

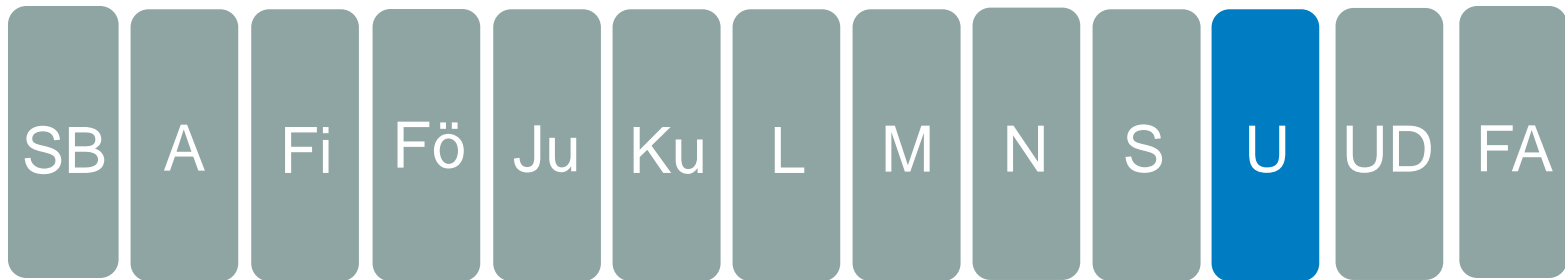
Registry-based research

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Government and Government Offices

GOVERNMENT



- **Government Offices – Prime Ministers Office, 11 government ministries and the Office for Administrative Affairs**
- **Around 4,600 members of staff are employed at the Government Offices, of whom around 200 are political appointees**

Ministry of Education and Research

POLITICAL LEADERSHIP

NON-POLITICAL AFFAIRS



Minister for Education, Deputy Prime Minister
Jan Björklund

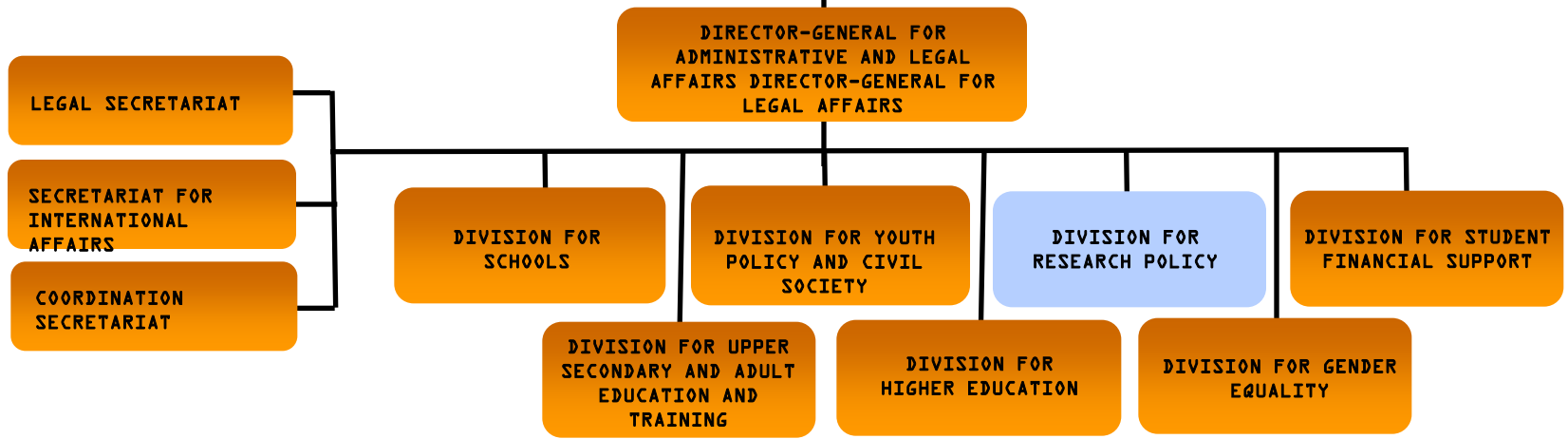
POLITICAL STAFF

State Secretaries
Peter Honeth
Bertil Östberg
Ulrika Stuart Hamilton

Political Advisers
Press Secretary



Minister for Gender Equality, Deputy Minister for Education
Maria Arnholm





Registry-based research – Ministry of Education and Research perspective

- **Government bill for Research and Innovation**
 - 2008
 - 2012
- **Swedish Research Council**
 - funding of research
 - funding of research infrastructures
- **Regulations that affect registry-based research**

