Regulations relating to the transfer of biobank material to other countries

Laid down by the Ministry of Health on 26 February 2004 pursuant to section 10, third paragraph, of the Act of 21 February 2003 No. 12 relating to biobanks.

Chapter 1. Purpose and definitions

§ 1. Purpose

The purpose of these regulations is to regulate exemptions from the general rule that approval from the Ministry is required if biobank material is to be transferred to another country. Exemptions may be made if the interests of ordinary international cooperation indicate that this is justifiable and appropriate, and if the biobank material will be used for the benefit of individual people and of society as a whole. The regulations are intended to ensure that such transfers of biobank material to other countries take place within a satisfactory framework.

§ 2. Definitions

For the purpose of these regulations, the following definitions apply:

a) anonymous/anonymised biobank material: biobank material from which the name, personal identity number and other characteristics serving to identify a person have been removed, so that the material can no longer be linked to a particular individual.

b) de-identified biobank material: biobank material from which the name, personal identity number and other characteristics serving to identify a person have been removed, so that the material can no longer be linked to a particular individual, and where the identity can only be traced through alignment with the same data that were previously removed.

c) diagnostic biobank or treatment biobank: a collection of human biological material contributed for the purpose of medical examination, diagnosis and treatment.

d) research biobank: collection of human biological material and data obtained directly by the analysis of this material, and that is used or is to be used for research purposes.

e) human biological material: organs, parts of organs, cells and tissue and parts of such material obtained from human beings, alive or deceased.

f) human cell cultures: cell cultures established from human cells or tissue and cultured *in vitro* in the laboratory.

Chapter 2. Transfer to other countries without approval for the specific case

§ 3. Anonymous or de-identified material

Anonymous or de-identified biobank material may as part of ordinary international cooperation be transferred to other countries without obtaining the Ministry’s approval provided that the following three conditions are met:

1. the biobank is based in Norway,
2. the material is transferred solely for the purpose of analysis and the results of such analysis are to be returned to the sender in Norway, or the material is transferred solely for the purpose of normal quality control of analytical methods, and
3. the biological material is destroyed by the recipient in the country to which it was transferred or returned to the sender after analysis.

§ 4. Exchange of research data

Data obtained by analysis of biological samples from current research projects that include Norwegian participants may be sent to partners in other countries without obtaining the Ministry’s approval.

Data such as mentioned in the first paragraph shall be anonymised or de-identified before they are transferred to another country.

§ 5. Participation in international courses

In connection with international courses that form part of systematic further and continuing training of health personnel, human biological material from diagnostic biobanks and treatment biobanks may be transferred to other countries.

Material such as is mentioned in the first paragraph shall be anonymised or de-identified before it is transferred to another country.

§ 6. Transformed human cell lines etc.

Individual transformed human cell lines and cells with a very high potential for self-renewal that are to be used in model systems, functional studies etc. may be transferred to partners in other countries without obtaining the Ministry’s approval.

Material such as is mentioned in the first paragraph shall be anonymised or de-identified before it is transferred to another country.

Chapter 3. Transfers of biobank material on the basis of general approval

§ 7. General approval for the transfer of biobank material to international partners

The Ministry may on application grant general approval for repeated transfers of biobank material to other countries in connection with ordinary international cooperation.

Biobank material that is transferred to another country on the basis of general approval shall as a general rule be anonymised or de-identified.
The Ministry may grant general approval for the transfer of identifiable material that is to be anonymised or de-identified by the recipient. In special cases, general approval may be granted for the transfer of identifiable material that will not be anonymised or de-identified by the recipient.

In evaluating whether to grant general approval, the Ministry shall among other things attach importance to how similar the different transfers will be as regards purpose, the type of material to be transferred, the type of cooperation with the recipient and the scope of the material to be transferred.

