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## Biobanks

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# **Biobanks: Obtainment, preservation and utilisation of human biological material**

Medical-ethical guidelines and recommendations

The German version is the original, binding version.

23 May 2006

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# Biobanks: Obtainment, preservation and utilisation of human biological material

Medical-ethical guidelines and recommendations

## I. Preamble

The obtainment, preservation and utilisation of human biological material for training and research, but also for other purposes, have long been common practice. Important technical innovations, especially in the fields of human genetics and electronic data processing, today make it possible to collect and compare biological material and personal data obtained from it on a large scale. In this way, important new epidemiological, diagnostic and therapeutic knowledge can now be obtained, which was not possible with the research tools available up till now. Biobanks can thus contribute to an important advance in the further development of medical research, particularly in the health-care sector, but also in the whole field of human sciences.

While on the one hand biobanks raise justified hopes and expectations, on the other they do involve certain risks and dangers. In particular, there is the fear that biological material and data may be used for purposes other than those for which the donor has explicitly given his<sup>1</sup> consent. But even when their use exclusively for research purposes is guaranteed, the problem arises of the possible existence, in the future, of new analytical methods and new objectives, which could not be foreseen by those responsible for the biobanks at the time that the samples and the data were received.

The setting-up of more and more extensive biobanks raises ethical and legal problems, which urgently require regulation. On the one hand the rights of the donors have to be protected. In this respect, the right to personal freedom<sup>2</sup> and to protection of the individual's private life<sup>3</sup> are of primary importance. This right also includes decisions regarding physical integrity and the use of personal data, namely the right to self-determination in regard to information. On the other hand, in the interests of the persons directly concerned, but also of society in general, it should be avoided that scientific progress<sup>4</sup> and the benefits that it can bring are hindered by excessive regulation.

These present guidelines<sup>5</sup> are intended as an aid to orientation until such time as corresponding federal regulations come into force. They take into account both present national and international legislation and the basic principles of bioethics, namely autonomy, health

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<sup>1</sup> For the purpose of simplicity, the masculine prepositions are used when the feminine are also meant.

<sup>2</sup> Art. 10, Para 2, of the Swiss Federal Constitution (Right to life and personal freedom): "Every person has the right to personal freedom, especially physical and mental integrity and freedom of movement".

<sup>3</sup> Art. 13, Para. 2, of the Swiss Federal Constitution (Protection of the private sphere): "Every person has claim to protection against misuse of his personal data."

<sup>4</sup> Art. 20 of the Swiss Federal Constitution (Freedom of science): "The freedom of scientific learning and research is guaranteed."

<sup>5</sup> The guidelines of the SAMS are not legally binding. They are however part of the deontological code of the Swiss Medical Association (FMH) and must be respected by its members.

care and justice. They are limited to dispositions concerning the protection of human dignity, the personal integrity of the donors and assurance of the quality and safety of the biobanks.

## II. Guidelines

### 1. Definition of “biobanks“

In the sense of these guidelines, biobanks are systematic collections of samples of human body substances (e.g. organs, tissue, blood, cells etc.) and DNA as carrier of genetic information. Data that contain information on the donor (demographic data, type of disease etc., but also genetic data) are stored, either together with the samples or separately.<sup>6</sup> At the time that the samples are taken into the biobank it can often not be foreseen what additional information may later be obtained and connected with the donor’s personal data.

### 2. Scope of the guidelines

These guidelines are addressed to all those responsible for managing biobanks and all users of biobanks and other collections of human biological material, irrespective of their professional background. They apply to research, teaching, training and postgraduate training.

The use of tissular material for individual-diagnostic, therapeutic or forensic<sup>7</sup> purposes, as well as for quality control and quality assurance, does not fall within the scope of these guidelines, provided it takes place within the framework of medical practice<sup>8</sup>. Any use of samples and data after the primary objective has been achieved (e.g. completion of a diagnosis) is considered, within the scope of the guidelines, as secondary use.

