Framework for setting up and operating Biobanks

With regard to the use of bio materials, there is a great need for clarification of the legal ramifications. And since procuring and storing bio materials is becoming an increasingly important point for answering molecular-genetic questions within medical research, finding an answer soon for the related legal and organisational questions is extremely important.

1. Using Bio Materials – what does that entail?
   1.1 Using bio materials longterm
   Modern medical research is undergoing a “cultural change” these days in that cooperative research structures are being formed which are geared toward longterm cooperation. Within these usually supra-regional cooperation, often central data and bio banks are installed. Bio materials are valuable starters for research since they contain molecular-genetic information which allows multiple use independent of the original purpose at the point in time of their collection. This information, however, is so very specific again that the materials may always be connected to their respective donor. Thus, a new step of ethical and personality rights related problems is reached. So far, there are no laws regulating specifically the use of bio materials. Some of the leading medical research networks have begun with the support to clarify the ramifications for a lawful set up and operation of bio material banks.

   1.2 Warrant data protection
   One central task when setting up and operating a biobank is protecting the property and personality rights of the donors. Further, In particular, the question regarding longterm use for at first undetermined research purposes may be answered only after an intensive analysis of the respective personality rights. These legal questions are somewhat covered up by questions of ethical principles which gain great importance especially in connection with patient consent.

2. Aspects of special interest:
2.1 Legal aspects
Already at the onset of setting up a biobank, many legal aspects must be considered.

Legal form and carrier
Which legal form or private carrier is possible?
Which pros and cons need to be considered herein?
Are there special needs for regulations in the respective cases?

Property and personality rights
Which property right applies to biobanks?
Which property right applies to stored samples?
Does a donor have the right to demand his samples back?
What are the consequences of anonymity?
What are the consequences of handing on materials with respect to property rights?
What rights apply to using the samples?
What is the situation when samples are used outside of a treatment context?

Laws pertaining to doctors and work
What defines a doctor-patient relationship?
Which procedures require supervision by a doctor?

Maintenance, usage, legal succession
Are there legal requirements as to the sample maintenance?
What are the options regarding the use of a dissolved biobank?
What regulations must be following in case of an insolvency?

Collecting, storing and using materials
What are the legal (including criminal law) requirements for collection, transportation
and storage of materials?
Are there obligations regarding storage of materials?
What are the rights to use of materials?

Liability
Who is responsible for warranty and liability?
What are regulations in this regard?
Which risks may be insured?

2.2 Aspects as to data protection rights
Very important are also questions about data protection as well as purely practical
questions regarding the set up and operation of biobanks.

Basic questions
Is it possible to effectively incorporate anonymity into biobanks?
Distinction between bio materials and data?

Declaration of patient consent
What is to be considered in order to make use of sample materials for research?
How loosely may a purpose restriction be phrased?
How long may samples be stored for research purposes?

Protection against confiscation
Is it possible to achieve effective protection against confiscation in biobanks? What type of legal protection is there against unwanted use by third parties? Do regulations pertaining to doctors play a role? Does the carrier play a role? What defines the need for a data trustee? What are possible regulations for and consequences of a research secret?

Set up
What are the requirements to be fulfilled by a biobank with respect to granting data protection? How should storage, data flow and communication be regulated? What are the technical preconditions?

What defines anonymity sufficient for maintaining data protection …
… if handing materials to third parties?
… if patient consent was not given?
… if additional questions surface?

It is not possible to comment in detail all of the interesting questions. However, after a first survey, it is necessary to go into some depth about some of the mentioned aspects, or at least explain what they are specifically concerned with.

Now with respect to the form of the organisation:

3. Carriership of biobanks and suitable types of legal entity

Recently, biobanks have developed very rapidly and their possible economic use has spurred the discussion which deals with the aspect of the carrier for such biobanks and the suitable type of legal entity.

The legal entity, on principle, may come under public or civil law. According to surveys in Germany and Europe, the majority of BB carriers come under public law in Germany as well as in Europe. These institutions are mainly run by clinics or are related to universities. Nevertheless, Germany does have biobanks with private carriers which are, f. ex., a registered association or a private limited association (GmbH).

