

Assisted Human Reproduction Canada

2007-08

Report on Plans and Priorities

Tony Clement
Minister of Health

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SECTION I – OVERVIEW

Minister's Message

It is my pleasure to present the 2007-2008 Report on Plans and Priorities for Assisted Human Reproduction Canada (AHRC). The Agency, through the administration of the Assisted Human Reproduction (AHR) Act, will regulate in the sector of assisted human reproduction, and will seek to protect and promote the health, safety and dignity of individuals who access assisted human reproduction technologies to help them build their families.

I am proud that the new President and board of directors have assumed office, and that they are implementing their governance and outreach role preparing the Agency to become operational in the 2007-08 fiscal year. In addition, the Agency continues to put in place the processes and structures that will enable it to administer the AHR Act, which became law in 2004.



The Act brought into force prohibitions against unacceptable practices such as human cloning, together with other measures to protect the health and safety of individuals using AHR technologies. The Act also includes provisions requiring that research using the in-vitro human embryo in Canada take place within a controlled environment, and establishes the Agency, Assisted Human Reproduction Canada.

Once the components of the regulatory framework have been developed, the Agency will license AHR controlled activities, enforce compliance with the regulations, monitor trends and developments, collect and safeguard personal health information and provide advice to the Minister of Health on these matters. Health Canada is continuing its work to complete a regulatory framework in this sector and introduce these regulations.

The Agency has an important leadership role to play in the area of assisted human reproduction and will be an important contributor to safeguarding the health and safety of Canadians

Management Representation Statement

I submit for tabling in Parliament, the 2007-08 Report on Plans and Priorities (RPP) for Assisted Human Reproduction Canada.

This document has been prepared based on the reporting principles contained in *Guide for the Preparation of Part III of the 2007-2008 Estimates: Reports on Plans and Priorities and Departmental Performance Reports*:

- It adheres to the specific reporting requirements outlined in the TBS guidance;
- It is based on the department's strategic outcome(s) and Program Activity Architecture that were approved by the Treasury Board;
- It presents consistent, comprehensive, balanced and reliable information;
- It provides a basis of accountability for the results achieved with the resources and authorities entrusted to it; and
- It reports finances based on approved planned spending numbers from the Treasury Board Secretariat.

Name: Elinor Wilson

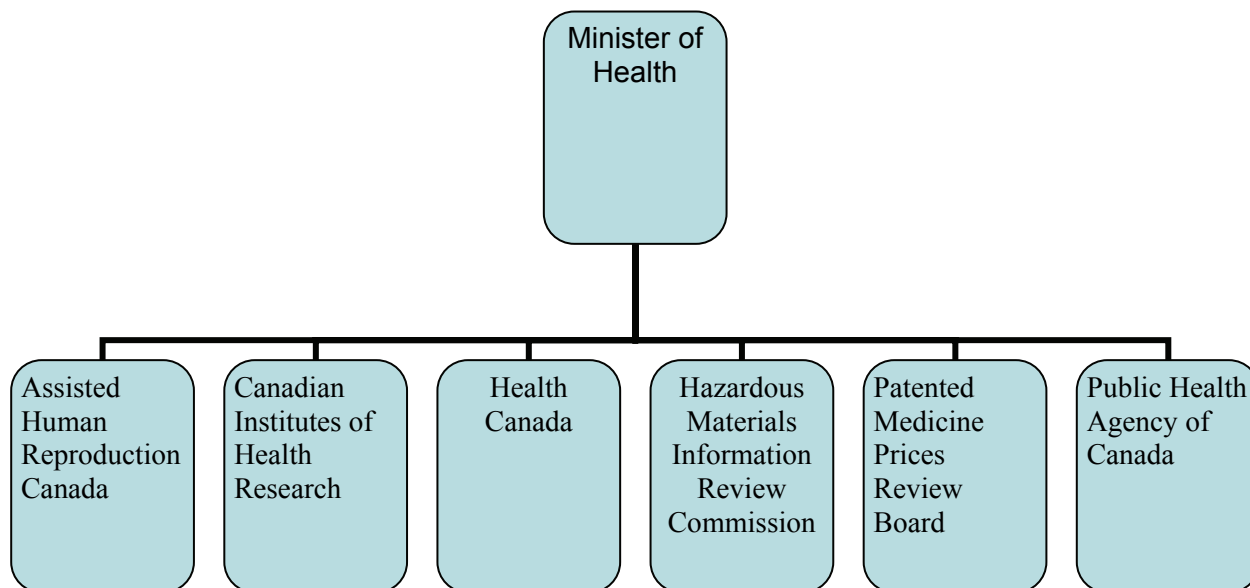
Title: President

Assisted Human Reproduction Canada

Health Portfolio Overview

The Minister of Health, through the work of the Health Portfolio, is responsible for maintaining and improving the health of Canadians. The Portfolio consists of Health Canada, the Public Health Agency of Canada, the Canadian Institutes of Health Research, the Hazardous Materials Information Review Commission, the Patented Medicine Prices Review Board and the newly-formed Assisted Human Reproduction Canada. Each member of the Portfolio prepares its own Report on Plans and Priorities.

