

**Programme on  
Human Biobanks and Health Data  
(BIOBANK)  
Work Programme 2012-2016**

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## 1. Summary

Biological material stored in biobanks is of major value for gaining a deeper understanding of the complex relations between genes, environmental factors and disease. There is broad agreement among policymakers and the health services about the importance and benefits of using biobank material and register data for research. This is highlighted in a number of strategic documents.

The Executive Board of the Research Council of Norway has decided to launch a new research programme – Human Biobanks and Health Data (BIOBANK) – with a total of NOK 110 million in funding from the Ministry of Education and Research for the period 2011-2016.

The programme is designed **to take advantage of the potential for research on human biological material in biobanks, by coupling analysis results with data from health surveys, health registers and the health services.** Research projects funded under the programme should exploit the full potential of the large biobanks and registers, unless there are scientific reasons for a smaller study sample. The primary objective of the programme is **to generate research-based new knowledge aiming at prevention, detection, diagnosis, treatment and survival of somatic and psychiatric diseases.**

All projects under the programme will address ethical, legal and social aspects (ELSA) as an integral part of project activities and will incorporate international cooperation.

## 2. Background

Biological material stored in biobanks is of major value for gaining a deeper understanding of the complex relations between genes, environmental factors and disease. Research combining Norwegian biobank material and national register data constitutes unique opportunities for a broad spectrum of research questions and applications. Many countries have ambitious plans and are investing in health research based on population studies and biobanks. The international research front is making rapid advances in this area, and it is important for Norway to act. The ethical, legal and social aspects of this research are also developing quickly, and must be an integral component of the programme.

The Executive Board of the Research Council of Norway has decided to launch a programme to take full advantage of Norway's population-based health surveys, biobanks and national health registers. The Ministry of Education and Research has allocated funding totalling NOK 110 million for the period 2011-2016. However, a significantly larger-scale effort is needed, and the Research Council's budget proposal for 2012 recommends that the Ministry of Education and Research and the Ministry of Health and Care Services allocate additional funding.

### 2.1 Strategic perspectives

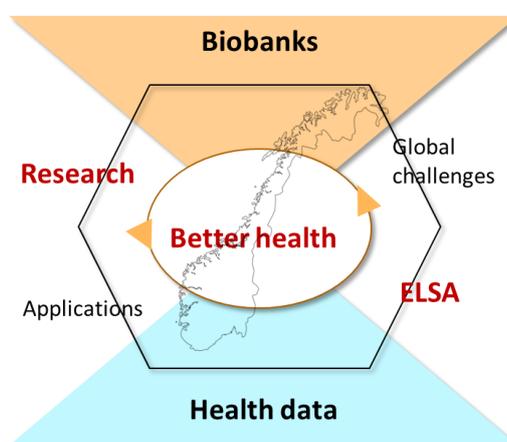
There is broad agreement among policymakers and the health services about the importance and benefits of using biobank material and register data for research. This is highlighted in documents such as the government white paper on research, *Climate for Research*,<sup>1</sup> the

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<sup>1</sup> Report No. 30 (2008-2009) to the Storting: *Climate for Research*.  
<http://www.regjeringen.no/nb/dep/kd/pressesenter/pressemeldinger/2009/klima-for-forskning.html?id=557382>

research strategy of the Ministry of Health and Care Services,<sup>2</sup> *The Coordination Reform* to improve coordination of health and care services<sup>3</sup> and the National Health and Care Plan.<sup>4</sup> Gender perspectives and women's health are important elements in these policy documents. Furthermore, the Government's new National Strategy for Biotechnology<sup>5</sup> and the very recent evaluation of biology, medicine and health research in Norway<sup>6</sup> underline the importance of using biobanks and register data for research.

The new research programme is being launched as part of the follow up to the recommendation in the biobank report *Gode biobanker – bedre helse* (the Research Council of Norway, 2008)<sup>7</sup> to establish a long-term research programme which takes full advantage of the major national investments in biobank infrastructure. The report also recommends that Norway's biobanks operate as a single unified national biobank, with decentralised localisation of biological material. A *functional national biobank* of this type is a prerequisite for optimal use of the resources, and a national biobank consortium has been established by means of substantial infrastructure funding.