For biobanks which are already subject to legal regulations at the Federal level – for example because they touch on research with stem cells, germinal cells and embryos<sup>9</sup> – the guidelines only apply if they envisage more detail regulations. Other Federal<sup>10</sup> and Cantonal<sup>11</sup> regulations concerning the handling of donor data and samples also have to be considered.

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<sup>6</sup> This information (samples and data) represents personal data that should be protected in accordance with the Federal Law on Data Protection (DSG)

<sup>7</sup> See Swiss Federal Law on the use of DNA profiles in criminal procedures and for the identification of unknown or missing persons (DNA Profile Law)

<sup>8</sup> In contrast to research products in the fields of quality control and quality assurance; see Item 41.

<sup>9</sup> See Federal Law on Medically-Assisted Reproduction (FedMedG) and the Federal Law on Research into Embryonal Stem Cells (StFG)

<sup>10</sup> Especially the Federal Law on Data Protection

<sup>11</sup> See, for example, Art 23, Para. 4 of the Law on Public Health of the Canton of Vaud: “A sample of human biological material may only be used for purposes approved by the person concerned and only if his personal integrity is respected. In principle, the sample must be destroyed once it has been used, unless a contrary decision by the person concerned or the special legislation on the subject require otherwise“.

### 3. Requirements of Biobanks

Those responsible for the management of a biobank must ensure that these guidelines are adhered to. They must take care, in particular, that

- the biobank has qualified personnel and suitable structures and material;
- an appropriate quality assurance system exists with regard to the storage and use of the samples;
- the rights of the donor, especially with regard to data protection, are guaranteed;
- if samples are transferred to third parties, the donor's right to personal integrity is assured;
- regulations exist, which govern the important points.

#### 3.1. Quality standards

The quality assurance measures that are established in medical practice and research must also be applied for biobanks. These include in particular the coordination of various activities, such as laying down of the policy and setting the objectives with regard to quality, as well as the planning, orientation, assurance and improvement of quality.

#### 3.2. Data protection

Appropriate technical and organisational measures must be taken to protect the data and the samples against improper use.<sup>12</sup> This applies both to storage in the biobank and to the use of the data and the samples.

For the protection of the donor, the samples should be coded as soon as possible, but at the latest when they are taken into the biobank.

With reversibly anonymised samples, there is only an indirect link to the donor. The sample is given a code. Access to the personal data is only possible with the key to the code, which must be stored and managed separately from the data. Double-coded samples have a second key.<sup>13</sup> The key to the code should be in the hands of a person who is sworn to secrecy and who is not directly involved in research with the samples and the data.

With irreversibly anonymised<sup>14</sup> samples, the personal data are changed in such a way that the information on personal or material aspects can no longer be identified with a particular person and the risk of re-identification of the individual is extremely slight, because the cost and effort required for this would be disproportionate.<sup>15</sup>

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<sup>12</sup> An easily decipherable code, made up from the donor's initials and date of birth, for example, does not constitute sufficient protection. See Committee for Proprietary Medicinal Products (CPMP): Position Paper on Terminology in Pharmacogenetics. See also List of References.

<sup>13</sup> The key to this second code is to be kept in a separate place.

<sup>14</sup> The terminology used may differ: Instead of "irreversibly anonymised", one also speaks of "anonymised". Instead of "reversibly anonymised", the terms "single coded" or "double-coded" are used, and "identified" is used instead of "not anonymised".

<sup>15</sup> With blood and tissue samples, theoretically a sample can be identified with a particular individual by means of identified reference samples or through results of other genome analyses.

Both in the interests of the patients and in the interests of research, samples and data should not be irreversibly anonymised, as far as this is possible. For the patient, irreversible anonymisation means that generally he can no longer be informed of relevant results; for research, it means that the samples and the data lose in informative value.

### **3.3. Transfer of samples and data**

Samples of human biological material may be transferred to third parties only in reversibly or irreversibly anonymised form. In the case of reversibly anonymised samples, the recipient may not have access to the key to the code.