The Health Portfolio consists of approximately 11,400 employees and an annual budget of over \$4.5 billion.



Program Activity Architecture (PAA) Crosswalk

The program for 2007-08 is unchanged from 2006-07. The appointments of the board of directors, including the Chairperson of the board, the President of the Agency and eight members were announced in December 2006. The President of Assisted Human Reproduction Canada took office in February 2007. There have been no changes to the PAA (strategic outcomes and program activities).

Summary Information

Assisted Human Reproduction Canada was established under the authority of the AHR Act. The legislation aims to protect and promote human health, safety, dignity and human rights in the use of assisted human reproduction (AHR) technologies, prohibits unacceptable activities such as human cloning and places controls over AHR related research. The Agency will be responsible for the issuance and review of licences, the collection and analysis of health reporting information, and carrying out inspections and enforcement related to activities controlled under the Act.

Financial Resources (indicate denomination)

2007-2008	2008-2009	2009-2010
\$13,476	\$12,412	\$10,544

Human Resources

2007-2008	2008-2009	2009-2010
44 FTE's	44 FTE's	44 FTE's

Departmental Priorities

Name	Type
Priority #1 Licensing and Enforcement of a Regulatory Framework for Assisted Human Reproduction Technologies	Ongoing
Priority #2 Health Information and Knowledge Management for Assisted Human Reproduction Technologies	Ongoing

Departmental Plans and Priorities

Assisted Human Reproduction Canada (AHRC), established on January 12, 2006, is a federal regulatory agency responsible for administering a regulatory regime that will be created under the AHR Act. The Agency's primary functions are to license and inspect activities controlled under the Act, to maintain a personal health information registry, and to provide the public and professions with information respecting AHR issues.

AHRC will seek to protect and promote the health and safety of Canadians who use, and children who are born of, AHR technologies. This will be accomplished by implementing a regulatory framework that will oversee AHR procedures and related research in Canada. The Agency will also become a focal point for AHR information to policymakers, practitioners, researchers, persons undergoing AHR procedures, children born of AHR technologies and the public.

AHRC may, in carrying out its mandate, draw upon the expertise of other organizations in areas of medicine, health professions, accreditation, standards, law, consumer representation, as well as provincial and territorial governments. AHRC will conduct its operations within this milieu on the principles of openness, transparency, accountability, ethics and broad-based representation.

AHRC's President began her term of office in February 2007. The immediate priorities are to fit up the new Agency, to build capacity to support the future implementation of the AHR regulatory framework, to design and implement a strong outreach and stakeholder engagement strategy and to develop a strategic plan in respect of enforcement and public information activities.

During the fiscal year 2007-08, the Agency will focus on establishing its management and governance structures and hiring staff as quickly as possible to begin implementing its systems in preparation to becoming operational. It will train staff, develop the organization's strategic plans, and implement its communications and outreach strategies. It will begin managing compliance and enforcement activities through a Memorandum of Understanding with Health Canada and will work with Health Canada to plan for the transition of the personal health information registry. It will also prepare its systems and processes to operate independently, while keeping abreast of Health Canada's progress in the development of the components of the AHR regulatory framework.

**SECTION II – ANALYSIS OF PROGRAM ACTIVITIES BY
STRATEGIC OUTCOME**

Analysis by Program Activity

Strategic Outcome:

Protection and promotion of the health and safety of Canadians against the risks associated with assisted human reproduction.

Program Activity:

Licensing and Enforcement of a Regulatory Framework for Assisted Human Reproduction Technologies.

Financial Resources: (\$ thousands)

2007-2008	2008-09	2009-10
\$6,076	\$7,802	\$5,962

Human Resources:

2007-2008	2008-09	2009-10
18 FTE	22 FTE	22 FTE

Program activity description and its expected results

Objective

To implement the AHR legislative framework.

Description

The AHRC's licensing activities to implement the AHR legislative framework are dependant on the finalization of regulations by Health Canada. (Health Canada is responsible for developing policy and ensuing regulations while the Agency is responsible for the implementation of these regulations.)

As it is expected that regulations will not be in place in 2007-08, the Agency's activities will be largely focused on developing and implementing a strong engagement and outreach strategy with the stakeholders (and those affected by their activities) with a view to promoting licensing compliance, and enforcement.