The following criteria have been discussed and are considered to be of deciding quality when dealing with a decision about the specific type of organisation and operation of a BB.
1. Lengthy decision-making processes are to be avoided.
2. Between research and the public needs to be a basis of trust (acceptance)
3. In case of insolvency, loss or abuse of specimens should be avoided if possible (conditions at the founding of the biobank in the case of insolvency; protection from access by third parties)
4. The carriership should have somewhat of a guarantee as to the duration (longevity)
5. Financial independence should be warranted as far as possible
6. Option for transformation from one type of legal entity into another (research project to an organisational entity)
7. Achieve liability exclusion for researchers, if possible
Economic efficiency or profitability so far has not been listed as a goal for a BB. However, this could play a central role in the future. Therefore, it makes sense to consider this aspect as a criterion also.

4. Rights of ownership and property rights for samples
A central aspect in the discussion on an international level is the rights of ownership and personality right with regard to the collected samples.

4.1. Who is the owner of a sample collected in a BB?
As per § 903 BGB (German Civil Code), the owner has all rights of use which are legally permitted, unless a law or rights of third parties are infringed. An infringement of the owner's rights may come under penal law or create the basis for a civil code liability for damages. Therefore, it is of the utmost importance for the individual doctor, researcher or operator of a biobank what his rights are regarding a sample. The leading opinion has it without question that the body of a living person considered as res extra commercium as well as his organs and the firmly attached body parts or aids (heart pace maker, tooth gold filling) are not considered things in the meaning of the law. Therefore, there is no ownership here. A person nevertheless has an "ownership-like right for decision" as a result from his general personality rights.

In Germany, samples are things or objects as defined by § 90 BGB, because they are body materials separated for good without the intention to be reunited with the human body.

The question arises how ownership may be argued considering the ruling law about separated body materials. Court rulings and the leading opinion in Germany assume that the object characteristics of body materials are defined after separation from a body analogue to § 953 BGB in favour of the person from whose body the separated materials came, and that includes ownership.

Ownership and personality rights have the same function to protect absolute rights from infringement by third parties. This results in the authority as per § 953 BGB to

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1 Auf die Relevanz dieser Beschränkung der Eigentümerbefugnisse wird bezogen auf menschliches Biomaterial im nachfolgenden noch einzugehen sein.
2 Spranger, NJW 2005, 1085 (1084); Halász, Das Recht auf bio-materielle Selbstbestimmung, S. 13 f. (mit einem Überblick über die verschiedenen Theorien); Palandt/Heinrichs, § 90 BGB RdNr 3; Taupitz, in: JZ 92, 1089.
3 Halász, aaO, S. 40.
grant the former carrier of separated body parts the same rights as to the owner of an object from which parts are separated. The legal relationship of a person with his body is a much more intensive one than the right to power over an object by its owner. However, if the ruling regarding separated object parts is such that they are part of the ownership of the object owner, then this must certainly also apply for separated body parts. Therefore, personality rights are reduced to ownership rights.\(^5\)

The human body as such and thereby also all of its parts and components have already undergone an ownership-like classification. The general personality right of the donor/patient continues to stay with the separated body part. Therefore, the donor/patient continues to be the owner of the separated body materials for the time being.\(^6\) There is no automatic transferral of ownership for the collected sample to a third party.\(^7\)

Ownership of collected body materials (samples), therefore, moves automatically to the person from whom the body materials have been taken.

### 4.2 Ownership of Biomaterials in a Biobank

After it has been determined that the ownership of the collected body materials for the time being resides with the person from whom the materials were taken, the question now rises whether this legal situation also applies for body materials which are stored in a biobank or whether and how the ownership of these body materials is transferred to a third party.

The question is whether there is consent about the transferral of ownership. Precondition for this is a consent between donor/patient and the biobank or a relevant third party (for example a doctor) which states that the ownership of the sample is to be transferred.\(^8\) Precondition for the consent are two concurring declarations of intention (offer and acceptance) each of which becomes valid upon receipt of the declaration by the recipient.