The transfer of human biological material must be documented in such a way that the data can be retrieved and must be covered by a material transfer agreement (MTA). With every transfer of samples and data, the donor's rights to personal integrity (especially the right of revocation) must be guaranteed. The transfer of samples and data is permitted only if it is guaranteed that the standards according to these guidelines are maintained.

If a biobank is transferred to a third party as a whole unit, the new holder of the biobank must meet the requirements of these guidelines.

### **3.4. Regulations**

The regulations must define the organisation, the responsibilities and the scope of application of the biobank. They should also contain dispositions concerning the origin of the samples stored, the purpose for which they are intended, the names of those with right of access to them and the preconditions for that access. The regulations should also protect the integrity<sup>16</sup> of the biobank.

If there are several biobanks within an institution (hospital, research centre etc.), it is recommended that they should be subject to the same regulations and run under the same joint management.

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<sup>16</sup> In this context, "integrity" means that the samples remain together, so that the biobank can keep to its objectives.

## 4. Research with human biological material

### 4.1. Requirements of research projects

All research projects with human biological material, which can affect the donor directly must first be assessed positively by the responsible ethical committee.

This concerns, in particular:

- research projects that involve the removal of human biological material for the purposes of research;
- research projects with reversibly anonymised and non-anonymised samples and data.

These requirements also apply to research projects with human biological material in the areas of quality control and quality assurance.

The ethical committee assesses the scientific quality and the ethical acceptance of the research project on the basis of the legal regulations and the recognised rules of research ethics.

The ethical committee also has to assess whether the coding process is secure. With research projects that are accompanied by storage of samples and the creation of genetic databases<sup>17</sup>, the committee checks, in particular, whether sufficient data have been extracted from the research protocols. In this way the risk that donors can be identified from the remaining data can be excluded.

### 4.2. Information

Donors must give their consent to the removal, storage and use of their samples for the purposes of research. Written explanatory information is a prerequisite for consent (informed consent). The extent of this information must however be proportionate to the use for which the samples and the data are to be used.

For the donors, the following points are particularly relevant:

- the area of use of the samples and data;
- consent is given voluntarily and may be withdrawn at any time;
- the measures for the protection of personal integrity and for the assurance of data protection;
- the length of the storage time;
- the donor's right of access to data relating to him which are stored in the biobank;
- access of controlling authorities and monitoring authorities to samples and data, the extent of their rights of access and any obligations to the insurances companies;
- the donor's right to information on the further use of his samples and data;
- the possibility of the transfer of samples and data and their use for commercial purposes in the field of medical research;

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<sup>17</sup> These are databases that contain samples of isolated DNA. For genetic investigations, the Federal Law of the Analysis of Human Genetics (LAHG) has to be observed, especially Art. 20: "Re-use of biological material" (not yet in force).

- subsequent information on the results, which could be relevant for the donor (the right to know) or the possibility of not being given this information (the right not to know).

#### **4.3. Consent**

Consent should be given in writing at the time the samples are taken, but at the latest at the time when the samples and data are taken into a biobank.

Consent can generally also cover the further use of the samples and data for future research projects (general consent). Restriction of their use to one specific field of research is possible.

The donor must however expressly give his consent to a research project if this

- requires the removal of human biological material;
- envisages research with non-anonymised samples;
- involves special risks for the donor.

#### **4.4. Donors who are incapable of discernment**

If biological material is taken, for diagnostic purposes, from a person who is incapable of discernment, it may be stored and later used for the purposes of research only with the consent of the donor's legal representative.<sup>18</sup> If there is no legal representative, the further use of the material is permitted provided that this is in accordance with the presumed wishes of the donor.<sup>19</sup>

If the incapacity for discernment is temporary, storage of the material for possible later use until the donor is again capable of discernment is permitted. From this point in time the general rules regarding information and consent are applicable.

If the biological material is obtained from children or adolescents, it is necessary to ensure that they can exercise their rights, as soon as they have become capable of discernment.

#### **4.5. Deceased persons**

If material is removed from a deceased person (e.g. in the course of an autopsy), that person's prior consent to the storage and further use of this material for the purposes of research is necessary (patient's prior instructions). If the deceased person had not given consent, the closest relatives may give their consent, provided this is not in contradiction of the deceased's wishes expressed or presumed during his lifetime.