Some enforcement activities are possible without the licensing scheme in place. This will initially be achieved through a regulatory compliance program with Health Canada's Inspectorate as the Agency ramps up its own capacity and assesses models for its ongoing roles.

With respect to penal proceedings, the RCMP has jurisdiction under their statute to enforce the AHR Act. Discussions are underway with the RCMP to develop a memorandum of understanding to support the RCMP in its penal investigations and proceedings under the Act.

Within the next years, AHRC would achieve the objective of implementing the AHR legislative framework by the following means:

- assessing applications for licences to determine whether the regulatory requirements are met as regulations are made;
- issuing licences for controlled activities conducted by qualified persons and for premises used to undertake these activities as regulations are made;
- conducting inspections of AHR clinics, service providers or researchers; and
- consulting persons and organizations in the development of other supporting policy instruments (e.g., standards, guidelines, accreditation models, etc.)

Expected Result

The preliminary key results for this program activity include:

- an effective and efficient licensing and inspection regime;
- compliance by medical practitioners and researchers of the legislative framework; and
- improved safety of the controlled activities undertaken

Strategic Outcome:

Protection and promotion of the health and safety of Canadians against the risks associated with assisted human reproduction.

Program Activity:

Health Information and Knowledge Management for Assisted Human Reproduction Technologies.

Financial Resources: (\$ thousands)

2007-2008	2008-09	2009-10
\$7,400	\$4,610	\$4,582

Human Resources:

2007-2008	2008-09	2009-10
22 FTE	22 FTE	22 FTE

Program activity description and its expected results**Objective**

To become a centre of expertise and focal point of AHR information for policymakers, practitioners, Canadians who use AHR procedures, children born of AHR procedures, researchers and the Canadian public.

Description

The Agency, in conjunction with Health Canada, will prepare the systems and structures for the transition to AHRC of the Personal Health Information Registry which is being developed by Health Canada. The PHIR will require further development after the transition of responsibility to the Agency. Data will be transmitted to the registry only after the regulations are made, which is not expected to occur until the 2008-09 fiscal year.

The reporting mechanisms will require development which will be a core activity of the Agency in 2007-08. The Agency will begin developing the reporting structures, which will be implemented once the regulations are made. Reports would follow the successful launch of the PHIR and input of the data.

The public information will begin to be available on their website during the 2007-08 fiscal year and increase as the operational capacity of the Agency increases over the subsequent years.

Within the next years, AHRC would achieve this objective by the following means:

- maintaining a personal health information registry (PHIR) to consolidate health reporting information concerning donors, persons who have undergone assisted reproduction procedures and children born of those procedures as specified in the regulations;
- providing ongoing reports of AHR controlled activities, including success rates, to inform prospective AHR users; and

- providing public information on AHR matters or issues via a public website or in other forms such as brochures.

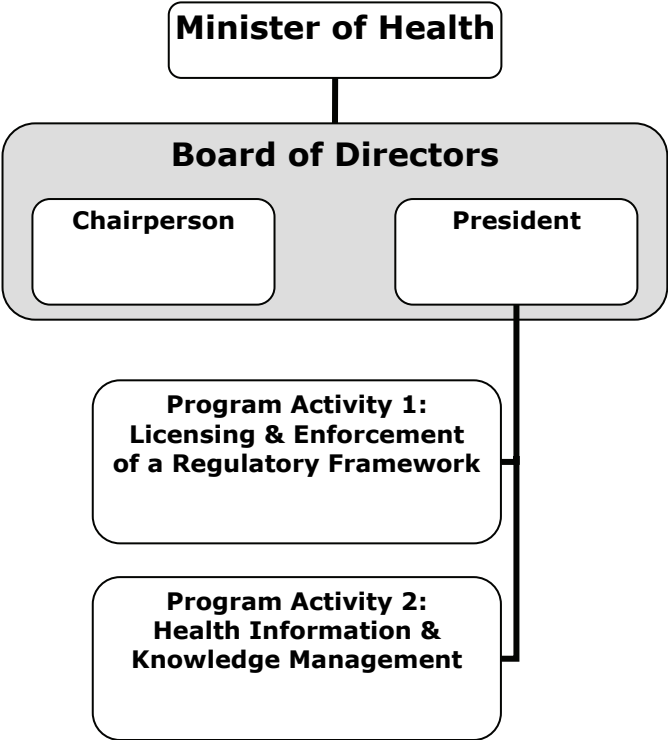
Key Results

The preliminary key results for this program activity include:

- a confidential and secure PHIR, once regulations are made;
- improved information for decision-making by practitioners and prospective users of AHR procedures;
- access by children born of AHR procedures to information on their genetic history once regulations are made;
- increased awareness of the Canadian public of AHR issues; and
- reaching out and engaging stakeholders and the public in the AHR community.