The Swedish Government bill for Research and Innovation

- **A Boost to Research and Innovation Government Bill 2008**
 - Strategic research areas in medicine e.g. epidemiology (SFO: KI, LU/UU)
 - Funding for research infrastructures incl. databases, biobanks and registries
- **Research and Innovation 2012**
 - Establish an information and advisory function for registry-based research within the Swedish Research Council

Research funding

- **Swedish Research Council**
 - Council for Research Infrastructures
 - Framework Grant SIMSAM – Swedish Initiative for Research on Microdata in the Social and Medical Sciences
 - Graduate School Within SIMSAM – Swedish Initiative for Research on Microdata in the Social and Medical Sciences
 - Scientific Council for Medicine and Health
 - Project Research Grant (incl. Gaps in Knowledge of Healthcare), Grant for Half-time Position in Clinical Research

Government offices, ongoing activities at other departments

- **Agreement on development and funding of National Quality Registries between Government and Swedish Association of Local Authorities and Regions – SKL (S)**
- **European General Data Protection Regulation (Ju)**
- **Swedish Government Official Reports – Vad är officiell statistik (SOU 2012:83), Registerdata för forskning (SOU 2012:15) (Fi)**

Agreement on development and funding of National Quality Registries

- **agreement between Government and Swedish Association of Local Authorities and Regions – SKL for 2012-2016**
- **national financing of National Quality Registries**
- **responsibilities and organisation**
- **provisions that will improve prerequisites för clinical research and registry-based research using National Quality Registries**



European General Data Protection Regulation, draft Jan 25, 2012

- **will supersede the Data Protection Directive (Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data)**
- **will be directly applicable in all member states of the European Union**
- **is subject of discussions by experts in the Working Party on Data Protection (DAPIX)**
- **a draft report will be discussed in the European Parliament, Committee on Civil Liberties, Justice and Home Affairs (LIBE)**



Swedish Government Official Reports

- **Review of Statistics Sweden (SCB) and the official statistics system – Vad är officiell statistik (SOU 2012:83)**
 - In the Ordinance containing instructions for Statistics Sweden it should be stated that the agency is responsible for supplying data to researchers.
 - If the agency is expected to continue working with micro simulation models there may be reason to mention that as well in the instructions.
- **Register data for research – Registerdata för forskning (SOU 2012:36) (Fi)**
 - proposing improvements concerning e.g.
 1. documentation and information,
 2. coordinating applications for ethical review and access to data for research purposes,
 3. handling of certain data incl. the use of data from different sources.

Ongoing activities at the Ministry of Education and Research

- **Inquiry on registry-based research – Registerforsknings-utredningen (U)**
- **Draft proposing the introduction of an act on certain registries for research – lagrådsremiss Vissa register för forskning om vad arv och miljö betyder för människors hälsa (U)**



Inquiry on registry-based research – Registerforskningsutredningen

- **propose regulations and other improvements, while improving the protection of the integrity of individual data subjects, in order to**
 - facilitate procedures for agencies responsible for official statistics to provide data for research,
 - facilitate procedures combining data from different data sources for research purposes,
 - enabling collection of personal data in registers for specific research purposes including longitudinal studies.
- **investigate if there is a need to improve protection regarding secrecy relating to an individual's personal circumstances when processing of personal data for research purposes.**



Draft proposing the introduction of an act on certain registries for research

Lagrådsremiss Vissa register för forskning om vad arv och miljö betyder för människors hälsa

- **A new act on certain registers for research on the impact on inheritance and environment for health and disease.**
- **Swedish universities will be able to collect personal data with the explicit consent of the research subjects, in order to create registries for certain research.**
- **Swedish public authorities will be able to use data from the registers, after approval by ethics committees, for research on the impact on inheritance and environment for health and disease.**
- **New rules in the Secrecy Act regulating absolute secrecy for personal data in these registers.**
- **Awaiting the Inquiry on registry-based research, the new regulations should be implemented from Oct 1, 2013 until Dec 31, 2015.**

Swedish research strengths in Life Sciences (Swedish Research Council, 2010)

- **Epidemiology and public health research**
- Cardiovascular diseases
- Chronic inflammatory diseases
- Medical ethics
- Microbiology, immunology and infectious diseases
- Neuroscience and diseases of the nervous system
- Odontology
- Regenerative medicine
- Research on the musculoskeletal system
- Systems biology
- Cancer and tumour biology
- Health care research
- Metabolic diseases

- a part of the Government