#### **4.6. Withdrawal of consent**

Donors have the right to withdraw their consent at any time. This is valid with regard to the future use of the samples and data and presupposes that the samples have not been irreversibly anonymised.

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<sup>18</sup> According to the Cantonal regulations, other persons may be authorised to give consent, for example a representative with authority in medical matters or a relative.

<sup>19</sup> Regarding this subject, see: "Right of patients to self-determination", medical-ethical guidelines of the SAMS (2005)

In the event of the withdrawal of consent, the samples must be destroyed.<sup>20</sup> The results that have been obtained with the material before this point in time, are not affected by this.

#### **4.7. Subsequent information on relevant results**

Donors have the right to be informed of diagnostically and therapeutically relevant results (right to know). This does not apply in the case of irreversibly anonymised samples and data. In principle, the information is provided by the responsible doctor. He also provides the donor with adequate advice. The management of the biobank ensures the satisfactory flow of information. The donor may refuse the subsequent information (right not know).

#### **4.8. Transfer of samples and data**

The management of the biobank or the investigator responsible for the primary research project<sup>21</sup> passes samples or data on to other researchers for further projects on in irreversibly anonymised or coded form. These researchers must return to the biobank or destroy any samples or remains of samples that they have not used. They are not allowed to transfer samples or data to third parties. The donors must have previously given their consent to the transfer of samples and data.

#### **4.9. Already existing biobanks**

For biobanks that were created before the present guidelines came into force and which intend to use samples and data for the purposes of research, basically the same principles apply as for biobanks created after these guidelines came into force.

It is a matter of priority to ensure that the donors have consented to the storage and further use of their samples and data. If the biobank does not have this consent it must be obtained retrospectively, provided this is not impossible, disproportionately difficult or burdensome for the donor. In this case the biobank must obtain the general authorisation of the expert committee for professional secrecy in medical research.<sup>22</sup>

For samples and data collected before 31 December 1995<sup>23</sup> which are not directly related to samples and data of the same donor, and which were obtained after that point in time, the expert committee gives its approval without providing general information.<sup>24</sup> Approval by the expert committee is not necessary for irreversibly anonymised samples and data.

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<sup>20</sup> The destruction of data is, however, in contradiction of the international requirements for clinical research in the framework of drug licensing; see Good Clinical Practice (GCP) Guideline E6 of the International Conference on Harmonisation of Technical Requirements of Pharmaceuticals for Human Use (ICH).

<sup>21</sup> Research projects in the course of which biological material has been removed are described as "primary".

<sup>22</sup> See Art. 321<sup>bis</sup> StGB and the Regulations on the Publication of Professional Secrets in the Field of Medical Research (VOBG).

<sup>23</sup> This is in line with the practice of the Federal Committee of Experts on Professional Secrecy in Medical Research.

<sup>24</sup> This provision consists, on the one hand, of a description of the circumstances under which the interested party has been informed of his rights, and on the other it contains confirmation that he has not expressly opposed the revelation of his data.

## **5. Teaching, training, postgraduate training and further training**

The use of irreversibly anonymised samples for teaching, training, postgraduate training and further training is permitted, on condition that the donor has not opposed this.

When a donor is being generally informed (patient information brochure), on his admission, it is recommended that the hospitals should point out the possibility of samples being used for teaching, training, postgraduate training and further training, and should also make the patient aware of the possibility of opposing this.

### III. Preparations from human tissue in collections, exhibitions and museums<sup>25</sup>

The manufacture, preservation, collection and processing of preparations from human tissue for scientific and didactic purposes are, in principle, permitted.

Preparations from human tissue are objects that consist entirely or mainly of organic human tissue and are permanently preserved by means of special procedures.

Human dignity must be respected in all measures for the manufacture, storage and presentation of these preparations.<sup>26</sup> Preparations that are accessible to the general public must be anonymised.