Provided an express offer of ownership transferral was received by the donor/patient, it is no problem to assume a transferral of ownership. Precondition for this is, though,

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\(^8\) Halász, aaO S. 60.
that the donor/patient expressly declares that he offers the collecting party to transfer ownership of the body materials taken from him and that the collecting party in fact accepts this offer.

Such an expressed agreement about ownership transferral is usually not existing. Usually, only the agreement about having samples collected and about having procedures executed with it (diagnosis, research, etc.) is available. The agreement as such, however, is no declaration of intent.\textsuperscript{9} The mere agreement of the donor/patient as to the collection of body materials is per se no agreement about the transferral of ownership.\textsuperscript{10}

There may be the option of a conclusive or silent declaration of intent, in particular by means of conclusive actions.\textsuperscript{11}

### 4.3 Legal foundation for the collection of body materials

Various constellations may be defined in which the collection of body materials from the donor is done.\textsuperscript{12}

- Collection for diagnosis/therapy reasons within the scope of a contract for treatment
- Collection within in the scope of a particular research project
- Collection for the purpose of storing samples for later unspecified research
- Other collection reasons (criminal law suits, donation of one's own blood, etc.)

### 4.3.1 Contract for treatment

A large portion – if not in fact the major portion – of samples stored in biobanks was collected within the scope of medical treatments, whether in a hospital or in a doctor's practice. The collection is done with the consent of the patient usually exclusively for diagnostic, sometimes for therapeutical purposes. The samples comprise, for example, tissue from medically indicated biopsies of various organs. In such a case, tissue is collected from living or dead persons for reasons of diagnosis. Usually, the diagnosis is not or not exactly known prior to the operation. The volume of tissue is limited.

\textsuperscript{9} BGHZ 24, 33; Lippert, in: MedR 2001 408 (406).


\textsuperscript{11} Palandt/Bassenge, § 929 BGB, RdNr. 2

\textsuperscript{12} Vgl. Stellungnahme der Zentralen Ethikkommission „Die (Weiter-) Verwendung von menschlichem Körpermaterial für Zwecke medizinischer Forschung (2003), http://www.zentrale-ethikkommission.de/cgi-bin/printVersion.cgi
Another source of tissue are operation materials (for example tumours from various tissue types, amputation material, organs in connection with transplants). Usually, large volume tissue is collected while only portions thereof are needed for further histological examinations. Usually, the diagnosis is known in advance. There is tissue left over (left-over materials).

Finally, there may be body materials which are not "collected", but "happen to come about", such as with the afterbirth (placenta, umbilical cord). This category includes also body secretions and other "waste materials".

4.3.2 Purpose of collection
If the collection of body materials is done within the scope of a contract for treatment, for example for the purpose of a diagnosis examination, the patient places his body materials at disposal in order to achieve healing.

4.3.3 Ownership transferral
Once the treatment is finished, the bio material which is left over remains with the doctor or the hospital where it was collected. An express agreement according to which ownership of the body materials is to be transferred to the doctor/clinic is not available. Such cases do not constitute a conclusive agreement to ownership transferral.

The leading opinion¹³ - which in particular also includes the National Ethic Council – assumes rather that the patient waives his ownership rights by leaving behind his body materials without comment. Thus, we assume a case of dereliction (disclaimer/waiver of ownership). The clinic or the doctor should then be able to take up ownership for the body materials which is then without owner. This opinion has met with firm opposition in recent publications.¹⁴ According to this opinion, the intent is the source of the idea. This more recent opinion should be followed for these reasons:

a) Priority for obligation of storage
If a patient does not demand his body materials back on his own accord, the doctor must examine after the end of the treatment and, thus, the contract for treatment

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¹³ Vgl. Stellungnahme des Zentralen Ethikrates, aaO; Spranger, in: NJW 2005, S. 1085 (1084) m.w.NW.
whether storing the body materials is obligatory. The reasoning as to storage is founded partially on a direct and partially on an analogue application of § 10 MBO-Ä. In accordance with this section, the doctor is obligated to store examination results and documentation of treatments. However, the collected body materials are neither examination results nor part of the treatment documentation but are examination objects. Therefore, the obligation for storage of body materials is considered a minor obligation of the contract for treatment with the doctor, and its duration lasts only as long as it is deemed medically necessary for the patient's healing process – for example with regard to follow-up examinations. Should it be in the interest of a successful treatment – albeit unknown to the patient – to continue to store the body materials, there must not be the assumption that the patient would waive his ownership rights of the collected body materials.

b) Lack of intent to waive ownership rights

Only if storing the body materials is not or not any longer considered necessary from a medical point of view, the question arises again whether the patient waived his ownership rights, thus enabling the doctor to gain ownership of the body materials. But even then we do not arrive at a different result.

