S. agency. The university fired Xu, and U.S. authorities, who had funded some of the research, ruled that he had engaged in ``significant" scientific misconduct and barred him from receiving U.S. funding for four years.

Under Canadian rules which many observers say need an overhaul allegations of research misconduct received by CIHR are forwarded to the university where the alleged misconduct occurred. The university is asked to investigate and report back to CIHR, which has the power to freeze projects, and bar researchers from receiving more research money.

A recurring theme at research integrity committee meetings is the need for the universities to take allegations of research misconduct more seriously.

``The investigation took too long and the rules/guidelines were not respected," the minutes say of one case in 2005.

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How one researcher _and his suspect health studies _ slipped through the cracks: Scientific misconduct: Second of two parts.

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Summary: EDS:All the doctors in story are MDs.

Canadian research officials received a tip two years ago that a doctor

at Newfoundland's Memorial University had been publishing ``partly or entirely fraudulent" studies.

``I believe an investigation is warranted," Dr. Seth Roberts of the University of California wrote in a January 2004 message to the Canadian Institutes of Health Research, the country's lead medical research agency. Roberts listed three suspect papers in the journals Lancet and Nutrition by Dr. Ranjit Chandra, who is now at the centre of one of Canada's most serious cases of suspected scientific misconduct.

Roberts never heard back from the CIHR. Documents released in response to an access to information by CanWest News Service request say the research agency did make inquiries, but CIHR decided not to pursue an investigation because it did not fund Chandra's research and Memorial University told them the once-acclaimed researcher had left the country and was ``impossible to locate."

The file was closed and Chandra, and his suspect research, slipped through the cracks in the Canadian research system.

It wasn't the first time. Chandra is alleged to have made up data on hundreds of non-existent babies for his studies on infant formula. He has been accused of inflating results of breastfeeding studies. And he is said to have fabricated the results of a 2001 study that claimed swallowing a combination of his patented multivitamins and minerals had a remarkable effect on seniors' memory and brain function.

Senior Canadian doctors, Chandra's former research nurse and partners, U.S. researchers, editors of leading research journals have on several occasions since 1993 raised concerns about the veracity of Chandra's research.

The allegations are so disturbing, and such a black mark on the Canadian academic community, that many are calling for a retraction of all the research papers Chandra ever published.

They also say the case, and the way Memorial University, Health Canada and CIHR handled it, point to major problems with the way Canadian health research is governed.

``We need an independent body for oversight of research and we don't have one," says Dr. Jocelyn Downie, director of the Health Law Institute at Dalhousie University. Downie has just completed a report calling for creation of a robust national agency to oversee medical research, protect research volunteers and follow up on allegations of misconduct.

``It seems to me there is a hole here," says Dr. Michael Kramer of McGill University. He wrote to Health Canada in 1997 about Chandra's infant nutrition studies, but was informed the agency could do nothing since it did not fund Chandra's work.

Chandra spent 27 years at Memorial, where he published hundreds of research papers, attracted lucrative research contracts from infant formula-makers, and won many accolades _ including the Order of Canada _ before retiring from the university under a cloud of suspicion in 2002. He reportedly now splits his time between Switzerland and India, but could not be reached for comment for this article.

Concern about his work dates back to 1993, when Chandra's research nurse Marilyn Harvey came forward with evidence that her boss had been fabricating babies and data for his ``landmark" studies on baby formula. The university appointed a committee to investigate and two years later decided there was ``not sufficient" evidence to take action against Chandra, who hired lawyers and claimed data on many of the babies in his studies had gone missing.

In 2000, the editor of the prestigious British Medical Journal raised ``concerns" about a study Chandra submitted on the benefits of his multivitamin and mineral supplements. The study claimed seniors showed striking cognitive improvement after taking daily multivitamin and mineral supplements that Chandra created and has since patented.

The university says it tried to investigate but Chandra refused to co-operate. The BMJ editors referred the case to the journal's ethics committee, which soon started asking about questionable data in some of Chandra's earlier studies.

Chandra then submitted his multivitamin study to a smaller U.S. journal, Nutrition, which published the report in 2001. The results were so startling they were picked up by the New York Times and caught Roberts' attention in California. ``They were not just implausible, they were impossible," Roberts said of Chandra's results, which he and a colleague publicly critiqued in Nutrition in 2003.

The editors of Nutrition retracted Chandra's paper in 2005. The retraction noted, among other things, that Chandra claimed his research subjects were normal but assigned some of them scores on a mental test that placed them in the demented category.

Memorial officials insist the university took the various allegations against Chandra seriously. ``However, in this case, with Dr. Chandra's lack of co-operation, developing a body of evidence that would support a finding of fraud and warrant discipline proved to be extremely

difficult, if not impossible," the university said in a statement in February.

Continued national and international media attention has prompted Memorial to review its handling of the allegations. A yet-to-be-named outside expert will be asked to take on the job, says Dr. Chris Loomis, Memorial's vice-president of research. The university is also pledging to pursue debate on developing a national strategy on research integrity.

Kramer, who studies infant nutrition and is also scientific director of the CIHR's Institute of Human Development, Child and Youth Health, says Memorial needs to clear the air on the Chandra case. ``I'd like to see Memorial admit that they made a mistake."

Memorial should write to every journal that published Chandra's work, says Kramer. ``They need to say that issues have been raised about a whole series of these studies and it makes us doubt the veracity of all of his research. And therefore we recommend that this article in your journal be retracted officially."

Loomis says Memorial is compiling a list of the ``hundreds" of research papers Chandra published over his 27 years at the university — a list he says Memorial will post on the Internet, along with the information on investigations into Chandra's work.

Roberts says he is still waiting for a response from the Canadian Institutes of Health Research regarding his call for an investigation into Chandra's suspect studies. But officials say it is not CIHR's job to investigate allegations of fraud in studies it does not fund.

``We're not a cop," says Dr. Mark Bisby, CIHR vice-president.

The agency has, however, flagged Chandra's name should he ever return to Canada and apply for funding. And officials concede they ``gave Dr. Roberts the impression that more information was to have been forthcoming. We will contact Dr. Roberts to explain why that is not part of the CIHR procedures and why he did not receive additional information."

Meanwhile, Chandra's suspect studies remain on the web and on the shelves of medical libraries in journals. Kramer says Chandra's studies are still used to help market baby formula purported to reduce infants' risk of developing allergies. Others are used to sell multivitamins.

All of which reinforces Roberts' belief that self-policing bodies like universities and research agencies are not up to dealing with

allegations of fraudulent research. ``There is no pressure on these agencies to do a good job, none whatsoever."

Memorial University and CIHR, Roberts says, ``should have followed up."

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