# 'Big data analytics' and processing of health data for scientific research purposes : the Norwegian legal framework

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# 1. Overview of the legal framework

First, we would like to get an overview of the current and upcoming legal framework applying to the processing of health data for research purposes in your country.

## a. Which laws regulate the processing of health data for research purposes (the current regime, in force until the implementation of the GDPR into Norwegian law)

**What are the relevant applicable provisions governing the processing of health data in your country? Please provide online references (also to an English version, if available), a brief description and any specific relevant information.**

- Personopplysningsloven: Personal Data Act 2000[1] replaced by Personal Data Act 2018[2]

Before the implementation of the GDPR into Norwegian law, the principal data protection legislation was the Personal Data Act (Act of 14 April 2000 No. 31), hereinafter referred to as the "Personal Data Act (2000)". The Personal Data Act (2000) implemented into Norwegian law the requirements of the EU Data Protection Directive (95/46/EC). The purpose of the Act was to protect natural persons from violation of their right to privacy through the processing of personal data. The Personal Data Regulations[3] laid down by Royal Decree of 15 December 2000 set out more detailed regulations on certain topics covered by the Personal Data Act (2000).

The Personal Data Act (2000) was replaced by a new Personal Data Act of 15 June 2018 No. 38 (hereinafter referred to as the "Personal Data Act (2018)") that implements the GDPR. The Personal Data Act (2018) entered into effect in Norway on 20 July 2018. Also on 20 July 2018, the Personal Data Regulations laid down by Royal Decree of 15 December 2000 were replaced by a new and much shorter Personal Data Regulations (Regulations of 15 June 2018 No. 876).

- Helseforskningsloven: The Health Research Act[4]

The Health Research Act applies to all medical and health research on human beings, human biological material or personal health data. Such research also includes pilot studies and experimental treatments. The Health Research Act made the process for application for approval of medical health research projects more efficient, due to the main principle in the Act that such an application only needs to be directed to one body, viz. to the Regional

[1] Act of 14 April 2000 No. 31 relating to the processing of personal data, in Norwegian 'Lov om behandling av personopplysninger' abbreviated as 'personopplysningsloven'.

[2] Act of 15 June 2018 No. 38 relating to the processing of personal data, in Norwegian 'Lov om behandling av personopplysninger' abbreviated as 'personopplysningsloven'.

[3] Regulations on the processing of personal data, laid down by Royal Decree of 15 December 2000 No. 1265 pursuant to the Personal Data Act (2000), in Norwegian 'Forskrift om behandling av personopplysninger' abbreviated as 'personopplysningsforskriften'.

[4] Act of 20 June 2008 No. 44 on medical and health research, in Norwegian, 'Lov om medisinsk og helsefaglig forskning', abbreviated as 'helseforskningsloven'



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Committee for Medical and Health Research Ethics (REK) in the applicant's geographical area. Upon the entry into force of the Health Research Act, the REKs took over the tasks that previously lay with the Data Protection Authority (i.e. licensing for the processing of health data) and the Directorate of Health (exemption from the duty of confidentiality and approval of the setting up of research biobanks). The REK shall furthermore carry out an ethical evaluation of the project, based on the project application and research protocol.

Research biobanks are regulated by the Health Research Act and may only be established after approval by the REK. Research biobanks that are established in connection with the collection and storage of human biological material without affiliation to a concrete research project must be approved by the REK. The same applies to research biobanks that are going to be used for the storage and new use of human biological material once the original objective of a research project has been fulfilled.[5]

**Shared electronic health records are indirectly relevant in this context because they can potentially be an important source for health-related research. Do shared electronic patient records exist in your country? How is the sharing of electronic patient records regulated? Can data stored in these records be used for research purposes?**

- Helsepersonelloven: Health Personnel Act[6]

The Health Personnel Act applies to health personnel and organisations that provide medical help in Norway. Its purpose is to contribute to patient safety and to the quality of the health and care service as well as to contribute to trust in health personnel and in the health and care services.

The main rule in the Health Personnel Act is that health personnel owe a duty of confidentiality and must therefore hinder that others obtain access to or knowledge of data about people's bodily condition, state of illness or any other personal condition that they get to know of in virtue of being health personnel (section 21). It is also forbidden to read, search or in any other manner acquire, use or possess the aforementioned health data unless it is to provide medical treatment to the individual, the administration of such treatment or unless this has a specific legal basis in a law or regulations (section 21a). However, pursuant to section 29, use of medical data for research may be permitted without breach of the duty of confidentiality provided authorisation is given by the REK.

- Pasientjournalloven: Patient Medical Record Act[7]

The Patient Medical Record Act applies to all processing of health data which is necessary to provide, administer or quality assure medical treatment to individuals. It applies to the processing of health care for primary health care, i.e. therapeutic purposes, and governs therapeutic registers/filing systems (*behandlingsrettet helseregister*).

Health data in therapeutic registers can only be processed when such data is necessary to provide medical treatment, or for the administration, internal control or quality assurance of the medical treatment.

[5] See section 25 third paragraph of the Health Research Act.

[6] Act of 2 July 1999 No. 64 on health care personnel, etc. in Norwegian 'Lov om helsepersonell m.v.' abbreviated as 'helsepersonelloven'.

[7] Act of 20 June 2014 No. 42 on the processing of medical data in the provision of medical treatment, in Norwegian 'Lov om behandling av helseopplysninger ved ytelse av helsehjelop' abbreviated as 'pasientjournalloven'.



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According to section 9 of the Patient Medical Record Act, two or more medical organisations may collaborate on therapeutic registers provided that such organisations enter into a written agreement about: (a) what the collaboration comprises; (b) how the patient's or user's rights shall be safeguarded, (c) how medical data shall be processed and secured, also by changes to or termination of the collaboration, and (d) data processor responsibility.

The Act also states that national therapeutic registers may be established by regulations (i.e. subsidiary legislation). Anyone processing health data pursuant to the Patient Medical Record Act is subject to a duty of confidentiality pursuant to section 21 of the Health Personnel Act. According to section 16, it is forbidden to read, search or in any other manner acquire, use or possess health data from a therapeutic register except to provide medical treatment to the individual, to administer such services or unless this has a specific legal basis in a law or regulations. However, the data controller can make medical data available for purposes other than medical treatment when the individual (the data subject) consents or if this is laid down in law or pursuant to law. Consent is defined in line with the definition in the main personal data legislation and thus, from the entry into effect of the Personal Data Act (2018), it is based on the definition in article 4 (11) of the GDPR (section 20). An example of a statutory legal basis is section 29 of the Health Personnel Act regarding the disclosure of health data for research purposes (see above).

- Helseregisterloven: Personal Health Data Filing System Act[8]

The Personal Health Data Filing System Act regulates secondary use of personal health data, i.e. it applies to health registers which are not used for direct treatment of patients but which are used as a basis for statistics, health analysis, research, quality improvement, planning, management and preparedness in the administration of health and in the provision of health and care services. It does not apply to the processing of health data that is regulated by the Health Research Act or the Patient Medical Record Act.

A personal health data filing system (*helseregister*) may be set up in one of three ways:[9]

(i) by statute, i.e. the legislator enacts a law that establishes a personal health data filing system where personal health data may be processed;

(ii) by regulations (i.e. secondary legislation), pursuant to special provisions in the Personal Health Data Filing Systems Act which contains detailed rules in sections 8 to 12 for the setting up of various types of health registers, e.g. consent-based registers; registers without directly identifying personal characteristics; registers where the data may be collected without the data subject's consent provided the data subject has the right to object to the processing of the personal data in the register; the power to set up specific registers in regulations where data is processed without the consent of the data subjects;

(iii) prior to 20 July 2018, by obtaining a licence from the Data Protection Authority, to the extent the data subject has provided consent or to the extent there is another necessary legal basis for the processing pursuant to the Personal Data Act (2000): in particular, section 9 first paragraph letter g (necessary for the purposes of preventive medicine, medical diagnosis, the provision of care or treatment or the management of health care services, and where the data are processed by health professionals subject to the obligation of professional secrecy) and letter h (necessary for historical, statistical or scientific

[8] Act of 20 June 2014 No. 43 on Personal Health Data Filing Systems and the Processing of Personal Health Data, in Norwegian 'Lov om helseregistre og behandling av helseopplysninger' abbreviated as 'helseregisterloven'.

[9] See Bygrave, L. and Schartum, D.W (2016), *Personvern i informasjonssamfunnet*, 3rd ed, Fagbokforlaget, pp. 254-255.



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purposes, and the public interest in such processing being carried out clearly exceeds the disadvantages it might entail for the natural person) are relevant.

According to section 11, regulations may be given regarding the processing of personal data in personal health data filing systems where the name, personal number and other directly identifiable personal characteristic can be processed without the data subject's consent to the extent this is necessary for the purposes of such register.[10]

Section 20 permits the disclosure of indirectly identifiable health data for research, health analysis, and quality assurance, administration, planning or management of health and care services. This only applies with regard to health data in personal health data filing systems established on the basis of section 11. The medical data may only be disclosed as long as their processing is of substantial interest for society, the patient's integrity and confidentiality are safeguarded, and the processing is not worrying from an ethical, medicinal or medical consideration. The data controller can set down conditions for such disclosure.

- Bioteknologiloven: Biotechnology Act[11]

With regard to medical and health research in the field of biotechnology, both the Health Research Act and the Biotechnology Act may be relevant.

The Biotechnology Act regulates the application of human medical use of biotechnology and comprises medically assisted fertilization, research on fertilized eggs and cloning, embryo diagnostics, postnatal genetic testing, gene therapy, etc. Medical and health research within these fields of study must be examined in accordance with the Biotechnology Act. According to section 1-2, the Biotechnology Act "does not apply to research that has no diagnostic or therapeutic consequences for the participant or where data about an individual person are not linked to that person. The provisions of Chapter 3 [research on redundant embryos and cloning] are excepted from this provision."

[10] According to section 11 regulations may be given on the following registers:

1. Causes of Death Registry
2. Cancer Registry
3. Medical Birth Registry
4. System of notification of infectious diseases (MSIS)
5. System for Vaccination Control (SYSVAK)
6. Defence Forces Health Records
7. Norwegian Register of Patient Records
8. National Register of Cardiovascular Disease.
9. System for reporting side effects
10. Municipal Patient and User Register (KPR).

[11] Act of 5 May 2003 No. 100 on the application of biotechnology in human medicine etc., in Norwegian 'Lov om humanmedisinsk bruk av bioteknologi m.m.' abbreviated as 'bioteknologiloven'.



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The guidelines on the Health Research Act issued by the Department of Health and Care Services (hereinafter referred to as the "Department Guidelines") clarify that:[12]

- All research projects in the area covered by the Biotechnology Act that may be linked back to the individual must comply with the requirements of the Biotechnology Act. The Directorate of Health may provide guidance on how such projects ought to be arranged.
- A prior evaluation of whether the planned research may have diagnostic or therapeutic consequences for the individual must be carried out.
- If there are grounds to believe that knowledge may be generated, during the research period, that can have a diagnostic or therapeutic significance for the individual, the Biotechnology Act applies with regard to such research.
- If the researcher considers that the research project will not have diagnostic or therapeutic consequences for the individual, the Biotechnology Act will not apply unless the research nevertheless plans to provide any such information to the research subject.