§ 8.  Applications for general approval

Applications for general approval pursuant to section 7 shall as far as possible include information on:

a) the purpose of the transfers, including the types of analyses that are to be carried out, the results that are expected and how these results are to be used,
b) the name of the person responsible for the research project and the person in charge in Norway,
c) the scope of the transfers, for example an estimate of the number of people or samples involved,
d) existing research cooperation and planned projects that are included within the scope of the application for general approval for transfer to other countries,
e) a description of the biobank material. This must make it clear whether the application applies to transfers of tissue, cells, blood, etc., components of human biological material such as RNA, DNA or proteins, or information derived from biological material,
f) the names of contact persons and cooperating institutions in other countries. The application shall also include information on how the results are to be published, for example in international journals,
g) consent from the donors of the material. A copy of a standard consent form shall be enclosed with the application,
h) information on whether samples are to be anonymised or de-identified before transfer to another country,
i) recommendations from regional committees for medical research ethics. Copies of any recommendations shall be enclosed.

§ 9.  Duty to provide reports

Any person who has been granted general approval pursuant to section 7 shall provide an annual report on his or her activities. The report shall be sent to the Ministry no later than 15 March the following year. The report shall include the following information:

a) a list of projects that involved the transfer of biobank material to other countries,
b) information on how many samples were transferred, the type of material they contained, the types of analyses carried out and how many patients/subjects were involved,
c) a list of any publications from the relevant projects.
§ 10. Changes in circumstances

Any changes in the circumstances on which general approval for transfers to other countries is based, cf. sections 7 and 8, shall be reported to the Ministry immediately. In the event of substantial changes, the Ministry may request a new application.

§ 11. Authority to withdraw approval

Approval may be withdrawn if the transfers are not justifiable pursuant to the Act relating to Biobanks and the legislation relating to the protection of privacy. In the event of breaches of the conditions attached to approval, such approval may be withdrawn if circumstances so indicate.

The Ministry may withdraw approval pursuant to section 7 in the event of non-compliance with the duty to provide reports.

Chapter 4. General provisions

§ 12. Agreements with recipients

The person in Norway in charge of a biobank shall ensure that agreements are concluded with recipients of biobank material so that the material is processed appropriately and in accordance with Norwegian rules.

§ 13. Entry into force

These regulations enter into force on 1 March 2004.

Comments on the provisions of the Regulations relating to the transfer of biobank material to another country

Re Chapter 1, Purpose and definitions

Re § 1 Purpose

These regulations describe exemptions from the general rule set out in section 10 of the Act relating to Biobanks, which requires the Ministry’s approval before biobank material may be transferred to another country.

The legal authority to make exemptions from the requirement for approval applies to the transfer of the whole or parts of a biobank if this is done in connection with ordinary international cooperation. The term “ordinary international cooperation” is taken to mean projects in which the Norwegian party plays an active role and is a genuine partner. In the case of research cooperation, this will for example mean that the Norwegian party is informed of research results, conclusions, etc., and to some extent plays an active role in determining the research questions to be studied, writing
reports and publications, and so on. The Norwegian partner must not be merely a passive supplier of biobank material for use in research projects in other countries.

The regulations are intended to ensure that valuable and necessary cooperation across national borders can take place without the need to obtain the Ministry’s approval for every single transfer of material. The regulations therefore lay down rules for certain types of transfers to other countries in situations where no conflict arises between cooperation with parties in other countries and considerations of public control and the protection of Norwegian resources and personal integrity.

Under these rules, material in Norwegian biobanks which originates from another country may freely be returned without obtaining approval for the transfer of biobank material to another country.

**Re § 2 Definitions**

a) Biobank material is considered to be anonymous/anonymised once all characteristics serving to identify a person have been removed so that it is no longer possible to trace the person from whom the biological material or information originates. Material that has been de-identified in such a way that it is possible to link it with data relating to an identifiable person is not considered to be anonymised, even if access to the coding system is very restricted.

b) Biobank material is considered to be de-identified when the name, personal identity number and other characteristics that can unambiguously be linked to an identifiable person have been removed. De-identified material is labelled in a way that makes it possible to trace the person from which it originated.

c) A diagnostic biobank or treatment biobank is a collection of human biological material contributed for the purpose of medical examination, diagnosis and treatment. Personal data linked to biological material that forms part of a diagnostic or treatment biobank are not considered to be part of the biobank.