**Figure 1. Research on biobanks and health data will contribute to better health (see Footnote 7).**

The Norwegian biobanks, including the population-based health surveys and the hospital-based clinical biobanks, together with the health registers and other population surveys, constitute a world-class research resource. Norway's public health system, unique national identity numbers and national health registers along with a population that is positive to medical research and the opportunity to follow individuals throughout their entire lifetime provide an excellent basis for long-term epidemiological and clinical research. There is considerable international interest in biobanks as a research resource, and the new programme aims at strengthening Norwegian researchers' ability to participate in international cooperation. This further underlines the importance of addressing the ethical, legal and social aspects of this

<sup>2</sup> Helse- og omsorgsdepartementets forskningsstrategi 2006-2011 ("The Ministry of Health and Care Services' Research Strategy 2006-2011") (Norwegian only). [www.regjeringen.no/hod](http://www.regjeringen.no/hod)

<sup>3</sup> Report No. 47 (2008-2009) to the Storting: *The Coordination Reform: Proper Treatment – at the Right Place and Right Time*. <http://www.regjeringen.no/nb/dep/hod/dok/regpubl/stmeld/2008-2009/stmeld-nr-47-2008-2009-.html?id=567201>

<sup>4</sup> Nasjonal helse og omsorgsplan (2011-2014) ("National Health and Care Plan 2011-2014") (Norwegian only). [www.regjeringen.no/hod](http://www.regjeringen.no/hod)

<sup>5</sup> National Strategy for Biotechnology.

[http://www.regjeringen.no/nb/dep/kd/dok/rapporter\\_planer/planer/2011/nasjonal-strategi-for-bioteknologi.html?id=666235](http://www.regjeringen.no/nb/dep/kd/dok/rapporter_planer/planer/2011/nasjonal-strategi-for-bioteknologi.html?id=666235)

<sup>6</sup> Evaluation of Biology, Medicine and Health Research in Norway (2011).

[http://www.forskningsradet.no/no/Artikkel/Evaluering\\_av\\_biologisk\\_medisinsk\\_og\\_helsefaglig\\_forskning\\_i\\_2011/1253954269442](http://www.forskningsradet.no/no/Artikkel/Evaluering_av_biologisk_medisinsk_og_helsefaglig_forskning_i_2011/1253954269442) (front page in Norwegian, all documents in English)

<sup>7</sup> *Gode biobanker – bedre helse* ("Good Biobanks – Better Health") (Norwegian only).

[http://www.forskningsradet.no/no/Publikasjon/Gode\\_biobanker\\_bredre\\_helse/1219128438465?lang=no](http://www.forskningsradet.no/no/Publikasjon/Gode_biobanker_bredre_helse/1219128438465?lang=no)

research as an integral component of the programme and the individual projects alike, as well as the importance of taking part in the public dialogue.

## 2.2 Biobanks in Norway

A significant biobank infrastructure effort is underway in Norway and Europe. Nationally the focus is to build capacity at the Norwegian Institute of Public Health in Oslo, and for the *Nord-Trøndelag Health Study (HUNT)* in Levanger. The project *Biobank Norway* has received NOK 80 million in funding from the Research Council. A consortium has been established, consisting of the four medical faculties at the four largest universities (University of Oslo, Norwegian University of Science and Technology (NTNU), University of Bergen and University of Tromsø), the four regional health authorities and the Norwegian Institute of Public Health. The project has coordinated Norway's cooperation with the European biobank effort *Biobanking and Biomolecular Resources Research Infrastructure* ([www.BBMRI.eu](http://www.BBMRI.eu)), aiming at the establishment of a *European Research Infrastructure Consortium* (BBMRI-ERIC). There is also close Nordic cooperation regarding biobank infrastructure and research, with activities funded by NordForsk.

The population-based health surveys and research biobanks in Norway are attractive for international researchers, and projects have received substantial international funding. The National Institutes of Health (NIH) in the US, the world's largest funder of basic biomedical research, is an active co-funder of the *Norwegian Mother and Child Cohort Survey (MoBa)*. MoBa is a collection of data and biological material from more than 100 000 mothers, their children (110 000) and a large number of fathers (approximately 70 000). This research biobank with corresponding data is one example of Norway's unique world-class resources for biomedical research.

HUNT is one of the largest and most complete population-based health surveys, also internationally. Altogether, the three HUNT surveys contain health data from close to 120 000 persons, of which a very large number have participated in all three surveys. Biological material is available from 100 000 participants. HUNT data have been used for a number of years by international research groups, for example in the US, the Netherlands and France, in collaboration with Norwegian researchers. HUNT is coordinated with the other Norwegian health surveys in Troms, Finnmark, Hordaland, Oslo, Oppland and Hedmark, into the *Cohort of Norway (CONOR)*. When the data collection is completed, CONOR will contain health data from 200 000 subjects and will be a valuable multiregional biobank.

Other population-based biobanks are the *Janus Serum Bank*, where blood samples reserved for cancer research were collected through the *National Health Screening Services* (more than 300 000 persons) and the *Norwegian Women and Cancer (NOWAC)* cohort study, which includes 170 000 women and blood samples from 50 000 of them.