Preparations from human tissue may only be manufactured and stored if the donor has given his consent in writing (patient's instructions). The general preconditions for the legally binding validity of a declaration of consent, especially capacity for discernment, must be met. The donor may withdraw his consent at any time.

This rule does not apply in the case of irreversibly anonymised samples and data, especially histological preparations.

In the case of collections that existed before these guidelines came into force, the origin of the preparations must be stated, as far as this is possible. If it is discovered that the deceased died because of his origins, his ideology, for political reasons or as a result of violent measures on the part of a state authority, or if there are other indications of unlawful manufacture or acquisition of human preparations, these are to be removed from the collections and interred with dignity.

If, after a long period of time the deceased person is no longer remembered and if the present life of his descendants is no longer directly affected, the preparations concerned may be left in the collection, especially if they are unique, irreplaceable items of great historical or cultural value.

Parts of cadavers that were obtained and preserved in the course of investigations carried according to criminal law or by other authorities may be kept in special collections after expiry of the storage time required for legal reasons and with the consent of the authorities ordering these measures, provided there are scientific reasons and reasons of education and general interest for doing so. In this respect, any objections to storage of the preparations on the part of close relatives must be taken into account.

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<sup>25</sup> See: Recommendations on the handling of preparations based on human tissue in collections, museums and public spaces – Working-group, “Human preparations in collections“. See also List of Literature References in the Appendix.

<sup>26</sup> See also especially Art. 262 of the Swiss Penal Code (STGB): Disturbance of the peace of the dead.

## IV. Recommendations

With these guidelines only basic, framework conditions are defined. The SAMS is aware that in many areas further regulations are needed. It recommends, in particular,

- the creation of registers of public and private biobanks;
- the setting of standards for training in the laboratory field;
- the creation of dispositions for the accreditation of biobanks;
- the preparation of an information-and-consent form to be completed by patients on their admission to hospital.

## V. Appendix

### Relevant laws

- Swiss Federal Constitution of 18 December 1998 (BV)
- Federal Law on Drugs and Medicinal Products of 15 December 2000 (HMG)
- Federal Law on Medically-Assisted Reproduction of 18 December 1998 (FmedG)
- Swiss Penal Code of 21 December 1937 (StGB)
- Federal Law on Data Protection of 19 June 1992 (DSG)
- Federal Law on Research on Embryonal Stem Cells of 19 December 2003 (StFG)
- Regulations on the Publication of Professional Secrets in the Field of Medical Research of 14 June 1993 (VBOG)
- Federal Law on the Use of DNA Profiles in Criminal Procedures and for the Identification of Unknown or Missing Persons of 20 June 2003 (DNA Profile Law)
- *Federal Law on Genetic Investigations in Humans of 8 October 2004 (not yet in force)*
- *Federal Law on the Transplantation of Organs, Tissues and Cells of 8 October 2004 (not yet in force)*

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## Information on the elaboration of these guidelines

<b>Mandate</b>	On 13 June 2003 the Central Ethical Committee of the SAMS appointed a sub-committee to draw up guidelines on the subject, «Biobanks: obtention, storage and utilisation of human biological material».
<b>Responsible subcommittee</b>	Prof. Dr. med. Volker Dittmann, Basel, (Chairman) PD Dr. med. Mario Bargetzi, Aarau Prof. Dr. theol. Alberto Bondolfi, Lausanne PD Dr. med. Bernice Elger, Geneva Dr. med. Monica Gersbach-Forrer, Geneva Dr. med. h.c. Hugo Kurz, Basel Dr. pharm. Werner Pletscher, Zurich lic.iur. Michelle Salathé, Basel (ex officio) Prof. Dr. med. Henning Schneider, Bern Prof. Dr. iur. Dominique Sprumont, Neuchâtel Dr. med. Edouard Stauffer, Bern Prof. Dr. med. Michel Vallotton, Geneva (ex officio)
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<b>Consultation procedure</b>	On 24 May 2005 the first version of these guidelines was passed by the Senate of the SAMS, for submission to the consultation procedure.
<b>Approval</b>	The definitive version of these guidelines was approved by the Senate of the SAMS on 23 May 2006.

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