d) A research biobank is a collection of human biological material that is used or is to be used for research purposes. Information and research data obtained by analysis of this material are considered to be part of the biobank. The same applies to data obtained by analysis of components of cells such as RNA, DNA and proteins. Information from earlier analyses carried out in connection with diagnosis or treatment, for example patient records, is not part of a research biobank.

e) Human biological material means organs, parts of organs, cells and tissue and parts of such material obtained from human beings, alive or deceased. It also includes body fluids and secretions containing cells. The term “parts of human biological material” includes DNA, RNA and proteins.

f) Human cell cultures means cell cultures established from human cells or tissue and cultured in vitro in the laboratory.

**Re Chapter 2 Transfer to other countries without approval for the specific case**

**Re § 3 Anonymous or de-identified material**
This provision makes an exception, on further specified conditions, from the requirement to obtain approval for transfers of anonymous or de-identified material. Three conditions are listed, and all three must be satisfied before transfers may take place without obtaining approval for the specific case.

Section 3, item 1 requires the biobank to be based in Norway. This means that the biobank operates in accordance with Norwegian legislation and is primarily intended to serve Norwegian interests. Transfers of biobank material should not result in the establishment of the entire biobank or a major part of it outside Norway. Nor should such transfers reduce the research value of the biobank in Norway or alter its ties to Norway.

The second requirement is that material must be transferred either in order to carry out analyses that are to be used in Norway, or solely in order to compare analytical methods and carry out quality control. However, this provision does not prevent the cooperation partner in another country from using the analytical results as well.

Finally, item 3 lays down that the biological material must not be retained outside Norway once the analyses have been completed. The sender in Norway may agree that the samples are to be returned, or that they are to be destroyed by the recipient.

If biobank material is transferred to another country pursuant to this provision, the person in charge of the biobank in Norway shall ensure that the material is used in accordance with an agreement.

A further condition follows from section 10, first paragraph, of the Act relating to Biobanks. According to this provision, transfers of biobank material to another country shall also be in accordance with the consent given by the donor of the material. In practice, this means that donors of biological material to a biobank should be informed of any plans to transfer material to another country, and give their consent to this, when the material is collected. If consent has not been obtained, transfer to another country may be considered as different, wider or new use that does not fall within the scope of the original consent. As a general rule, this will require new consent to be obtained. However, the Directorate for Health and Social Affairs may make exemptions from the requirement to obtain new consent in the event that this is impossible or very difficult to obtain, cf. section 13 of the Act relating to Biobanks. A recommendation from a regional committee for medical research ethics shall be provided.

The Personal Health Data Filing System Act, the Personal Data Act and appurtenant regulations set out further security requirements for transfers to other countries.

Re § 4 Exchange of research data
Data obtained directly by analysis of the biological material in a research biobank are considered to be part of the biobank, cf. the definition of a research biobank. This means that if information or updated data are to be sent to partners in another country, part of a research biobank is being transferred.

Section 4 allows for the transfer of research data without obtaining the Ministry’s approval in connection with current research projects involving one or more partners.
abroad. It is a requirement that such research projects include Norwegian participants, so that transfers of data also serve Norwegian research interests. This requirement must be seen in the context of the purpose of the regulations and the comments on section 1, which state that the Norwegian party to the international cooperation must be an active and genuine partner, and not merely a passive supplier of material.

When research data are exchanged, the data are often coded or numbered. In many cases, a researcher in Norway can link such data to a particular individual. Such data are therefore not considered to be anonymised, even if the recipient in another country cannot identify the person. Data of this kind are exchanged regularly as part of research projects. International cooperation requires that the partners to keep each other updated on the progress of the project and the results that have been achieved. The exchange of data is also valuable in connection with quality control.

Pursuant to section 10 of the Act relating to Biobanks, research data that form part of a biobank shall only be transferred to another country in accordance with the consent given by the donor of the material. See also the comments on section 3 of these regulations as regards section 10 of the Act.