- Behandlingsbiobankloven: Therapeutic Biobanks Act[13]

Diagnostic and therapeutic biobanks are regulated by the Therapeutic Biobanks Act, whereas research biobanks are regulated by the Health Research Act. The Therapeutic Biobanks Act does not contain any provisions on the processing of personal health data that is derived from human biological material. Instead, section 3 second paragraph cross-refers to other legislation that protects personal and health data, i.e. the Personal Data Act, the Personal Health Data Filing System Act, the Health Personnel Act "and any other law which specifically regulates the protection of personal data". Biobanks that are set up for diagnosis and therapy must be notified to the Health and Care Department. Section 5 of the Therapeutic Biobanks Act lays down what information needs to be notified.

The Therapeutic Biobanks Act does not apply to human biological material or personal health data that is derived from such material and which is used in research. The collection, storage, processing and destruction of human biological material and data for research purposes is regulated by the Health Research Act.

## b. Revision of the current legal framework under the GDPR

### How are the necessary changes to the national data protection framework introduced by the GDPR addressed in your country? What is the adopted legislative approach?

[12] See Department Guidelines, available in Norwegian, (full title "Veileder til lov 20. juni 2088 nr. 44 om medisinsk og helsefaglig forskning (helseforskningsloven)"), version 25th March 2010, pp. 14-15.

[13] Act of 21 February 2003 No. 12 on therapeutic biobanks, in Norwegian 'Lov om behandlingsbiobanker' abbreviated as 'behandlingsbiobankloven'.



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From 25 May 2018, the principal data protection legislation in the EU will be the GDPR (Regulation 2017/679). A bill proposing a new Personal Data Act and implementing the GDPR by referring to its incorporation in the EEA Agreement (hereinafter referred to as the "Bill"), was presented in Parliament on 23 March 2018.[14] The new Personal Data Act (2018) entered into effect on 20th July 2018.

As Norway is not an EU member state, the GDPR had to first be incorporated into the European Economic Area ("EEA") Agreement before it could be implemented as national law in Norway by means of the Personal Data Act (2018).

The Bill is preceded by an extensive Explanatory Statement. This statement details the approach followed by the Norwegian government in proposing the Bill and in implementing the GDPR. The Bill deals with those GDPR provisions that give some leeway to the EU/EEA states. An unofficial translation of the GDPR into Norwegian was published with the Bill.

The analysis in this study of the legal framework that is applicable after the GDPR is implemented into Norwegian law relies on the Bill and its extensive Explanatory Statement as well as the new Personal Data Act (2018).

## c. The national data processing authority

### Can you provide a short description of the role of the data protection supervisory authority in your country in the domain of processing health data for research purposes under the current legal framework?

In Norway, applications for prior authorisation of medical and health research on human beings, human biological material or personal health data, including pilot studies and experimental treatments, must be made to the Regional Committee for Medical and Health Research Ethics (REK) in the applicant's geographical area. There are four such regional committees:

- REK West
- REK Central
- REK North
- REK South East

[14] Prop. 56 LS (2017-2018) Proposisjon til Stortinget (forslag til lovvedtak og stortingsvedtak) – Lom om behandling av personopplysninger (personopplysningsloven) og samtykke til deltakelse i en beslutning I EØS-komiteen om innlemmelse av forordning (EU) nr. 2016/679 (generell personvernforordning) i EØS-avtalen, available, together with an extensive Explanatory Statement from https://www.regjeringen.no/no/dokumenter/prop.-56-ls-20172018/id2594627/.



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The REKs are set up by the Ministry of Education and Research pursuant to the Research Ethics Act[15] (section 10). Each committee shall have competence in the relevant research disciplines, ethics and law. According to the Health Research Act, an application for prior approval of a research project must be submitted with the research protocol to the relevant REK. The REK undertakes a standard evaluation of the research ethics of the project and determines whether the project satisfies the requirements laid down in or pursuant to the Health Research Act. The REK may specify conditions for approval.

Decisions regarding prior approval of the research project may be appealed to the National Committee for Medical and Health Research Ethics, c.f. section 10 third paragraph of the Health Research Act.

The Data Protection Authority (*Datatilsynet*) carries out inspections regarding the use of personal health data pursuant to the Health Research Act (section 47). The primary duty of the Data Protection Authority under the Personal Data Act (2000) was to oversee and enforce the Personal Data Act (2000) and it continues to hold this responsibility after the GDPR is implemented. It is an independent administrative body that reports annually to the Norwegian Parliament.

## Can you describe the adopted or proposed changes to this role of the national data protection authority to ensure compliance with the GDPR?

National independent supervisory authorities are governed by the provision of Chapter VI of the GDPR (Articles 51 to 59). Article 54 of the GDPR provides that each Member State must set in law the rules establishing the supervisory authority.

Accordingly, section 20 of the Personal Data Act 2018 states that the supervisory authority pursuant to article 51 of the GDPR is *Datatilsynet* (Data Protection Authority). Furthermore, section 20 states that the Data Protection Authority's authority pursuant to article 58 of the GDPR shall apply accordingly for supervision regarding compliance with: (a) the provisions of the Personal Data Act (2018) and regulations made pursuant to such law; (b) provisions on the processing of personal data in other laws and regulations, insofar as the processing falls within the scope of the Personal Data Act (2018) and the GDPR.

In the case of medical and health research on human beings or human biological material, an application for approval of the research project should still be made to the REK in the applicant`s geographical area. Prior to the implementation of the GDPR into Norwegian law, the prior approval from REK has been regarded as a necessary and adequate legal ground for the processing of health data in medical and health research. After the implementation of the GDPR, however, such prior approval is no longer regarded as a necessary and adequate legal ground for the processing of health data and such processing must therefore be based on one of the grounds in Articles 6(1) and 9(2) of the GDPR.[16] The Personal Data Act (2018) underlines that this change does not mean that there is need for prior approval from the Data Protection Authority. However, the rules in the GDPR regarding the requirement for a

[15] Act of 28 April 2017 No. 23 on the organisation of research ethical work, in Norwegian 'Lov om organisering av forskningsetisk arbeid' abbreviated as 'forskningsetikkloven'.

[16] See Explanatory Statement to the Bill, paragraph 32.3.2 pp. 184-185.



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data protection impact assessment (DPIA) and prior consultation with the Data Protection Authority, will also apply to processing that falls within the Health Research Act.[17]

The requirement for prior ethical approval of a medical and health research project by the REK remains unchanged.

# 2. Transposition of Article 8.4 of Directive 95/46

**Did your national legislator insert any additional exemptions for the processing of health data for research purposes? How is it/are they formulated? Please explain. Are there additional exemptions issued by the DPA?**

Art. 8.4 of Directive 95/46: "4. Subject to the provision of suitable safeguards, Member States may, for reasons of substantial public interest, lay down exemptions in addition to those laid down in paragraph 2 either by national law or by decision of the supervisory authority."

## a. Transposition of Article 8.4 of Directive 95/46

In Norway, pursuant to the Personal Data Act (2000), sensitive personal data can only be processed provided one of the legal basis in section 9 first paragraph of the Act is fulfilled. Among the applicable grounds regarding the processing of health data for research purposes are the consent of the data subject (section 9 first paragraph letter a), and where there is statutory authority for such processing (section 9 first paragraph letter b). Furthermore, according to section 9 first paragraph letter h, the processing of sensitive personal data is permitted if "the processing is necessary for historical, statistical or scientific purposes, and the public interest in such processing being carried out clearly exceeds the disadvantages it might entail for the natural person".

Thus, the exemptions, as taken up by the Norwegian legislator in applying Article 8.4 of the Directive, are laid down in section 9 first paragraph letter h as well as section 9 third paragraph.

According to section 9 third paragraph of the Personal Data Act (2000), the Data Protection Authority may decide that sensitive personal data may also be processed in cases other than those listed in section 9 first paragraph "if this is warranted by important public interests and steps are taken to protect the interests of the data subject". The preparatory works to the Personal Data Act (2000) emphasize that the requirement for important public interests implies that this provision is meant to be applied restrictively.[18] In cases falling within section 9 third paragraph, prior approval of the Data Protection Authority in the form of a license is required.

[17] See Explanatory Statement to the Bill, paragraph 32.3.2 p. 185.

[18] Ot.prp.nr.92 (1998-1999) p. 112.



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## b. The regime applying to the processing of personal data for health research purposes

### Is there a specific regime applying to data processing for research in the field of health purposes?

The Health Research Act applies to all medical and health research on:

(i) human beings,

(ii) human biological material or

(iii) personal health data.

All the above mentioned three aspects are regulated in an integrated manner and there are, for example, common provisions regarding consent irrespective whether one is referring to human biological material, personal health data or research on human beings.[19]

The research falling within the Health Research Act also includes pilot studies and experimental treatments, c.f. section 2 first paragraph second sentence.

By "medical and health research" is meant activity conducted using scientific methods to generate new knowledge about health and disease. The Personal Data Act and its regulations supplement the Health Research Act, unless otherwise provided in the Health Research Act. The clinical testing of medicinal products on human beings is regulated by section 3 of the Medicines Act[20] and its regulations. Clinical testing of medical equipment is regulated by the Act on Medical Equipment[21] and its regulations. In these contexts, the provisions of the Health Research Act apply as a supplement, where relevant.

As explained in the preparatory works to the Health Research Act, research on human beings is research that involves direct contact with research participants by intervention and invasive studies (e.g. clinical trials of drugs, surgeries), the collection of human biological material (blood samples, tissue samples) or by obtaining personal health information through direct contact with the research participant (interview, observation, questionnaires).[22] The actual use of collected biological material is deemed to be research on biological material whereas the actual use of collected health data is deemed to be research on personal health data.

Whereas the term "human being" refers to the whole human being, the term "human biological material" is defined as "organs, parts of organs, cells and tissues and components of this kind of material from living and deceased human beings" (section 4 letter b). The term "personal health data" is defined as "confidential information pursuant to

[19] See also Bygrave and Schartum, footnote 9, p. 252.

[20] Act of 4 December 1992 No. 132 on medicines, in Norwegian 'Lov om legemidler m.v.' abbreviated as 'legemiddelloven'.

[21] Act of 12 January 1995 No. 6 on medical equipment, in Norwegian 'Lov om medisinsk utstyr'.

[22] See Ot.prp.nr.74 (2006-2007) p. 148.



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section 21 of the Health Personnel Act and other information and assessments concerning health issues or that are significant for health issues that can be linked to an individual person" (section 4 letter d).

The main rule is that medical and health research must be organised and carried out in a responsible manner, be based on respect for the research participants' human rights and dignity. The participants' welfare and integrity shall have priority over scientific and social interests. Medical and health research must take into account ethical, medical, health, scientific and privacy factors.