## 2.3 Scientific, ethical and legal perspectives

The international evaluation of the Large-scale Programme on Functional Genomics in Norway (FUGE)<sup>8</sup> identifies Norwegian biobanks as a world-class resource, first and foremost due to the ability to link data from population-based biobanks and disease-based biobanks to data from various registers. It is a unique starting point for studying how genes and environmental factors affect health. New high throughput analysis technologies enable us to extract extensive amounts of information from the biological samples. Coupled with other

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<sup>8</sup> See the programme's webpages [www.rcn.no/fuge](http://www.rcn.no/fuge); the link to the evaluation (Norwegian only) may be found to the right.

health data and information on environmental and lifestyle factors, this will create a unique basis for understanding the causes and development of diseases in more detail.

Furthermore, the research opens up new opportunities for the development of new diagnostic and prognostic tools, better regimens for prevention, new medicines as well as therapies tailored to the individual patient or patient group. In addition to the gains for the individual patient, the research should also have a positive impact on society by reducing the need for health services and promoting a healthier work force.

Although Norway has the best conditions for utilisation of population-based biobanks and health registers significant work remains to be done in order to take full advantage of this potential. There is a need for additional national disease registers (endpoint registers). There is also a need for infrastructure that facilitates the exchange of biological material as well as guidelines for operating high-quality research biobanks. Better coordination and management are necessary in order to improve researchers' access to data. The infrastructure project *Biobank Norway* aims at meeting these needs and challenges.

Through effective and optimal use of data from the population-based health surveys and biobanks, society shows respect for the participants (owners of the information) and motivates for continued high compliance and participation in the health surveys. It is a fundamental premise that the research has the trust of the population. This means that the data material is handled in an ethically and legally correct manner, and that the research questions are of relevance to society. A prerequisite for all research funded under the programme is compliance with all relevant legislation (the Health Research Act, the Biobank Act, the Biotechnology Act, etc.). Researchers are also expected to keep up to date on all ethical guidelines and possible pitfalls regarding the use of human material and data, and when formulating research questions, preparing protocols and drawing conclusions. To ensure correct processes and avoid duplication, researchers are strongly encouraged to register their projects in international databases, such as [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov), when relevant. Projects are based on and will generate national data and results which will be made accessible through the Research Council's open access policy, in compliance with international data sharing policies such as those of the OECD<sup>9</sup> and Wellcome Trust.<sup>10</sup>

### 3. Objectives of the programme

The overall objective of the programme is **to develop research-based knowledge about human health and disease through better use of human biobanks and health data as unique resources.**

#### 3.1 Primary objective

The programme is designed **to take advantage of the potential for research on human biological material in biobanks,<sup>11</sup> by coupling analysis results with data from health surveys, health registers and the health services.** (See Figure 2 below.)

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<sup>9</sup> OECD Principles and Guidelines for Access to Research Data from Public Funding.

<http://www.oecd.org/dataoecd/9/61/38500813.pdf>

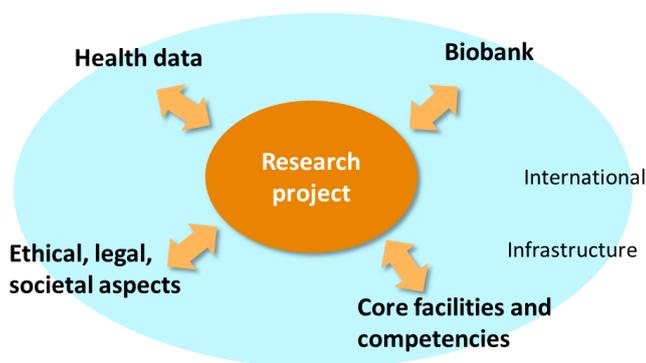
<sup>10</sup> Wellcome Trust policy on data management and sharing. <http://www.wellcome.ac.uk/About-us/Policy/Policy-and-position-statements/WTX035043.htm>

<sup>11</sup> Norwegian legislation classifies human biobanks into diagnostic, treatment and research biobanks (the Biobank Act and the Health Research Act).

The primary objective of the programme is thus to **generate, research-based new knowledge aiming at prevention, detection, diagnosis, treatment and survival of somatic and psychiatric diseases.** (See Figure 1, in Section 2.1)

Important **premises** for the research:

- The programme is open to all hypotheses and research questions related to human health and disease, and it is not limited to particular thematic areas, topics or methods. The projects may address basic biomedical, clinical, epidemiological or social health questions.
- The research shall be based on the use of human biobanks, in combination with data from health surveys, health registers and the health services, as well as other relevant registers. The research projects should use the full potential of the large biobanks and registers, unless there are scientific reasons for a smaller study sample/population.
- The use of analysis capacity and competencies built up under national infrastructure efforts, such as the biobank infrastructure (Biobank Norway) and the FUGE-supported technology platforms, is encouraged.
- Each project shall address ethical, legal and social aspects (ELSA) relating to the use of human biological material and health data in the project, and such aspects may also be included as a sub-project or activity. (See also the ELSA programme.<sup>12</sup>)
- Priority will be given to projects incorporating international collaboration.