SECTION III – SUPPLEMENTARY INFORMATION

Organizational Information



Departmental Links to the Government of Canada Outcomes (for RPPs)

2007-2008

(\$ thousands)	Budgetary						Net	Non-Budgetary Loans, Investments and Advances	Total Main Estimates	Adjustments (planned spending not in Main Estimates)	Total Planned Spending
	Operating	Capital	Grants	Contributions and Other Transfer Payments	Gross	Respendable Revenue					
Program Activity											
Strategic Outcome: Protection and promotion of the health and safety of Canadians against the risks associated with assisted human reproduction											
Program Activity #1 Licensing and Enforcement of a Regulatory Framework for AHR Technologies	6,076				6,076		6,076		6,076		6,076
Strategic Outcome: Protection and promotion of the health and safety of Canadians against the risks associated with assisted human reproduction											
Program Activity #2 Health Information and Knowledge Management for AHR Technologies	7,400				7,400		7,400		7,400		7,400
Total	13,476				13,476		13,476		13,476		13,476

Program Activity #1 contributes to the achievement of the Government of Canada's "Healthy Canadians" outcome.
 Program Activity #2 contributes to the achievement of the Government of Canada's "Healthy Canadians" outcome.

Table 1: Departmental Planned Spending Table and Full-time Equivalents

(\$ thousands)	Forecast Spending 2006-2007	Planned Spending 2007-2008	Planned Spending 2008-2009	Planned Spending 2009-2010
Licensing and Enforcement of a Regulatory Framework for AHR Technologies	4,320	6,076	7,802	5,962
Health Information and Knowledge Management for AHR Technologies	5,361	7,400	4,610	4,582
Budgetary Main Estimates (gross)	9,681	13,476	12,412	10,544
Non-budgetary Main Estimates (gross)	0	0	0	0
Less: Respendable revenue	0	0	0	0
Total Main Estimates	9,681	13,476	12,412	10,544
Adjustment				
Less: Spending Authorities Available-Reprofiled in annual reference level update	-1,484	0	0	0
Supplementary Estimates				
N/A	0	0	0	0
Total Adjustments	-1,484	0	0	0
Total Planned Spending	8,197	13,476	12,412	10,544
Total Planned Spending	8,197	13,476	12,412	10,544
Less: Non-respendable revenue	0	0	0	0
Plus: Cost of services received without charge	0	0	0	0
Total Departmental Spending	8,197	13,476	12,412	10,544
Full-time Equivalents	44	44	44	44

Table 2: Voted and Statutory Items listed in Main Estimates

Vote or Statutory Item	Truncated Vote or Statutory Wording (\$ thousands)	2007-2008 Main Estimates	2006-2007 Main Estimates
10	Operating expenditures	12,834	9,022
(S)	Contributions to employee benefit plans	642	659
	Total Department or Agency	13,476	9,681

Table 3: Internal Audits and Evaluations

Internal Audits or Evaluations
<p>No audits have been set as the Agency's board of directors could not begin functioning until the President took office in February 2007. In effect the Agency will begin operations in the 2007-08 fiscal year. The Agency is required to comply with the Treasury Board's Internal Audit Policy and related directives as applicable. The Agency is expected to report on the performance of all its initiatives on a regular basis through Main Estimates, using the Report on Plans and Priorities and the Agency's Performance Report. The preliminary Program Activity Architecture (PAA) has been developed for AHRC and will be used to build the Management Resources and Results Structure (MRRS) for the Agency, as a vehicle to report performance.</p> <p>As a new organization, AHRC is expected to initially focus on the start up of the Agency. Subsequently, performance indicators are anticipated to be developed in accordance with the coming into force of regulatory instruments under the AHR Act, to gauge and report on progress towards fulfilling the Agency's legislated mandate.</p> <p>The President of the Agency, as chief executive officer, is responsible for managing the Agency's day-to-day activities, including management of the financial resources allocated to the Agency, and supervising the direction of the Agency's work and staff. In carrying out these responsibilities, the President will take direction from the board of directors, which is the overall manager of the Agency, and is responsible for, among other things, approving the Agency's budget and operational policies.</p> <p>It is expected that the comprehensive parliamentary review of the provisions and operation of the Act, mandated under section 70 of the Act to take place three years after the establishment of the Agency, will in fact be the first opportunity to evaluate progress toward the achievement of desired results. Once the Agency has gained more experience with program delivery, it is anticipated that external resources would be engaged on a periodic basis to provide an independent review of the Agency's operations, addressing management issues relating to the operation of the Agency, risk management and performance data.</p>