Pursuant to section 6, medical research must be organised as a project under the direction of a person or body responsible for the research (usually a hospital or a research institution such as a university) and it must be managed by a project manager. The proposed research must be described in detail in a research protocol. The sources of funding must be indicated in the protocol. Internal control must be carried out in a manner that is adapted to the size, nature, activities and risk factors of the research. Further requirements concerning the organisation of medical and health research, the requirement for internal control, the requirements concerning the contents of the application and the contents of the research protocol, the duties of the project manager, as well as the appointment of a project manager for multicentre studies are laid down in the Regulations on the Organisation of Health Research.[23]

Medical research concerning identifiable individuals in general require both prior approval of the research as well as exemption from the duty of confidentiality of the health personnel involved in the project. The Health Research Act made the process for application for approval of medical health research more efficient due to the main principle in the Act that such an application only needs to be directed to one body, namely to the REK in the applicant's geographical area. There is, thus no need to also seek a licence from the Data Protection Authority, or to apply for exemption from the duty of confidentiality from the Directorate of Health. This is because, upon the entry into force of the Health Research Act, the REKs took over the tasks that previously lay with the Data Protection Authority (i.e. licensing for the processing of health data) and the Directorate of Health (i.e. regarding exemption from the duty of confidentiality and the approval of the setting up of research biobanks).

Pursuant to section 32 of the Health Research Act, prior approval from the REK is deemed to be a necessary and adequate legal basis to process personal health data in medical and health research.

An application for approval of research projects (project application), general research biobanks (biobank application) or dispensation from professional secrecy requirements for other research (dispensation application) should be submitted in accordance with the specific application deadlines which are published by the REK one year at a time. The project application or dispensation application must be submitted by the project manager, and a biobank application must be submitted by the project manager responsible for the general research biobank. An application must include the completed application form, protocol and other documents and information required to gain a full understanding of the application.

In accordance with the provisions of the Public Administration Act[24] and the rules on clinical trials of medicines, the case management period of an application runs from the time REK confirms receipt of the application. A reply may be expected within three weeks following the date of the first upcoming meeting of the REK which will review the

[23] Regulations of 1 July 2009 No. 955 on the organisation of medical and health research, in Norwegian 'Forskrift om organisering av medisinsk og helsefaglig forskning' abbreviated as 'Forskrift om organisering av helseforskning'.

[24] Act of 10 February 1967on the procedure in administrative cases, in Norwegian 'Lov om behandlingsmåten I forvaltningssaker' abbreviated as 'forvaltningsloven'.



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application. The REK may decide to postpone its (final) decision and give a deadline for any providing a reply to questions or comments.[25]

## From which generally applicable data protection provisions are researchers exempted and under what conditions?

With regards to correction or deletion of personal health data, according to section 36 it is a duty of the project manager to, on his/her own initiative, correct incorrect information, update obsolete information and supplement incomplete information. Incorrect and obsolete information must be deleted or changed in a way that allows the change(s) to be tracked. Section 36 specifies that incorrect and obsolete information may only be permanently deleted if this is required by someone on whom the information may have a direct impact and the deletion will not have a decisive effect on the validity or representativeness of the research data. It is the project manager who makes the final decision on a request to have data deleted. If deletion is denied, the decision may be appealed to the REK.

Prior to the entry into effect of the Personal Data Act (2018), there were also special conditions regarding data transferred to and from project participants in third countries (i.e. countries outside the EEA). Pursuant to section 37, identifiable personal health data that are processed as part of a research project may only be transferred between Norway and a non-EEA country if the following conditions are satisfied:

a) the overseas person in charge of data processing assures the person or body responsible for the research in writing that data have been processed or will be processed in conformance with Directive 95/46/EC, AND

b) the person the data pertains to has given their consent, OR

c) the data subject has not stated that he/she does not wish to be involved in research, and has been informed that the data will be transferred to a non-EEA nation.

According to the preparatory works of the Health Research Act, the written assurance referred to in a) above can be generically formulated, and no requirement is made that the third country satisfies the requirement of the Data Protection Directive.

Personal health data that have been anonymised or given a pseudonym may be transferred to a country outside the EEA if the data cannot be linked to personal identification as long as the data are in such non-EEA country, c.f. section 37 second paragraph.

Following the entry into force of the Personal Data Act (2018), section 37 has been deleted since articles 44 to 50 of the GDPR are deemed to suffice to regulate transfers to and from third countries.

[25] See further information on the REK's English web pages at https://helseforskning.etikkom.no/reglerogrutiner/administrativerutiner/soknadskrav?p_dim=35026&_ikbLanguageCode=us.



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## c. Are there additional specific conditions governing the processing of data for scientific research purposes?

### What are the suitable safeguards applied to the exemption foreseen by Article 8.4 of the Directive in your country?

The text of Article 8(4) of the Directive requires that the processing of sensitive personal data, when authorised by the Member States for reasons of significant public interest, are subject to suitable safeguards. In the Norwegian legal framework, processing of sensitive personal data that is necessary for scientific purposes where the public interest in such processing being carried out clearly exceeds the disadvantages it might entail for the natural person, is permitted (section 9 first paragraph letter h of the Personal Data Act (2000)). In the case of medical and health research, the Health Research Act furthermore lays down detailed requirements on the organisation of the research.

As stated earlier, internal control must be carried out in a manner that is adapted to the size, nature, activities and risk factors of the research. The Regulations on the Organisation of Health Research specify further what internal control means, i.e. systematic measures which advance good research and which ensure that the research is planned, organised, implemented and concluded in accordance with the requirements set down in or pursuant to the Health Research Act.

According to section 13 of the Personal Data Act (2000), the controller and the processor shall by means of planned, systematic measures ensure satisfactory data security with regard to confidentiality, integrity and accessibility in connection with the processing of personal data. The Department Guidelines state that, in order to comply with such requirement for information security, measures must be taken to prevent any health information from the project from unauthorised disclosure.[26] Measures should at least be assessed depending on the technical equipment used, access control, routines for identification and anonymization of information and the handling of non-conformities. The routines must also include what will happen to the information upon completion of the project.[27]

### Are there any specific provisions concerning: (i) professional secrecy, (ii) express consent for specific data, or specific provisions for (iii) deceased data subjects, or (iv) specific provisions for minors or persons subject to guardianship?

**Specific provisions on professional secrecy**: As stated earlier, the main rule in section 21 of the Health Personnel Act is that health personnel owe a duty of confidentiality and must therefore hinder that others obtain access to or knowledge of data about people's bodily condition, state of illness or any other personal condition that they get to know of in virtue of their being health personnel. It is also forbidden to read, search or in any other manner acquire, use or possess the aforementioned health data unless it is to provide medical treatment to the individual, the administration of such treatment or unless this has a specific legal basis in a law or regulations (section 21a).

[26] See Department Guidelines, section 2.5.2.1, p. 10.

[27] Ibid.



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However, pursuant to section 29 of the Health Personnel Act, use of medical data for research may be permitted without breach of the duty of confidentiality provided authorisation is given by the REK.

Section 7 of the Health Research Act lays down a duty of confidentiality on anyone who has access to health data related to a health research project. Section 7 states that any party that has access to personal health data and other personal data that are used in a research project must prevent other people from gaining access to or knowledge of the data. The duty of confidentiality does not impede the information being communicated to the person it concerns directly or being surrendered when the recipient has legal grounds for having the information disclosed (e.g. consent or where there are statutory grounds). Thus, and as stated in the Department Guidelines, the duty of confidentiality is not just a duty of silence; it is also an active duty to hinder third parties from getting access to confidential information.[28]

**Specific provisions on consent**: The main rule with regard to medical and health research is that the consent of the participants must be obtained, unless otherwise laid down in the law, c.f. section 13 first paragraph, Health Research Act. Consent must be voluntary, express, informed and documented, c.f. section 13, second paragraph first sentence. The reasons behind the aforesaid main rule on consent are respect for human rights, personal integrity and human value.[29]

Consent must be voluntary, i.e. freely given such that the participant must not be under any kind of pressure when he or she gives consent. If the research participant can be regarded as being in a relationship of dependency with the person requesting consent, meaning that the research participant might feel pressured to give their consent, informed consent must be obtained by another person with whom the research participant does not have this kind of relationship, c.f. section 13 third paragraph. The Department Guidelines provide a number of examples where a relationship of dependency may exist, such as, between a patient and the doctor providing medical treatment to such patient, between a student and teacher, situations where a patient feels a debt of gratitude to a medical institution providing him/her treatment and who needs research subjects, etc.[30] In assessing research projects, the REK must assess the extent to which research subjects can be deemed to be in such a situation of dependency to those requesting consent such that the research subjects may feel pressured to give consent. The REK will evaluate how close the relationship is, the nature and scope of the research project, risks and sensitivity and whether the research project is significant for the patient's illness and/or condition.[31]

The consent must also be express, i.e. passive consent is insufficient. For consent to be express, the research participants must actively consent to participating in the research project. Furthermore, consent must be capable of being documented. This means that consent ought, as a rule, to be written. However, as the Department Guidelines state, consent may also be provided by other means, e.g. recorded on tape, by providing a fingerprint or electronically.[32]

For consent to be informed, it must be based on relevant and objective information. As provided in section 13 second paragraph second sentence, consent must be based on specific information about a concrete research project,

[28] See Department Guidelines, p. 19.

[29] See Department Guidelines, paragraph 4.3.1, p. 20.

[30] See Department Guidelines, paragraph 4.3.1, p. 20-21.

[31] See further Department Guidelines, paragraph 4.3.1, p. 21.

[32] See Department Guidelines, paragraph 4.3.1, p. 21.



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unless there is a case for the granting of so-called "broad consent", c.f. section 14. According to section 14, research participants may consent to human biological material and personal health data being used for specific, broadly defined research purposes. The REK may specify conditions for use of broad consent and may order the project manager to obtain new consent if the committee deems it necessary. Furthermore, participants who have given broad consent are entitled to receive information about the project at regular intervals.

**Specific provisions on deceased data subjects:** Where a research participant has died and there is a change in use of collected human biological material or personal health data, section 15 second paragraph of the Health Research Act applies.[33] According to this provision, the regional committee for medical and health research ethics may approve a new or changed use of previously collected human biological material or personal health data (without new consent being obtained) provided that the research in question is of significant interest to society and the participants' welfare and integrity are ensured.

Research on biological material taken from a deceased person is subject to section 7 first to third paragraphs of the Autopsy Act[34] regarding the provision of information and the right of next-of-kin to refuse autopsy etc. According to section 7 of the Autopsy Act, a medical autopsy can only be carried out when there are no grounds to believe that the deceased person will have objected to such an investigation. The next-of-kin shall, as far as possible, be asked whether there are circumstances which suggest that the deceased person would have objected to the autopsy. Medical autopsy cannot be carried out if one of the next-of-kin refuses that an autopsy be carried out. The next-of-kin shall, as far as possible, be informed that an autopsy is desirable, what the autopsy involves and about the possibility of refusing that an autopsy is carried out. These rules apply correspondingly to the extraction of biological material from a deceased person for use in teaching or in research.

**Specific provisions on minors or persons subject to guardianship:** According to section 17 of the Health Research Act, minors between 16 and 18 years of age may consent to participate in medical and health research, unless otherwise follows from specific statutory provisions or the nature of the activity. Such competence to give consent may cease to apply in the situations referred to in section 4-3, second paragraph of the Patients' Rights Act, i.e. if the patient, on account of a physical or mental disorder, senile dementia or mental retardation, is clearly incapable of understanding what the consent entails. For persons who lack competence to give consent as aforesaid, the person's next-of-kin shall have authority to grant consent.

Consent must be obtained from parents or other people with parental responsibility for research on minors between 16 and 18 years which entail bodily intervention or testing of medicinal products.