As already explained, ownership waiver or disclaimer is a one-sided disposition. It comprises according to the leading opinion a declaration of intent not requiring a recipient and an action, the waiver of proprietorship. The declaration of intent must be concerned directly with the waiver/transferral of ownership. Further, the intention to waive rights must be recognizable.

This intention to waive rights is supposed to have been expressed in that the patient leaves his body materials behind without comment. This is supposed to constitute a waiver of ownership rights. The underlying assumption for this is that the superfluous and not needed body materials are considered to be waste by the patient and, therefore, he waives his ownership rights in order not to have to deal with the disposal.

This reasoning shows a certain closeness to the so called "bulky trash cases". The ruling in such "bulky trash" cases assumes an ownership waiver by the person who puts out objects to be picked up as bulky trash. From this point of view, the reasoning can be followed at first. However, different from the bulky trash cases, the patient

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16 aaO FN 26.
does not give his body materials to the doctor/clinic right away with the intention or wish for disposal thereof, but for the purpose of diagnosis and treatment. Further, even the Federal Supreme Court (BGH – Bundesgerichtshof) in the bulky trash cases has indeed not always assumed a waiver to ownership rights which corresponds to the right of taking possession by some third party.

If an artist puts out paintings made by himself, this is not considered a waiver of ownership, but a declaration of intent toward the carrier of the trash removal to have the paintings destroyed. In the case of forgotten objects there is no waiver to ownership rights due to the lack of intent to waive.

However, a formal declaration is not always necessary. Alone from a waiver of proprietorship one may conclude a waiver of ownership. In the rulings so far this is assumed only in the case of objects which are not discernibly personal (diaries, personal notes, self-made paintings).

Since the rulings assume for separated body materials which cannot be reattached to be property which is covered to a large extent by the general personality rights of the person from whose body the body materials come, one may assume that the property right of body materials is assumed to be purely personal. Thus, a dereliction may be considered only if an express declaration of the donor/patient was given.

This presupposes, however, that the patient is aware of left-over body materials. Usually, this will not be the case since he has no idea of how the body materials are processed within the scope of diagnostic measures nor that body materials are in fact left over. Without this awareness one may not assume, with a view on the mentioned ruling of the BGH, that the patient waives his ownership rights of his remaining body materials.

c) Conclusion

If the collection of body materials is done on the basis of a contract for treatment, the doctor is obligated to destroy the body materials or hand them out to the patient once the necessity for storing body materials has ceased to exist. A silent agreement about ownership transferral may not be considered. Only if the patient declared expressly

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17 LG Ravensburg NJW 1987, 3142.
18 Hefermehl, Rdnr. 2.
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20 BGH NJW 1994, 128 f.
21 Es ist darauf hinzuweisen, dass diese Ansicht der oben angeführten herrschenden Meinung widerspricht. Sie scheint aber konsequenter zu sein.
– prior or after the treatment – that the ownership of his body materials is to transfer
to the doctor in charge or the clinic, only then a transferral of ownership rights has
been effected.

4.4. Collection for certain research projects
A proportion of samples is taken for purely research purposes within the scope of
certain studies without having a concrete treatment as a goal. Usually, these are
specialized studies regarding specific diseases. The goal of these research projects
is to examine causes and treatment methods for certain diseases which the donor
might also suffer from. Recently, broad sample collections have been initiated without
knowing whether a specific disease occurs. These collections were executed with the
goal to research whether and to what extent a certain disease occurs in the
population.23

A further manner of collection may be done in that body materials (for example tissue
or blood) are taken with the consent of the patient in addition for scientific research
reasons in the course of an otherwise medically indicated removal of body materials.

a) Consent to collection
Collection of body materials is done in such cases on the basis of a declaration of
intent by the donor. The donor’s declaration of intent refers usually the consent to
have the collection as such done, i.e. the medical operation. Further, the consent
includes the use of body materials within the scope of a certain research project, in
part even a specific subject of the research. Additionally, the consent usually refers to
the collection of certain person-related data.