**Figure 2. Research projects will respond to the objectives and premises of the programme.**

### **3.2 International cooperation**

A number of countries are investing large sums in research biobanks and health registers. International collaboration will increase the value, quality, applicability and benefit to society of the research outcomes. Norway and Norwegian researchers have unique samples and health data at their disposal, and international collaboration will expand the range of hypotheses formulated and analyses performed. In collaborations involving international funding, it is important that Norwegian researchers have sufficient national funding to ensure that they can participate as equal partners. Patient treatment as well as health policies must be built on research-based knowledge of high quality. Thus cooperation and network-building between

<sup>12</sup> The Research Council's programme Ethical, Legal and Social Aspects of biotechnology, nanotechnology and neurotechnology (ELSA) [www.forskningradet.no/elsa](http://www.forskningradet.no/elsa)

Norwegian and international research groups are considered key components of projects funded under the programme.

Internationalisation and research policy are major priorities in the **two most recent government white papers on research** (*Commitment to Research* and *Climate for Research*). **The Research Council of Norway's Strategy on International Cooperation** states that all research programmes must include clearly defined objectives and plans for international collaboration. Furthermore these documents recommend that Norway engages in joint programming across national borders and that greater focus be placed on international collaboration and mobility in grant application review processes. With biobanks and health registers as a major resource, Norwegian researchers are in an excellent position to participate in international cooperation under the **EU Framework Programmes and other large-scale European programmes**, and with US research groups as indicated in the **Letter of Intent between the Research Council of Norway and the National Institutes of Health**.

The programme will work to promote researcher mobility and further development of international collaborative partnerships, as well as encourage new international cooperation at the project and programme levels. Special focus will be placed on the EU countries, the US and Canada as collaborative partners.

### **3.3 Communication and dissemination activities**

Projects funded under the programme must disseminate knowledge and research results through publication in peer-reviewed journals as well as communication activities targeting relevant users and the public at large. Seminars and open meetings will be organised to communicate with the scientific community as well as the public at large and special interest organisations.

Specific communication measures will be set out in an annual communication plan, which is a mandatory attachment to the programme's action plan.

### **3.4 Budget**

A total of NOK 110 million has been allocated by the Ministry of Education and Research for the period 2011-2016. However, a significantly larger-scale effort is needed, and the Research Council's budget proposal for 2012 recommends that the Ministry of Education and Research and the Ministry of Health and Care Services allocate additional funding.

Two major calls for proposals are planned during the programme period, and will be published on the Research Council website.

### **3.5 Funding instruments**

The funding instrument employed in the first call for proposals will be the *Researcher Projects* application type. Funding to increase recruitment at the post-doctoral level may be sought within the framework of a Researcher Project or in the form of a *Personal Post-doctoral Research Fellowship*. The programme board will consider including *Innovation Projects for the Public Sector* in later calls in order to address the potential and opportunities for innovation and application opened up by the research results.

## 4. Coordination with other instruments at the Research Council

The programme board will seek to coordinate the programme's activities with those of other relevant medical and health science research programmes at the Research Council, and with activities and programmes being established as part of the implementation of the National Strategy for Biotechnology. First and foremost this means dialogue with the new *Research Programme on Biotechnology for Value Creation (BIOTEK2021)*, which is being launched in parallel with the BIOBANK programme. The BIOTEK2021 programme will encompass research addressing commercial utilisation, and will thus be relevant for commercial applications resulting from research related to human biobanks and health register data. The BIOBANK programme will also share an interface with thematic and practice-oriented medical and health science programmes, such as *the Research Programme on Public Health (FOLKEHELSE)*, *the Programme on Clinical Research (KLINISKFORSKNING)*, *the Programme for Publicly-initiated Clinical Cancer Studies (KREFT)* and other targeted health-related programmes (see [www.rcn.no](http://www.rcn.no)). Furthermore, the open competitive arenas for basic research, *Independent projects (the FRIPRO scheme)*, and for innovation, *the Programme for User-driven Research-based Innovation (BIA)*, both accept grant applications for studies related to human biobanks and health data. The programme *Ethical, Legal and Social Aspects of biotechnology, nanotechnology and neurotechnology (ELSA)* is highly relevant for in-depth studies of these aspects of research using human biobank and health data.

## 5. Organisation

The programme board was appointed and follows a mandate established by the Research Board of the Division for Society and Health. Together with the programme administration, the programme board is responsible for ensuring that the programme achieves its stipulated objectives and is implemented as efficiently as possible within the financial framework approved by the division research board. The tasks of the programme board include drawing up calls for proposals, following up the application review process, taking final decisions regarding grant awards and following up the projects. The programme board has a special responsibility for strategic planning in relation to the programme's activities.