The rules concerning consent stipulated in section 4-4 of the Patients' Rights Act apply correspondingly to consent to research including participants under the age of 16. If children between the ages of 12 and 16 do not want their parents, others with parental responsibility for them or the child welfare service to be informed about personal data relating to the child, for valid reasons, this wish must be respected.

The Regulations on Children's Right to Consent to Participate in Research[35] provide further rules where children between the age of 12 and 16 may themselves consent to research projects. Such projects must be approved by the

[33] See Department Guidelines, section 4.3.4.1, p. 27.

[34] Act of 7 May 2015 No. 26 on autopsy and the provision of a corpse for teaching and research, in Norwegian 'Lov om obduksjon og avgjeving av lik til undervisning og forskning' abbreviated as 'obduksjonslova'.

[35] Regulations of 28 June 2017 No. 1000 on the right of children between 12 and 16 to consent to participate in medical and health research, in Norwegian 'Forskrift om barn mellom 12 og 16 år sin rett til selv å samtykke til deltakelse i medisinsk og helsefaglig forskning'.



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REK before children between 12 and 16 years of age can themselves consent to research on personal health data in a limited quantity of concretely specified research projects. This does not apply to research that involves bodily intervention or testing of medicinal products. Among the additional requirements to those required by the Health Research Act, the Regulations on Children's Right to Consent to Participate in Research state that: (a) the societal usefulness of such a project must clearly override the disadvantages that can arise for the individual child to participate in the project; (b) it must be assumed that the project cannot be carried out with parental consent because the project can reveal information that the parents, or others with parental authority, have a personal interest not to have revealed. This can, inter alia, include information on violence, gross neglect of care, or other assault/attack by the parents, others with parental authority or others who are closely related; (c) the project manager shall beforehand have considered special challenges related to (i) the implementation of the project and be prepared to meet and handle situations where it turns out that the child needs medical help, and (ii) the trust relationship between the child and the health care service as well as the parents. The Regulations also lay down specific rules on how information shall be provided to children participating in such research projects. Information must be provided face-to-face and before consent is obtained; it must be adapted to the child's prerequisites and ability to understand what consent means, and it must include how the child should proceed to withdraw consent. Consent must be provided without pressure or persuasion. The REK can decide that consent shall be documented by other means than writing, for example, by means of image and sound recording or witnesses.

## Are there specific requirements about the data subject's information or about the person from whom the data was collected?

According to section 7 first paragraph letter d of the Regulations on the Organisation of Health Research, the application for prior approval by the REK must include details about the information that shall be provided to the research participants.

The general duty of the data controller to provide information about the processing to the data subjects shall apply, c.f. sections 19 and 20 of the Personal Data Act (2000). According to sections 19 and 20, the controller must inform the data subject: (a) the name and address of the controller and of his representative, if any; (b) the purpose of the processing; (c) whether the personal data will be disclosed, and if so, the identity of the recipient; (d) whether the provision of information is voluntary; and (e) any other circumstances that will enable the data subject to exercise his rights pursuant to the Personal Data Act (2000) in the best possible way, such as information on the right to demand access to data, cf. section 18, and the right to demand that data be rectified, cf. sections 27 and 28.

However, where the personal data are not collected directly from the data subject, the data subject is not entitled to notification if:

(a) the collection or communication of data is expressly authorized by statute;

(b) notification is impossible or disproportionately difficult, or

(c) there is no doubt that the data subject already has the information which shall be contained in the notification.

Where notification is omitted pursuant to the abovementioned letter (b), the information must nonetheless be provided at the latest when the data subject is contacted on the basis of the data.



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As stated above, for consent to be valid, it must be informed. Research participants must be informed about what the research project involves and which consequences it can have for them as participants. As stated in the Department Guidelines to the Health Research Act, consent shall be based on information about the purpose, method, risk, discomfort, consequences and other information that is relevant for the validity of consent, such as, for example, the degree of personal identification of the information, the extent to which the information shall be linked with other registers, or if data from different projects shall be accumulated. The extent and level of detail must be adapted according to the project's invasive nature, risk factors, sensitivity of the material, the participant's vulnerability and similar considerations. The more invasive a project is, the higher the requirement to provide information is.[36] As stated above, there is a duty to provide information even where broad consent has been provided, though the level of detail is less. However, the Department Guidelines clarify that it is not permissible to give a broad consent to "all medical research" or to "genetic research".[37] It should, however, be possible to give a broad consent to, for example, cancer research or to research on diabetes, without there being further detail about what the project wishes to research regarding these diseases.[38]

Nevertheless, participants who have given broad consent are entitled to receive information about the project at regular intervals.[39]

## Are there specific penalties if the conditions for processing for scientific research in the field of health purposes are not respected? What do those penalties entail?

According to section 50 of the Health Research Act, with regards to injuries that arise under medical trials, the provisions in the Patient Injury Act[40]shall apply accordingly. The person or body responsible for the research must compensate injuries that arise as a result of human biological material or personal health data being processed in a manner that contravenes provisions in or pursuant to the Health Research Act, unless it can be proven that the injury was not due to errors or negligence on the part of the person or body responsible for the research. The compensation must correspond to the financial loss that the injured person has incurred as a result of the unlawful processing of their human biological material or personal health data. The person in charge of data processing may also be ordered to pay reasonable compensation for injuries of a non-financial nature (compensation for non-pecuniary loss).

If research projects or research biobanks are being run in a way that can have harmful consequences for research participants or others, or in some other way are unfortunate or unsound, the Norwegian Board of Health Supervision can order that the matter must be rectified (section 51). If the Norwegian Board of Health Supervision deems it necessary, it may order that the research project is discontinued or the research biobank is closed.

[36] See Department Guidelines, section 4.4, p. 33.

[37] See Department Guidelines, section 4.3.2, p. 21.

[38] Ibid.

[39] Ibid.

[40] Act of 15 June 2001 No. 53 on damages in case of patient injury etc., in Norwegian 'Lov om erstatning ved pasientskader mv.' abbreviated as 'pasientskadeloven'.



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Furthermore, according to section 52, the Norwegian Data Protection Authority may issue orders that processing of personal health data that is in contravention of provisions in or pursuant to the Health Research Act must stop or it may also stipulate conditions that must be fulfilled to ensure that personal health data are processed in accordance with such legislation.

The Norwegian Board of Health Supervision and the Data Protection Authority may impose a coercive fine to accrue for each day, week or month after expiry of the time limit set for compliance with an order pursuant to section 51 or 52 abovementioned, until the order has been complied with. Coercive fines may also be imposed as a single-payment fine.

Furthermore, anyone who wilfully or through gross negligence violates the provisions laid down in the Health Research Act or provisions laid down pursuant to such law shall be liable to fines or imprisonment not exceeding one year or both. The punishment is increased to up to three years if there are particularly aggravating circumstances.

# 3. Formalities prior to processing: the general regime under the current framework

### Is there a regime requiring the fulfilment of certain conditions prior to any processing activities different from that applicable to research in the field of health? If yes, what does that regime entail?

Under the general regime pursuant to the Personal Data Act (2000), the general rule is that all processing of identifiable personal data is subject to a duty to notify such processing to the Data Protection Authority unless the processing is: (a) subject to an obligation to obtain a licence from the Data Protection Authority; or (b) exempted from the obligation to obtain a licence or to notify pursuant to Chapter 7 of the Personal Data Regulations of 2000. Examples where a licence must be obtained from the Data Protection Authority in order to process data are, as a main rule, where sensitive personal data are processed, as well as the processing of personal data in the telecommunications, insurance, bank and financial sectors.

The central provision on the obligation to obtain a license was section 33 of the Personal Data Act (2000). According to section 33, a licence from the Data Protection Authority is required for the processing of sensitive personal data. This does not apply, however, to the processing of sensitive personal data which have been volunteered by the data subject (i.e. unprompted, spontaneous). The Data Protection Authority may decide that the processing of data other than sensitive personal data shall also be subject to licensing, if such processing otherwise will clearly violate weighty interests relating to protection of privacy. In assessing whether a licence is necessary, the Data Protection Authority shall, inter alia take account of the nature and quantity of the personal data and the purpose of the processing. If the Data Protection Authority determines that a processing licence will clearly be unnecessary, it may decide that the processing does not require a licence. The controller may demand that the Data Protection Authority decide whether processing will be subject to licensing. Chapter 7 of the Personal Data Regulations contains further rules as to which processing requires a licence from the Data Protection Authority; which processing is exempt from the duty to obtain a license but is subject to a duty to notification; and which processing is exempt from both the duty to obtain a licence and notification.



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According to section 7-27 of the Personal Data Regulations of 2000, personal data processing in connection with a research project that is not medical or health research is exempt from the obligation to obtain a licence pursuant to section 33, first paragraph, of the Personal Data Act (2000) but is subject to a duty of notification if the project is recommended by a data protection officer. Several research institutions in Norway have appointed Norsk senter for forskningsdata (known also by its abbreviated name "NSD") as their data protection officer. If the project involves medical and healthcare research, it must obtain prior approval from a REK.

As explained in the comments to section 7-27, for projects that are not deemed to be medical or healthcare research, it is sufficient to have the support of the data protection officer. Since there is presently only a requirement for referral to a REK in respect of medical and healthcare research, this assumes that researchers in other areas of study must exercise special care. At the same time, it also assumes that the data protection officer is familiar with research ethics and will, on his/her own initiative, refer projects that are deemed ethically dubious to a committee. The data protection officer should also refer cases for which recommendation seems problematic, to the Data Protection Authority, or advise the Data Protection Authority to undertake a prequalification process.[41]

Pursuant to section 7-27 second paragraph, research projects that have a large scope and long duration, as well as research on large data sets that have not been pseudonymised or de-identified in some other secure manner, are not exempted from the duty to obtain a license. It is presumed that projects which comprise over 5000 research subjects have a "large scope", and that projects that have a longer duration than 15 years are of "long duration".[42] Data sets which are not pseudonymised or de-identified require prior authorisation. The comments to section 7-27 of the Personal Data Regulations clarify that the establishment of large data collections (registers) of personal data, which are meant as a basis for other separate projects, require a license.[43] Furthermore, research on large datasets would be exempted from the duty to obtain a license if the material that the researchers hold is pseudonymised or de-identified in a secure manner. The requirement for pseudonymisation or de-identification in a secure manner implies that the research, or the institution where the researcher is employed, cannot store the identification key.[44] It also implies that the amount and types of parameters cannot be of such a character that it is possible to backwards identify persons who are included in the dataset.[45]

The exemption from the duty to obtain a license covers only analyses of non-participation (analyses of the distribution of education, income, benefits, etc. among participating and non-participating persons to determine the significance of the non-participation) to the extent these are based on consent.

[41] Ibid.

[42] See comment to section 7-27 in the Personal Data Regulations. See also website, in Norwegian, of NSD at http://www.nsd.uib.no/personvernombud/hjelp/andre_godkjenninger/meldeplikt_konsesjon.html.

[43] Ibid.

[44] See comment to section 7-27 in the Personal Data Regulations.

[45] Ibid.