In addition to the consent, a special contract dealing with the legal rights concerning
the body materials is made with the patient in only few cases.24

The consent to using body materials for research is usually given free of charge.
Only in exceptional cases (for example in the case of blood donation – this being a
special case) is a remuneration paid.25

The available declarations of consent and the patient information coming with it show
that the patient has the right as a rule to withdraw his consent at any time and without
giving reasons.

128.
24 So ist dies zumindest den Ergebnissen von TP0 zu entnehmen.
25 Gleichwohl wird der Blutspende im Wesentlichen der rechtliche Charakter einer Schenkung zugesprochen.
Further the donor sometimes has the option to have his samples destroyed.\textsuperscript{26} In other cases, the declaration of consent does not deal with this point except that the general withdrawal of consent is permitted. The question of transferral of ownership rights of body materials or further use of already collected body materials after withdrawal of consent – even in the case that the destruction of the samples is not requested – is not even mentioned.

**b) Transferral of ownership**

It is controversial whether under these circumstances the ownership of body materials collected has been transferred to the research institute or the researcher. In that case, the research institute would have had to have acquired the ownership by means of a legal transaction or by law.

**aa) Express declaration about transferral of ownership**

If an express declaration is available that the ownership of the body materials is to transfer, the legal situation is simple. As already explained, this is –although recommended\textsuperscript{27} –usually not the case.

The declaration of consent as such is definitely not sufficient since a declaration of consent is not declaration of intent.

**bb) Conclusive declaration about transferral of ownership**

It is controversial whether one may assume under the given circumstances that the donor makes a conclusive offer transferral of ownership regarding the body materials collected from him. One could consider the fact a conclusive declaration that the donor made his body materials available for use including consumption.

The assumption of a conclusive offer for ownership transferral is opposed by the fact that the donor is given an unlimited right to withdraw and the right for return and destruction of the sample. Thus, the donor is given considerable options of influence on the body materials – in particular rights which are usually the rights of owners. Under these circumstances, the opinion here is that one cannot assume the donor or the contracting parties to be dealing with a legal transferral of ownership of the collected body materials or that it was intended.

\textsuperscript{26} So ausdrücklich in der Patienteninformation und Einwilligungserklärung zum Kompetenznetz HIV/AIDS.

The point that the donor is given the right to withdraw his consent up to the collection of body materials is stipulated by law. Further stipulated is that the donor may request to have all person-related data deleted for the purpose of maintaining his personality right or may withdraw his consent regarding this point.

With regard to "the object" body materials, the right to request return or destruction is not understandable. In any case, the opposite assumption harbours considerable risks for the mentioned reasons, since an express declaration is usually not available.

**dd) Conclusion**

All this goes to show that an ownership transferral usually is excluded unless an agreement was made expressly about the ownership transferral between research institute and the donor. A conclusive or silent transferral of ownership applies according to this opinion only if the donor was not given the right to request return or destruction of the collected body materials. The option for a withdrawal of consent to the collection or the right to demand anonymity do not oppose the assumption of a conclusive transferral of ownership.

**4.5 Summary**

Considered owner of collected body materials as per § 953 BGB is the person from whom the body materials were taken. This applies also if the body materials were taken within the scope of a contract for treatment and remain after the end of the treatment/diagnosis. Should an express declaration of the patient be available to the effect that the body materials is to transfer to the clinic/doctor, a transferral of ownership is possible. A conclusive ownership transferral does not take place.

If the collection of body materials is done outside of a contract for treatment and alone for research purposes, the ownership rights of the body materials transfer to the BB, if an express or conclusive agreement about the transferral of ownership or an express or conclusive waiver of ownership is available. However, if the declaration of consent or the patient information contain a passage allowing the donor to request destruction or return of the body materials, one may not assume an express nor a conclusive transferral of ownership or waiver thereof.