Re § 5 Participation in international courses
This provision makes it possible for Norwegian health personnel to take part in international courses and contribute biobank material to them without being required to obtain approval to take the material out of the country. The courses involved must deal with preventive medicine, quality control and/or methodological development. Further and continuing training of health personnel who need to analyse and evaluate specimens in connection with diagnosis and treatment may for example be considered relevant to quality control of diagnosis. The participants increase their expertise, and the evaluation of specimens by several people constitutes quality assurance. It may for example provide the basis for revision of a diagnosis or reclassification of disease groups. Provided that such use of the material in a diagnostic biobank can benefit the donor of the material or patients with the same disease/diagnosis, biobank material may be transferred to another country without the need to obtain approval for each transfer.

The second paragraph specifies that material that is transferred to another country shall be anonymised or de-identified.

Re § 6 Transformed human cell lines, etc.
This provision makes it possible, on certain conditions, to transfer transformed cell lines established from human cells or tissue to partners in other countries without obtaining the Ministry’s approval. Such exemptions also apply to cell lines with a very high capacity for self-renewal, such as T cells and certain mesenchymal stem cells. They apply only to single cell lines. In other words, the provision does not permit the transfer of all or part of a biobank consisting of several cell lines to another country without approval. The provision also lays down that the cell line must be transferred for use in model systems, functional studies, etc. If the recipient intends to establish a larger biobank for another purpose, the general rule is that the Ministry’s approval must be obtained in advance.
The term transformed cell lines means cells that have been immortalised. The term cell lines with a very high potential for self-renewal means cell lines that are able to divide 40-60 times or more when cultured in vitro. In accordance with good research practice, cell lines that are described in publications should be made available to other researchers. If cell lines have been transformed and immortalised, or have a very high potential for self-renewal, the transfer of material to another country will not result in any depletion of valuable material in Norwegian biobanks. On the other hand, human cell lines with a more limited lifetime are a limited resource.

Material that is transferred must first be anonymised or de-identified. When biological material that may be used to established cell lines is collected, the person from whom the material originates must give consent to possible use of the material for this purpose.

Re Chapter 3 Transfers of biobank material on the basis of general approval

Re § 7 General approval for the transfer of biobank material to international partners
This provision allows for applications to the Ministry for general approval to transfer biobank material from one or more biobanks to another country in connection with ordinary international cooperation. Such approval may be granted for ongoing or planned projects.

The biobank material should as a general rule be anonymised or de-identified before it is transferred to another country. One reason for this requirement is to ensure that data relating to identifiable persons are not misused in countries with less restrictive legislation than Norway. In cases where material from Norway makes up part of a larger international collection of research material, it may be appropriate to anonymise or de-identify all the material in the country where the central biobank is maintained. General approval may therefore be granted for the transfer of material that will be de-identified by the recipient. In such cases, the biological material should be transferred separately from any personal data. The regulations also provide for general approval, in special cases, for the transfer of identifiable material that will not be de-identified by the recipient. In such cases, the applicant shall give reasons why it is necessary to transfer samples or analytical results that have characteristics serving to identify a person.

A condition for granting general approval is that the repeated transfers of material will be so similar that they can be evaluated together. They should therefore have the same general purpose and have a certain scope if general approval is to be given. The type of cooperation and links with other countries, the way in which the biobank material is to be used in other countries, and whether the data are anonymous or can be linked to identifiable persons are other factors that should be given weight when applications are considered. The value of the biobank material to Norwegian society should also play a key role in the evaluation.

The degree of similarity between analyses may for example be indicated by whether genetic investigations concern one specific disease. Material may for example be considered to be similar if blood samples or a specific type of tissue are to be collected, and cells, tissue or parts of such material (DNA, RNA, proteins) are to be
analysed. See also comments relating to section 8.

Re § 8 Applications for general approval
Applications for approval for transfers of biobank material to other countries may be submitted for both planned and ongoing projects. Applications shall as far as possible include the information on the activities and projects involved and details of the need to transfer material to other countries mentioned in section 8 a) - i).