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# 4. Further processing of health data (for research purposes): the current regime

## How is the notion of further processing regulated in your national framework?

A basic requirement for the processing of personal data is that the personal data processed are not used subsequently for purposes that are incompatible with the original purpose of the collection, without the consent of the data subject (section 11 first paragraph letter c of the Personal Data Act(2000)). However, according to section 11 second paragraph of the Personal Data Act (2000), subsequent processing of personal data for historical, statistical or scientific purposes is not deemed to be incompatible with the original purposes of the collection of the data if the public interest in the processing being carried out clearly exceeds the disadvantages this may entail for natural persons.

## Are there specific conditions to the further processing for scientific research in the field of health purposes?

The Health Research Act contains a specific provision regarding new or changed use of collected human biological material or personal health data. According to section 15 of the Health Research Act:

"In the event of substantial changes to the research project, new consent must be obtained in accordance with section 13 if the changes are deemed to have consequences for the participant's consent.

If it is difficult to obtain new consent, the REK may approve new or changed use of previously collected human biological material or personal health data without new consent being obtained. This may only be applied if the research in question is of significant interest to society and the participants' welfare and integrity are ensured. The regional committee for medical and health research ethics may specify conditions for use."

Thus, upon a new or changed use of collected human biological material or personal health data, new consent must be obtained if the changes are substantial. The requirement for substantial changes implies that there is no need to obtain new consent for every little change in the research project. Section 15 should be read together with section 11 which states that if the project manager wants to make substantial changes to the objective, method, timeframe or organisation of the research project, an application must be sent to the REK that had granted prior approval. Section 15 is different to section 11 in that, according to section 15, a substantial change must have consequences for the participant's consent for the requirement in section 15 to obtain new consent to apply. In other words, even if a substantial change to the project requires that an application is sent to the REK, it does not automatically imply that a new consent must be obtained.

As explained in the Department Guidelines, whether a change is substantial must be determined on the basis of the facts, depending on what the research participant has consented to. An example of substantial change is where a specific consent is given for research on a certain type of cancer, but the project is extended to find causes of cancer in general. Example for changes that may be deemed to have consequences for the participant's consent can be that unexpected or undesired incidents or risk factors arise which necessitate new consent. Furthermore, changes in



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discomfort, sensitivity, the type and/or scope of research may have consequences for the participant's consent. In case of doubt, the REK should be asked to determine whether a new consent must be obtained.[46]

As stated above, section 15 second paragraph of the Health Research Act contains an exception to the requirement to obtain new consent provided the following three cumulative conditions apply: (i) it is difficult to obtain new consent, (ii) the research in question is of significant interest to society and (iii) the participants' welfare and integrity are ensured.

## What are the rights of the data subject when it comes to further processing?

Chapters 3 and 4 of the Personal Data Act (2000) set out the data subject's rights. As stated above, according to section 19 and 20, the controller must inform the data subject: (a) the name and address of the controller and of his representative, if any; (b) the purpose of the processing; (c) whether the personal data will be disclosed, and if so, the identity of the recipient; (d) whether the provision of information is voluntary; and (e) any other circumstances that will enable the data subject to exercise his rights pursuant to the Personal Data Act (2000) in the best possible way, such as information on the right to demand access to data, cf. section 18, and the right to demand that data be rectified, cf. sections 27 and 28.

As stated above, provided the subsequent processing of personal data for scientific purposes satisfies the provisions of section 9 first paragraph letter h, i.e. the public interest in the processing being carried out clearly exceeds the disadvantages this may entail for natural persons, the subsequent processing would qualify as "further processing" pursuant to such provision. In such a case, there will be no need to provide information about any further processing since this would be deemed to be processing for a purpose which is incompatible with the original purpose of the collection, c.f. section 11 first paragraph letter b c.f. second paragraph of the Personal Data Act (2000). However, all other data subject rights, such as the right of access, right to demand rectification and deletion in some cases, and the right to demand review by a physical person of a fully automated decision, apply.

## What about the data subject's rights and further processing for scientific research purposes?

See above with regard to the main rule requiring that new consent is obtained in the event of substantial changes to the research project.

The Health Research Act contains a specific provision regarding the right to use biological material collected by the health and care services for research. According to section 28, the REK may rule that human biological material collected by the health and care services in connection with diagnosis and treatment may or shall be used for research purposes without the patient's consent being obtained. This may only be applied if the research in question is of significant interest to society, and the participants' welfare and integrity are ensured. The REK may specify conditions for such use. The patient must have been informed in advance that in some cases human biological material may be used for research and must have been given the opportunity to refuse to be involved in research on human biological material. Pursuant to section 28 third paragraph, an electronic register has been set up with the details of the patients that have stated that they do not wish their biological material to be used for research.

[46] Department Guidelines, section 4.3.4.1, p. 26.



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# 5. The GDPR's impact on the current regulatory framework for the processing of health data for research purposes

## a. The impact of the GDPR on the rules applying to processing for research in the field of health

### Please provide a summary of the main relevant characteristics of the new law/Bill (as far as it is relevant for processing health data for research purposes). How is (or will be) Article 9(2)(j) implemented in your country?

As stated earlier in this study, a bill proposing a new Personal Data Act, and implementing the GDPR was presented in Parliament on 23 March 2018. The new Personal Data Act (2018) was passed on 15 June 2018 and entered into effect on 20 July 2018.

In the context of this study, sections 8, 9 and 10 of the Personal Data Act (2018) are particularly relevant. They deal respectively with:

- processing of personal data for archiving purposes in the public interest, scientific or historical research purposes or for statistical purposes (section 8);
- processing of special categories of personal data without consent for archival purposes in the public interest, scientific or historical research purposes or for statistical purposes (section 9);
- duty to consult with regard to processing of special categories of personal data for scientific purposes on the basis of consent (section 10).

Section 8 in the Personal Data Act (2018) provides a supplementary legal basis for the processing of non-sensitive personal data that is necessary for 'inter alia' scientific or historical research purposes on the basis of article 6(2)(3) of the GDPR. As stated in the Explanatory Statement to the Personal Data Act (2018), section 8 applies alongside other supplementary legal basis for 'inter alia' research purposes and is not meant to limit the possibility of processing personal data for research purposes on the basis of the other alternatives in article 6(1).[47] The Explanatory Statement underlines that the term scientific or historical research purposes shall be understood in the same way as this term is used in the GDPR, inter alia in article 5(1)(b) and article 89(1) as well as in recitals 158 to 162.[48] The second sentence in section 8 states that the processing must fulfil the requirements of article 89(1) of the GDPR.

Section 9 also provides a supplementary legal basis and permits, subject to certain conditions, the processing of special categories of personal data without the data subject's consent for the purposes of 'inter alia' scientific or

[47] See Explanatory Statement, paragraph 38.1, p. 213.

[48] Ibid.



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historical research purposes, c.f. article 9(2)(j) GDPR. Section 9 first paragraph states that the legal basis for such processing is that the public interest for the processing to take place clearly overrides the disadvantages for the data subjects. It also states that such processing must be covered by appropriate safeguards in accordance with article 89(1) GDPR. The second paragraph of section 9 obliges the data controller to consult with the data protection officer or any other person who fulfils the requirements of article 37(5)(6) GDPR and article 38(3) first and second sentence, where there is processing of special categories of personal data for the purposes of 'inter alia' research pursuant to section 9 first paragraph. Such consultation will include an assessment whether the processing will fulfil the requirements in the GDPR and the other requirements laid down in statute or having a legal basis in the Personal Data Act (2018). There is no duty to consult if a data protection impact assessment has been carried out pursuant to article 35. Section 9 third paragraph states that regulations may be enacted regarding the processing of special categories of personal data for 'inter alia' scientific or historical research purposes.

Section 10 states that the duty to consult a data protection officer or similarly qualified person pursuant to section 9 second paragraph of the new Personal Data Act shall correspondingly apply when special categories of personal data are processed for scientific or historical research purposes on the basis of the data subject's consent. Pursuant to the Personal Data Act (2018), section 33 of the Health Research Act was amended to state that 'inter alia' section 10 of the Personal Data Act (2018) does not apply for medical and health research.

## b. Modification to the processing authorisation procedure applying to research in the field of health

### How will the processing authorisation procedure (if any exists) be affected by the implementation of the GDPR? Can you describe any such change?

Prior to the implementation of the GDPR into Norwegian law and as stated earlier in this study, prior approval from the REK was regarded as a necessary and adequate legal ground for the processing of health data in medical and health research. After the implementation of the GDPR, however, such prior approval is no longer be regarded as a necessary and adequate legal ground for the processing of health data and such processing must be based on one of the grounds in article 9(2).[49] Sections 8 and 9 in the Personal Data Act (2018) contain two new provisions which permit processing of personal data for research purposes without consent, one provision applying to non-sensitive personal data (section 8) and the other regarding special categories of personal data (section 9). In the Explanatory Statement to the Personal Data Act (2018), the Ministry of Justice states that sections 8 and 9 apply to medical and health research. However, as explained earlier in this study, Norway has a number of health sectorial laws. These sectorial laws, combined with article 6(1)(e) and article 9(2)(j) will provide a supplementary legal basis to the exceptions from the prohibition of processing special categories of personal data. If the processing is in line with such sectorial health legislation, according to the Ministry of Justice, there is no need to also fulfil the requirements in sections 8 and 9 of the new Personal Data Act (2018).[50]

However, no change is proposed to the assessment of research ethics that the REKs currently also carry out. Thus, there is still be requirement for prior approval of the research ethics by the REK for processing of health data in medical and health research to be allowed, c.f. Health Research Act section 9. Such prior approval will ensure that

[49] See also Explanatory Statement, paragraph 32.3.2, pp 184 and 185.

[50] See Explanatory Statement, paragraph 32.3.2, p. 185.



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research ethics are safeguarded.[51] However, the Explanatory Statement states that REK's assessment of the data protection part of the processing cannot be binding for the Data Protection Authority if there is an eventual inspection by the Authority. The data controller will still be responsible to ensure that the processing is in accordance with data protection legislation. The Data Protection Authority may assess on an independent basis whether the processing is in accordance with the GDPR, e.g. whether consent has been provided, whether the information provided to the data subjects is sufficient, whether the principle of data minimisation is safeguarded. The Data Protection Authority will also, independently of REK's prior approval, be able to impose coercive fines (*tvangsmulkt*) or sanctions (*overtredelsesgebyr*) if the requirements in the GDPR are not complied with.[52]

The Explanatory Statement to the Personal Data Act (2018) states that the Department of Health and Care Services' or REK's statutory right to give a dispensation or exemption from the duty of confidentiality provides the supplementary legal basis pursuant to article 6(3) and 9(2)(g)(h)(i)(j) of the GDPR.[53]

### What about the right of the data subject and the obligations of the controller?

The Norwegian legislator has opted to introduce derogations from the data subject's rights in the case of processing of personal data for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes, c.f. section 17 of the Personal Data Act (2018).

Section 17 states that the right of access pursuant to article 15 GDPR does not apply to the processing of personal data for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with article 89(1) GDPR insofar as:

(a) it will require a disproportionate large effort to provide access or

(b) the right of access will likely render impossible or seriously impair the achievement of the purposes of the processing.

Section 17 second paragraph states that the right of rectification and the right to demand restriction of processing pursuant to GDPR articles 16 and 18 do not apply for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with article 89(1) GDPR insofar as such rights will likely render it impossible or seriously impair the achievement of the purposes of the processing.

Section 17 third paragraph states that the first and second paragraphs of section 17 do not apply where the processing has legal effects or direct factual effects on the data subject.

## 6. Further processing for research purposes under the GDPR

### The notion of further processing under the GDPR:

[51] See Ibid.

[52] See ibid.

[53] See Explanatory Statement, paragraph 32.3.3, p. 186.



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Further processing can be defined as "the processing of personal data for purposes other than those for which the personal data has been initially collected". Further processing is allowed only when its purpose is compatible with the purpose for which the data has been initially collected. Further processing for a compatible purpose of personal data is possible using the same legal basis as the one used for the initial processing. For example, if personal data is initially processed based on the data subject's consent, then further processing for a compatible purpose is possible on the same legal basis. It is, in other words, not required to contact the data subject again for a new consent authorising the further processing of the same data.

### How to measure the compatibility of purpose of the further processing:

Further processing for a purpose other than that for which the personal data has been collected is governed by article 6(4) of the GDPR. In particular this article tries to address how to measure whether or not the purpose of the further processing is "compatible". This is particularly relevant to big data analytics. Article 6(4) establishes a test to measure such compatibility.

Where this processing is not based on the data subject's consent, or EU or Member State law, but on another legal ground, the controller will ascertain the compatibility of the processing's purpose with the initial purpose stated during the data collection. To do so the controller will take several elements into account, in particular: any link between the initial purpose and the further processing purpose, the context of the collection and the relation between the data subject and the controller, the nature of the data, in particular if it is considered to be sensitive data under article 9 of the GDPR. The controller will also consider the possible consequence of further processing for the data subject and the existence of appropriate safeguards. If the result of the test is positive for the controller, and shows none of the elements have been significantly altered to make the further processing unfair or illicit, no further legal basis is necessary for the further processing. If this is not the case, then the further processing will have to rely on a separate legal basis.

If this test is successfully met, then the further processing is possible. However, it will be up to the data controller to demonstrate the compatibility of the purposes.

### The particularities of scientific research: a presumption of purpose compatibility

However, the processing for scientific research purpose is an exception. Indeed, under article 5(1)(b) of the GDPR the compatibility of the processing purpose of further processing in accordance with article 89(1) with the initial purpose of the collection is presumed. Here the GDPR establishes a presumption of compatibility of purposes for scientific research purposes. The reasoning behind this exception can be easily imagined. Scientific research is very often based on existing data. This is why allowing the processing of personal for different (if not incompatible) purposes is fundamental for scientific research.

This presumption made for the benefit of scientific research is limited by some requirements, which are set out in article 89(1) of the GDPR: the appropriate safeguards for the data subject's rights and freedoms, and ensured technical and organisational measures, such as pseudonymisation. A different scenario would require different technical and organisational measures to ensure the safeguards for the data subject's rights and freedoms. This is clearly indicated in recital 156 of the GDPR: "The further processing of personal data for (…) scientific (…) research purposes (…) is to be carried out when the controller has assessed the feasibility to fulfil those purposes by processing data which does not permit or no longer permits the identification of data subjects, provided that appropriate safeguards exist (such as, for instance, pseudonymisation of the data)."



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Additionally, further processing of personal data is connected to the principle of storage limitation (article 5(1)(e) of the GDPR), as it also constitutes a derogation to that principle, "personal data may be stored for longer periods insofar as the personal data will be processed solely for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with article 89(1) subject to implementation of the appropriate technical and organisational measures required by this Regulation in order to safeguard the rights and freedoms of the data subject".

### Given the regime applied to further processing in the GDPR, can you describe the consequences, if any, in your national legal framework?

The Explanatory Statement to the new Personal Data Act (2018) refers to the principle of purpose limitation in article 5(1)(b) and the compatibility test in article 6(4) of the GDPR.[54] If the new purpose is not compatible with the purposes for which the data were collected, the further processing must have a legal basis in either consent or a statutory provision.[55] This means, according to the Explanatory Statement, that the statutory basis or consent must be linked to the actual further processing for incompatible purposes.[56] Thus, it is not enough to have a general legal basis and an eventual supplementary legal basis; there must in addition be a legal basis for the further processing. If there is no legal basis for further processing, the consequences are that the personal data must be collected anew if they are to be processed for the new purpose. The Explanatory Statement states that article 6(4) sets limits to the possibility for further processing for incompatible purposes in national law. Such statutory provisions must constitute "a necessary and proportionate measure in a democratic society to safeguard the objectives referred to in Article 23(1)".[57] The Explanatory Statement furthermore states that, where further processing includes special categories of personal data, article 9 will also set limits. [58] Article 9(2) can set down requirements for national legislation, proportionality and for appropriate safeguards to protection the data subjects' fundamental rights and interests.

Recital 50 of the GDPR states that where there is further processing for compatible purposes, there is no need for a legal basis separate from that which allowed the collection of the data. However, according to the Explanatory Statement the presumption here is that the processing and further processing are being carried out by the same data controller.[59] As long as the processing is in accordance with article 89(1), the data controller can further process the personal data for archival, research and statistical purposes without there being need for a separate legal basis for the further processing.[60] Furthermore, the Explanatory Statement states that if the further processing consists in disclosing/transmitting the personal data to another data controller, the data controller receiving the personal data must be able to show that it has its own separate legal basis for the processing.[61]

[54] Explanatory Statement, paragraph 6.6, p. 37.

[55] Ibid.

[56] Ibid.

[57] Ibid.

[58] Ibid.

[59] Explanatory Statement, paragraph 11.1.2, page 70.

[60] Ibid.

[61] Ibid.



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# 7. Health data sources for research purposes

## a. Sources of data and their regulation

### Does your national framework contain specific provisions for anonymised or pseudonymised health data?

As discussed above, under the regime preceeding the implementation of the GDPR into Norwegian law, pursuant to section 7-27 second paragraph of the Personal Data Regulations, research on large data sets that have not been pseudonymised or de-identified in some other secure manner, are not exempted from the duty to obtain prior authorisation.

According to section 20 of the Health Research Act, consent is required for the collection of human biological material and personal health data that shall subsequently be anonymized. However, consent is not required for research on anonymous human biological material and anonymous data.

Furthermore, section 38 prohibits the storage of unnecessary personal health data and 'inter alia' states that if the heath data are not going to be kept after the final report of the research project has been sent to the REK in accordance with the Archives Act[62] or other legislation, such data must be anonymised or deleted.

As stated above, personal health data processed as part of a research project that have been anonymised or given a pseudonym may be transferred to a country outside the EEA if the data cannot be linked to personal identification as long as the data are in such non-EEA country, c.f. section 37 second paragraph of the Health Research Act.

Section 40 of the Health Research Act furthermore states that the research participants have the right to access identifiable personal data and pseudonymous personal health data about themselves, as well as information about the security measures used in connection with processing personal health data, as long as such access does not jeopardise security.

As stated earlier in this study, the Department Guidelines state that, in order to comply with such requirement for information security, measures must be implemented to prevent any health information from the project from unauthorised disclosure.[63] Measures should at least be assessed depending on the technical equipment used, access control, routines for identification and anonymization of information and the handling of non-conformities. The routines must also include what will happen to the information upon completion of the project.[64] Information about security must be specified in the application for prior approval by the REK, c.f. section 7 letter f, Regulations on the Organisation of Health Research. As regards routines for de-identification of the data, it is important that the application informs how the identification key shall be stored, e.g. whether by a data protection officer or by a

[62] Act of 4 December 1992 No. 126 relating to archives, in Norwegian 'Lov om arkiv' abbreviated as 'arkivlova'.

[63] See Department Guidelines, section 2.5.2.1, p. 10.

[64] Ibid.



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trusted pseudonym manager or a trust third party. It is also important that the number of variables are described since the quantity of such variables cannot be so many as to pose a danger for backwards identification.[65]

In the Personal Health Data Filing Systems Act, the Department of Health and Care Services may, by regulations or individual administrative decision require regional health enterprises, hospital trusts, county municipalities and municipalities (local councils) to report anonymous data or indirectly identifiable health data, irrespective of the duty of confidentiality, for statistical purposes.

## What are the different sources of health data that can be used for research purposes?

- **DIRECT COLLECTION FROM PATIENTS:**

**Under the current legal framework: please explain the currently applying rules that a researcher, who intends to collect health data directly from individuals (e.g. via a survey, or by asking patients to wear a monitoring device, etc.), should follow.**

Health data is sensitive personal data and as such, its processing is only permitted for at least one of the legal basis in section 9 of the Personal Data Act (2000) is satisfied, e.g. there is statutory authority for such processing (section 9 first paragraph letter b). Processing of health data in medical and health research is permitted provided the provisions of the Health Research Act as explained earlier in this study, are complied with. A researcher who would like to collect health data directly from the patient must apply for and obtain prior approval from the REK before any such collection is permitted. The main rule in the Health Research Act is that the research participant's consent is required, unless other specified in law (c.f. section 13 first paragraph). Such consent, as explained earlier in this study, must be freely given, specific, informed and capable of being documented. The research should provide the patient specific information about the concrete research project that the health data shall be used for, and shall give the patient information as specified in section 18 of the Personal Data Act (2000) (referred to earlier in this study).

Where the data is collected by a health professional for medical and therapeutic purposes, and if such a person then wishes to use the data collected for study and research purposes, the provisions of the Health Research Act must nevertheless still be followed, i.e. requirement for prior approval by the REK.

As stated earlier in this study, under the legal framework prior to the implementation of the GDPR, prior approval from REK is regarded as a necessary and adequate legal ground for the processing of health data in medical and health research. The REC also carries out an ethical evaluation of the research and provides an exemption to health personnel from the duty of confidentiality, where necessary.

**Under the revised legal framework: will the currently existing procedures and rules change in view of the implementation of the GDPR in your country?**

According to the Explanatory Statement to the Personal Data Act (2018), the sectorial legislation in the field of health that existed prior to the implementation of the GDPR shall continue to remain in force,[66] although some rather minor amendments were made to ensure that such laws are in line with the GDPR.

Although the Health Research Act remains in force, after the implementation of the GDPR prior approval from the REK is no longer regarded as a necessary and adequate legal ground for processing of health data and processing of

[65] Ibid.

[66] See Explanatory Statement, paragraph 32.1, p. 183.



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special categories of health data must be based on one of the grounds in article 9(2) of the GDPR, in addition to one of the grounds of article 6(1). Such article 9 ground could, for example, be consent (article 9(2)(a)) or processing for scientific research purposes (article 9(2)(j)) with section 9 of the Personal Data Act (2018) as supplementary legal basis. Relevant article 6(1) legal basis are consent (letter a) or a task carried out in the public interest or in the exercise of official authority vested in the controller (letter e) supplemented by section 8 of the Personal Data Act (2018). Sectoral legislation such as the Health Research Act may also provide a supplementary legal basis for processing.[67]

However, no change was proposed to the assessment of research ethics that the REKs also carry out. Thus, there is still a requirement for prior approval of the research ethics by the REK for processing of health data in medical and health research to be allowed, c.f. Health Research Act section 9. Such prior approval will ensure that research ethics are safeguarded.[68] However, the Explanatory Statement states that REK's assessment of the data protection part of the processing cannot be binding for the Data Protection Authority if there is an eventual inspection by the Authority. The data controller will still be responsible to ensure that the processing is in accordance with data protection legislation. The Data Protection Authority may assess on an independent basis whether the processing is in accordance with the GDPR, e.g. whether consent has been provided, whether the information provided to the data subjects is sufficient, whether the principle of data minimisation is safeguarded.