Information on the purpose or intention of the transfers shall be provided. This could for example include information on whether biochemical analysis of biological samples or statistical analysis of research data is to be carried out in other countries.

The name of the person in charge of the biobank in Norway shall be given. In addition, the name(s) of the person(s) responsible for the research project or projects shall be given.

Information on the scope of the transfers shall be given. This means estimates of the number of projects that are or will be involved and of the numbers of samples or patients that will be included in the transfers related to the different projects.

A description of existing research cooperation and planned projects that will involve transfers of biobank material shall be included. Acceptable types of project descriptions include copies of research protocols or a summary of the background, purpose, analytical methods, etc., for a project.

The application shall include a description of the material to be transferred. This must indicate whether the material to be transferred consists of organs, tissue, cells or blood, components of such material (RNA, DNA, proteins), or information or research data obtained by direct analysis of human biological material.

The names of contact persons and cooperating institutions in other countries must be given. The applicant must also indicate whether the recipient is part of a commercial undertaking. Further, the applicant must indicate whether it is intended to publish research data in national or international journals, and whether the data is to be used in quality assurance efforts, reports, etc.

If a standard consent form is used, a copy shall be enclosed with the application. If not, consent form and information leaflet for each project should be enclosed. It is important that donors’ consent to provide material also includes informed consent to the transfer of the material to other countries. This must be made clear by the consent form. See also the comments relating to section 3 of these regulations and the reference to section 13 of the Act relating to biobanks.

It must be made clear whether the samples are de-identified or anonymised before they are transferred to another country. If anonymisation is to be carried out by the recipient, this shall be made clear in the application. In cases where it is considered necessary to transfer biological material or data that include patients’ names, personal identity numbers or other characteristics serving to identify a person, specific grounds for this must be given.
If a regional committee for medical research ethics has evaluated the project(s), its recommendations shall be enclosed with the application.

Re § 9 Duty to provide reports
Any person who has received general approval pursuant to section 7 has a duty to provide an annual report on his or her activities. The report shall be sent to the Ministry no later than 15 March the following year. The Ministry may on application from a person who is required to provide such a report extend this time limit.

The report shall include a list of projects that involved the transfer of biobank material to other countries. It is sufficient to provide the title of the project and the name of the person responsible for the project.

For each project, information is required on how many samples have been transferred and the number of patients who have provided material (several samples may have been collected from the same person). Furthermore, information on the type of material that has been transferred (cf. the comments on section 7 e), the types of analyses that have been carried out (e.g. mutation analyses for genes X, Y, Z, measurements of protein levels for protein a, b, c).

If any papers, reports, etc., have been published in connection with any of the projects, a list of such publications shall be enclosed with the report. The list shall include information on the types of publication involved and if appropriate, complete references to journals.

In the event of non-compliance with the duty to provide reports, the Ministry may withdraw approval for transfers, cf. section 11.

Re § 10 Changes in circumstances
Any changes in the circumstances on which general approval for transfers to other countries pursuant to section 7 (cf. section 8) is based shall be reported to the Ministry immediately. In the event of substantial changes, the Ministry may request a new application. The Ministry will determine the types of changes that are to be regarded as substantial.

Re § 11 Authority to withdraw approval
The Ministry may withdraw general approval granted pursuant to section 7, cf. section 8, if transfers of biobank material are not justifiable pursuant to the Act relating to Biobanks and the legislation relating to the protection of privacy. Approval may also be withdrawn in the event of breaches of the conditions attached to approval, for example non-compliance with the duty to provide reports pursuant to section 9.

Re Chapter 4 General provisions

Re § 12 Agreements with recipients
Before biobank material is transferred to another country, the person in charge of the biobank in Norway must ensure that agreements are concluded with recipients so that the material is processed in accordance with Norwegian rules. This provision applies both when transfers are made pursuant to Chapter 2 of these regulations and when they are made in accordance with general approval granted pursuant to Chapter 3. The
person in charge of a biobank under section 7 of the Act relating to biobanks is responsible for ensuring compliance with such agreements.

*Re § 13 Entry into force*
These regulations enter into force on 1 March 2004.