Moreover, the REK is still the competent body to grant exemption from the duty of confidentiality.

It should be emphasised that after the implementation of the GDPR in Norwegian law, the data controller must determine whether the processing of personal data is permitted by determining the consequences that the proposed processing shall have for privacy. Where required (e.g. large scale processing of special categories of personal data, c.f. article 35(3)(b)), the controller must carry out a data protection impact assessment and put in place necessary measures to address the risks, including safeguards, security measures and mechanisms to ensure the protection of personal data, jf. article 35 GDPR.

- **COLLECTION FROM HEALTH PROFESSIONALS AND HEALTH INSTITUTIONS**

**Under the current legal framework: please explain the rules currently applying that a researcher, who intends to obtain health data from medical staff, hospitals, etc., should follow.**

Collection by a researcher of health data from (other) health professionals and health institutions for research purposes is possible under certain conditions.

Pursuant to section 35 of the Health Research Act, the REK may decide that personal health data can or shall be handed over by health personnel for use in research, and that this may be done notwithstanding the duty of confidentiality. The same applies to data gathered by the health and care services. This may only be applied if the research in question is of significant interest to society, and the participants' welfare and integrity are ensured. The REK may specify conditions for use. The rules on the duty of confidentiality pursuant to section 7 of the Health Research Act apply accordingly to the party (e.g. the researcher) that receives the data.

The Health Personnel Act has a corresponding provision. Section 29 thereof permits use of medical data for research without breach of the duty of confidentiality provided authorisation is given by the REK.

[67] See further the Explanatory Statement, paragraph 38.2, p. 229.

[68] See Ibid.



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As regards hospitals or health institutions, according to section 20 of the Patient Medical Record Act, the data controller, for example, the hospital, can make medical data available for purposes other than medical treatment when the individual (the data subject) consents or if this is laid down in law or pursuant to law. An example of such a statutory provision is section 35 of the Health Research Act.

With regard to human biological material that is collected in connection with diagnosis and treatment, pursuant to section 28 of the Health Research Act, the REK may rule that such human biological material may or shall be used for research purposes without the patient's consent being obtained. This may only be applied if the research in question is of significant interest to society, and the participants' welfare and integrity are ensured. The REK may specify conditions for use. The patient must have been informed in advance that in some cases human biological material may be used for research and must have been given the opportunity to refuse to be involved in research on human biological material. An electronic register was established in 2009 and contains the details of the patients that have stated that they do not wish their biological material to be used for research. This register (*Registeret Biologisk forskningsreservasjon*) is managed by the Norwegian Institute of Public Health.

**Under the revised legal framework: Under the revised legal framework: will the currently existing procedures and rules change in view of the implementation of the GDPR in your country?**

The changes abovementioned regarding the collection of personal data directly from the patient apply to data collected from health professionals and health institutions following the entry into effect of the Personal Data Act (2018). Among the minor amendments to the Health Research Act that were made by the Personal Data Act (2018) was the replacement of the verb "disclose" by "make available" (*tilgjengeliggjøres*), see for example, section 34.

- **PRIVATE DATABASES**

**Under the current legal framework: please explain the rules currently applying for the setting up of and the use of a private database with health data for research purposes.**

While creating a private database containing health data is not prohibited, its legal basis must be carefully applied. The processing of health data is possible if the data subject has given his/her consent, c.f. section 9 first paragraph letter a of the Personal Data Act (2000). Furthermore, all the other requirements in the Personal Data Act (2000), e.g. purpose limitation, etc. must be complied with.

Where the database is set up in connection with a medical and health research project pursuant to the Health Research Act, i.e. an activity carried out using scientific methods to generate new knowledge about health and disease, the provisions of the Health Research Act apply and prior authorisation must be obtained from the REK.

Where the private health data database falls outside the Health Research Act, i.e. it is not established for a health and research project, a license must be obtained from the Data Protection Authority. As explained above in this study, an exception to licensing is provided in section 7-27 of the Personal Data Regulations which states that a personal data officer can approve less comprehensive projects.

**Under the revised legal framework: will the currently existing procedures and rules change in view of the implementation of the GDPR in your country?**



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The current procedure whereby certain types of processing, such as processing of sensitive personal data, require prior authorisation from the Data Protection Authority in the form of a licence, shall be removed.[69] Prior control by the Data Protection Authority is being replaced by a duty on the data controller to ensure that processing is in compliance with all the requirements of the GDPR.[70] Thus, where there is large scale processing of special categories of data (e.g. health data), a data protection impact assessment is required pursuant to article 35(3)(b) of the GDPR. If the type of processing envisaged is likely to result in a high risk to the rights and freedoms of natural persons, the controller must also, prior to the commencement of the processing, carry out a data protection impact assessment.

The use of private databases of personal health data for the purposes of a health and research project pursuant to the Health Research Act will still require approval of the ethical side of the project from the REK and, where applicable, the exemption from the duty of confidentiality. However, the legal basis of such processing for the purposes of scientific research must be based on one of the legal basis in article 6(1) and article 9(2) of the GDPR.

- **PUBLIC DATABASES**

**Under the current legal framework: do public authorities make available health data for research purposes in your country and under what conditions?**

As mentioned earlier in this study, Norway has a number public registers, e.g. central health registers. As at 30 April 2018, the Norwegian Institute of Public Health (*Folkehelseinstitutt*) lists 18 central health registers that are established or under establishment. The Norwegian Institute of Public Health is the data controller of 10 of these central health registers. The Personal Health Data Filing Systems Act regulates the establishment of personal health data filing systems, i.e. health registers/databases. However, this legislation only applies to the establishment of such health registers and to processing that does not fall within the Health Research Act. If a health register is set up as part of a specific research project which falls within the definition of medical and health research, the Health Research Act shall be applicable. The actual establishment of health registers without any relation to a concrete research project falls outside the remit of REK.

If health data is to be obtained from a personal health data filing system (i.e. health register), such disclosure must have a legal basis pursuant to the Personal Health Data Filing System Act or pursuant to the regulations setting up the various public health registers.

Section 20 of the Personal Health Data Filing Systems Act provides a legal basis for the disclosure of indirectly identifiable personal data for research purposes from central health registers established pursuant to regulations in terms of section 11. Such disclosure is only permitted if the processing is of significant interest to society, the patient's integrity and confidentiality are safeguarded, and the processing is not worrying from an ethical, medicinal or medical consideration. The data controller can set down conditions for such disclosure. It is the organisation that has responsibility for the health register, e.g. the Norwegian Institute of Public Health or the Department of Health and Care Services, that will decide whether to make available such personal health data. However, REK must evaluate the ethical, medical, health, scientific and privacy issues that such projects raise, including the processing

[69] See Explanatory Statement, paragraph 12.6.1, p. 93.

[70] Ibid, p. 94.



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of health data.[71] Before an application for prior authorisation is sent to REK, the applicant should contact the manager of the registers concerned for more information about the use of the actual register.

**Under the revised legal framework: will the currently existing procedures and rules change in view of the implementation of the GDPR in your country?**

Under the revised legal framework, the use of public databases of personal health data for the purposes of a health and research project pursuant to the Health Research Act will still require approval from the REK of the ethical side of a disclosure request.

Furthermore, as explained in the Explanatory Statement to the Personal Data Act (2018), the data controller's decision to make available health data pursuant to section 20 of the Personal Health Data Filing System Act provides a supplementary legal basis for the processing of personal data pursuant to article 6(3) and pursuant to article 9(1).[72]

## b. Application of the national framework to the AEGLE cases

In the AEGLE project, the "research objective is to establish the use of Big data analysis in the prediction of outcomes in three working scenarios: Chronic Lymphotic Leukemia (CLL), Intensive Care Units and type 2 diabetes for the prediction of adverse outcomes. The research methodology is Big Data analysis to establish predictive values that may apply in three clinical scenarios and to see if this can be generalised to other healthcare disease models". [73]

To achieve its objective, the AEGLE project must base its approach on the study, and thus the processing, of data concerning health. This section aims to address each of the three proposed AEGLE cases, and to determine the requirements in general terms for access and the processes relevant to data under the Directive (the current framework) and the GDPR.

### 1. Type 2 diabetes

The AEGLE project uses, after pseudonymisation, existing databases with health data collected from patients who expressed their consent to their data being used for research purposes.

- Current legal framework: Which procedural or other steps would the researcher have to follow to use this data for 'big data' analytics on the AEGLE platform? Is a new ethical or other type of approval required? From which body? Should the patient be informed about the new research project?

A researcher wishing to use and process pseudonymised data from the AEGLE platform for medical and health research as defined in the Health Research Act (see above Part II B) must, before the start of any processing, obtain

[71] See further the preparatory works to the Personal Health Data Filing System Act, Prop.72 L (2013-2014), p. 197.

[72] See Explanatory Statement, paragraph 38.2, p. 234.

[73] AEGLE Grant Agreement, Annex 1, p. 83.



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the authorisation from the REK for the processing of the personal data and for approval of the ethical side of the project.

We have been informed that the patients from whom the data was collected have "expressed their consent to their data being used for research purposes". The main rule in the Health Research Act is that the research participant's consent – which must be informed, freely given, specific and capable of being documented – must have been obtained, unless otherwise laid down in law (section 13, first paragraph). Consent must be based on specific information about a concrete research project, unless there is a case for the granting of so-called "broad consent", c.f. section 14, Health Research Act. The question that arises here is whether the consent that had been given by the patient upon the collection of the data is specific enough or, alternatively, whether it could fall within the notion of "broad consent". Mere consent to data being "used for research" is too broad to be considered as falling within the original legal purpose having "broad consent" as a legal basis, see above Part II C of this study.[74] Thus, consent would need to be obtained anew since, according to section 32 second paragraph of the Health Research Act, "[p]ersonal health data may not be used for purposes that are incompatible with the original objective without the consent of the research participant, unless otherwise laid down in law." However, if the consent was for "research on diabetes", this is likely to be deemed to fall within the definition of broad consent in section 14 of the Health Research Act and the purpose is likely to be deemed to be compatible for the purposes of section 32 second paragraph.

Personal health data may be processed without the data subject's consent if the provisions of section 35 of the Health Research Act apply. Pursuant to section 35, the REK may decide that personal health data can or shall be handed over by health personnel for use in research, and that this may be done notwithstanding the duty of confidentiality. The same applies to data gathered by the health and care services. This may only be applied if the research in question is of significant interest to society, and the participants' welfare and integrity are ensured. The REK may specify conditions for use. The rules on the duty of confidentiality pursuant to section 7 of the Health Research Act apply accordingly to the party (e.g. the researcher) that receives the data.

Data subjects have a right to be notified of the use of their personal data pursuant to sections 18 and 19 of the Personal Data Act (2000) (referred to earlier in this study). If the data is not collected directly from the data subject and the notification "is impossible or disproportionately difficult" or "there is no doubt that the data subject already has the information which shall be contained in the notification", the data subject is not entitled to notification, c.f. section 20 second paragraph letters b and c of the Personal Data Act (2000). When notification is omitted pursuant to letter b aforesaid, the information shall nonetheless be provided to the data subject at the latest when the data subject is contacted on the basis of the data.

- Once the GDPR has been implemented: Will the currently existing procedures and rules change in view of the implementation of the GDPR in Norway?

The combination and disclosure of personal data to another data controller – the researcher – who shall use the personal data for scientific research purposes is deemed to be compatible further processing pursuant to article 5(1)(b) of the GDPR. The data controller (who originally collected the data) who discloses such personal data does not need a special legal basis for such disclosure to the researcher (we assume that the original data controller has a lawful basis for its processing pursuant to the requirements of the GDPR). However, such original controller must ensure that the combination and disclosure satisfies the requirement for appropriate measures pursuant to article 89(1). Provided such personal data are and remain pseudonomysed also in the hands of the researcher, it appears that the requirement of article 89(1) are satisfied. However, one must bear in mind that, in a big data scenario, the

[74] See also Department Guidelines, section 4.3.2, p. 21, referred to earlier in this study.



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situation can arise that, if enough additional big data variables are added to those extracted from AEGLE, the data might no longer be pseudonymous and hence no longer satisfy the requirements of article 89(1) and article 5(1)(b).

A big data scenario may also trigger the need for a data protection impact assessment pursuant to article 35 of the GDPR if there is either "processing on a large scale of special categories of data referred to in Article 9(1)" (article 35(3)(b)) or if the processing planned by the researcher, in particular if use of the AEGLE platform is deemed to be use of a "new technology" pursuant to article 35(1) of the GDPR and the other requirements of article 35(1) exist.

The researcher must, in turn, have a legal basis for obtaining and further processing the data. Such a legal basis could be sections 8 and 9 of the Personal Data Act (2018) regarding processing of, respectively, non-sensitive and sensitive personal data for research purpose without consent. It could also be consent of the data subject. The Explanatory Statement to the Personal Data Act (2018) states that according to recital 33 of the GDPR, the "data subjects should be allowed to give their consent to certain areas of scientific research when in keeping with recognised ethical standards for scientific research".[75] This type of consent is referred to as "broad consent" in the Explanatory Statement.[76]

Approval from the REK of the ethical side of the research must still be obtained as well as, where appropriate, dispensation from the duty of confidentiality, as explained earlier in this study.

## 2. Intensive Care Unit (ICU)

AEGLE uses data generated by ICU devices without collecting the patient's consent (after pseudonymisation).

- Current legal framework: Which procedural or other steps would the researcher have to follow to use this data for 'big data' analytics on the AEGLE platform? Is a new ethical or other type of approval required? From which body? Should the patient be informed about the new research project?

A researcher wishing to use and process pseudonymised data from the AEGLE platform for medical and health research as defined in the Health Research Act (see above Part II B) must, before the start of any processing, obtain the authorisation from the REK for the processing of the personal data and for approval of the ethical side of the project.

As stated above, the main rule with the processing of health data for research purposes is that the consent of the data subject is obtained beforehand. However, personal health data may be processed without the data subject's consent if the provisions of section 35 of the Health Research Act apply. Pursuant to section 35, the REK may decide that personal health data can or shall be handed over by health personnel for use in research (e.g. to the researcher mentioned in this part of the study), and that this may be done notwithstanding the duty of confidentiality. The same applies to data gathered by the health and care services. This may only be applied if the research in question is of significant interest to society, and the participants' welfare and integrity are ensured. The REK may specify conditions for use. The researcher thus has the burden of convincing the REK that "the research in question is of significant interest to society, and the participants' welfare and integrity are ensured". The rules on the duty of

[75] Explanatory Statement, paragraph 11.1.2 p. 70.

[76] Ibid.



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confidentiality pursuant to section 7 of the Health Research Act apply accordingly to the party (e.g. the researcher) that receives the data.

Data subjects have a right to be notified of the use of their personal data pursuant to sections 18 and 19 of the Personal Data Act (2000) (referred to earlier in this study). If the data are not collected directly from the data subject and the notification "is impossible or disproportionately difficult" or "there is no doubt that the data subject already has the information which shall be contained in the notification", the data subject is not entitled to notification, c.f. section 20 second paragraph letters b and c of the Personal Data Act (2000). When notification is omitted pursuant to letter b aforesaid, the information shall nonetheless be provided to the data subject at the latest when the data subject is contacted on the basis of the data.

- Once the GDPR has been implemented: Will the currently existing procedures and rules change in view of the implementation of the GDPR in Norway?

The combination and disclosure of personal data to another data controller – the researcher – who shall use the personal data for scientific research purposes is deemed to be compatible further processing pursuant to article 5(1)(b) of the GDPR. The data controller (who originally collected the data) who discloses such personal data does not need a special legal basis for such disclosure to the researcher (we assume that the original data controller has a lawful basis for its processing pursuant to the requirements of the GDPR). However, such original controller must ensure that the combination and disclosure satisfies the requirement for appropriate measures pursuant to article 89(1). Provided such personal data are and remain pseudonomysed also in the hands of the researcher, it appears that the requirement of article 89(1) are satisfied. However, one must bear in mind that, in a big data scenario, the situation can arise that, if enough additional big data variables are added to those extracted from AEGLE, the data might no longer be pseudonymous and hence no longer satisfy the requirements of article 89(1) and article 5(1)(b).

A big data scenario may also trigger the need for a data protection impact assessment pursuant to article 35 of the GDPR if there is either "processing on a large scale of special categories of data referred to in Article 9(1)" (article 35(3)(b)) or if the processing planned by the researcher, in particular if use of the AEGLE platform is deemed to be use of a "new technology" pursuant to article 35(1) of the GDPR and the other requirements of article 35(1) exist.

The researcher must, in turn, have a legal basis for obtaining and further processing the data. Such a legal basis could be sections 8 and 9 of the Personal Data Act (2018) regarding processing of, respectively, non-sensitive and sensitive personal data for research purpose without consent.

Approval from the REK of the ethical side of the research must still be obtained as well as, where appropriate, dispensation from the duty of confidentiality, as explained earlier in this study.

## 3. Chronic Lymphocytic Leukemia (CLL)

The AEGLE project re-uses, after pseudonymisation, data coming from biobanks. In this instance, patients have given their informed consent for the samples and for the processing of their data. But this consent was given in general terms and not specifically for AEGLE.

- Current legal framework: Which procedural or other steps would the researcher have to follow to use this data for 'big data' analytics on the AEGLE platform? Is a new ethical or other type of approval required? From which body? Should the patient be informed about the new research project?



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According to the preparatory works of the Health Research Act, information that is derived from human biological material is to be deemed to be personal health data.[77]

A researcher wishing to use and process pseudonymised data from the AEGLE platform for medical and health research as defined in the Health Research Act (see above Part II B) must, before the start of any processing, obtain the authorisation from the REK for the processing of the personal data and for approval of the ethical side of the project.

We have been informed that the patients from whom the data was collected "have given their informed consent for the samples and for the processing of their data. But this consent was given in general terms and not specifically for AEGLE". The main rule in the Health Research Act is that the patient's (i.e. data subject's) consent – which must be informed, freely given, specific and capable of being documented – must have been obtained, unless otherwise laid down in law (section 13, first paragraph). Consent must be based on specific information about a concrete research project, unless there is a case for the granting of so-called "broad consent", c.f. section 14, Health Research Act. The question that arises here is whether the consent that had been given by the patient upon the collection of the samples and regarding the processing of data derived from such biological samples is specific enough or, alternatively, whether it could fall within the notion of "broad consent". Did the patient consent to the use of their personal data derived from those samples for some specific type of research? One would have to analyse what the patient had actually consented to by examining how the consent form that was used when the samples were obtained from the patient, was formulated. Mere consent to data being "used for research" is too broad to be considered as falling within the original legal purpose having "broad consent" as a legal basis, see above Part II C of this study.[78] Thus, consent would need to be obtained anew since, according to section 32 second paragraph of the Health Research Act, "[p]ersonal health data may not be used for purposes that are incompatible with the original objective without the consent of the research participant, unless otherwise laid down in law."

Personal health data may be processed without the data subject's consent if the provisions of section 35 of the Health Research Act apply. Pursuant to section 35, the REK may decide that personal health data can or shall be handed over by health personnel for use in research, and that this may be done notwithstanding the duty of confidentiality. The same applies to data gathered by the health and care services. This may only be applied if the research in question is of significant interest to society, and the participants' welfare and integrity are ensured. The REK may specify conditions for use. The rules on the duty of confidentiality pursuant to section 7 of the Health Research Act apply accordingly to the party (e.g. the researcher) that receives the data.

Data subjects have a right to be notified of the use of their personal data pursuant to sections 18 and 19 of the Personal Data Act (2000) (referred to earlier in this study). If the data is not collected directly from the data subject and the notification "is impossible or disproportionately difficult" or "there is no doubt that the data subject already has the information which shall be contained in the notification", the data subject is not entitled to notification, c.f. section 20 second paragraph letters b and c of the Personal Data Act (2000). When notification is omitted pursuant to letter b aforesaid, the information shall nonetheless be provided to the data subject at the latest when the data subject is contacted on the basis of the data.

[77] See Ot.prp.nr.74 (2006-2007) p. 151.

[78] This is also the opinion of the Department of Health and Care Services, see Department Guidelines, section 4.3.2, p. 21, referred to earlier in this study.



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The combination and disclosure of personal data to another data controller – the researcher – who shall use the personal data for scientific research purposes is deemed to be compatible further processing pursuant to article 5(1)(b) of the GDPR. The data controller (who originally collected the data) who discloses such personal data does not need a special legal basis for such disclosure to the researcher (we assume that the original data controller has a lawful basis for its processing pursuant to the requirements of the GDPR). However, such original controller must ensure that the combination and disclosure satisfies the requirement for appropriate measures pursuant to article 89(1). Provided such personal data are and remain pseudonomysed also in the hands of the researcher, it appears that the requirement of article 89(1) are satisfied. However, one must bear in mind that, in a big data scenario, the situation can arise that, if enough additional big data variables are added to those extracted from AEGLE, the data might no longer be pseudonymous and hence no longer satisfy the requirements of article 89(1) and article 5(1)(b).

A big data scenario may also trigger the need for a data protection impact assessment pursuant to article 35 of the GDPR if there is either "processing on a large scale of special categories of data referred to in Article 9(1)" (article 35(3)(b)) or if the processing planned by the researcher, in particular if use of the AEGLE platform is deemed to be use of a "new technology" pursuant to article 35(1) of the GDPR and the other requirements of article 35(1) exist.

The researcher must, in turn, have a legal basis for obtaining and further processing the data. Such a legal basis could be sections 8 and 9 of the Personal Data Act (2018) regarding processing of, respectively, non-sensitive and sensitive personal data for research purpose without consent. It could also be consent of the data subject. The Explanatory Statement to the Personal Data Act (2018) states that according to recital 33 of the GDPR, the "data subjects should be allowed to give their consent to certain areas of scientific research when in keeping with recognised ethical standards for scientific research". This type of consent is referred to as "broad consent" in the Explanatory Statement.

Approval from the REK of the ethical side of the research must still be obtained as well as, where appropriate, dispensation from the duty of confidentiality, as explained earlier in this study.



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