The body materials which were collected from a donor for research purposes only with his consent, usually do not transfer to the collecting research institute. The donor remains owner of the collected body materials.
The research institute acquires a right for utilization similar to usufruct which includes even consumption. With regard to utilization, questions pertaining to data protection as well as the personality rights in question shall not be covered at this time since they are not relevant for the question who the owner is of the collected bio materials.

5. Who is the owner of a Biobank?
Considered owner is the natural or legal person who has the ownership rights of a biobank. This person is the operator of a BB.

5.1 Biobank as object entity
We need to note the following particularity with biobanks: "Biobanks are collections of samples of human body materials... which are or may be linked to person-related data and information about the donors". This makes a biobank a connection for several independent objects which, therefore, are to be seen as a class or entirety in itself on the one hand, and which need to be considered to be a systematic collection of data which may qualify as a databank in the sense of copyright law (UrhG).
Object classes are also legal objects. Although they are gathered under the same term in legal matters, they are not objects capable of doing business. Their value and their functionality are determined by their completeness and functional connection. Objects of disposals may only be individual objects.
If we assume – as before – that the ownership of body materials does not usually transfer to the collecting institute, then this means that the carrier of the biobank, i.e. the doctor, the clinic or a research institute, is the owner of the necessary operating means for the biobank (storage means, examination means etc.), however, he is not the owner of the body materials. With regard to these, he only has the right to utilization.
Person related data only have a classificational function. Data are no objects and, thus, not ownable. Only if the data of a biobank achieve the quality of databank, there may be an exclusive right to utilization in favour of the biobank as per § 87 UrhG (copyright law).

5.2 Summary

28 Begriffsbestimmung des Nationalen Ethikrates in Stellungnahme „Biobanken für die Forschung“ v. 17.03.2004, S. 11
Owner of the BB on principle is its operator who should be recognizable from outside (in particular by all contracting parties). The following distinctions need to be made:
a) Owner of the biobank being a storage facility for samples is he who installed this storage facility. Thus, it is the carrier or company.
b) Owner of the contents of the biobank, i.e. the materials, may be
   - the donor/patient if no express or unambiguous transferral of ownership ha taken place,
   - a cooperation partner who placed the material at disposal (doctor, another biobank, etc.), provided he is in fact the owner of the materials (see above) or
   - the operator of the biobank if an express or unambiguous transferral of ownership has taken place.
This must be defined quite exactly.
c) There exist no ownership right of person-related data of a biobank since they are no objects. The biobank, however, does have the right of disposal based on the consent of the donor/patient within the scope of the data protection laws. Should the data collection of a bank for body materials achieve the legal quality of a databank in the sense of § 87 a I UrhG (systematic, methodical order of data using electronic means), an exclusive right of utilization is given to him who carried the costs (investments) for setting up the databank (comp.. § 87 a II UrhG).

6. May the sample's ownership rights of the donor be given or transferred to third parties?
According to § 903 BGB the owner of an object may do with it as he pleases, provided the law or rights of third parties are not infringed. Transferral of ownership according to § 929 ff. BGB is one of the rights the owner has. Therefore, a biobank may on principle transfer ownership rights of a sample as per § 903, 929 BGB (agreement and transferral) to a third party without problems, if the transferring BB has the ownership rights of the sample.²⁹
It is controversial whether the transferral of ownership infringes upon the law or rights of third parties.
With regard to samples, this may be possible since two peculiarities need to be observed. First, we need to note that together with the samples for the biobank usually person-related data are gathered. Often, the sample itself has a person's name or is

²⁹ Also in dem Fall, dass abweichend von der hier vertretenen Auffassung nicht nur ein Nießbrauch vorliegt, sondern ausdrücklich ein Eigentumsübergang vereinbart worden ist.
related to a particular person. In addition, information was or is to be gathered from the sample. As mentioned before, data protection regulations, in particular the pertinent federal or state data protection regulation, must be observed as far as they apply. The data protection regulations are laws which may be infringed in the sense of § 903 BGB.

Further we must note that the BGH and the leading opinion assume that the object ownership of separated body materials is superimposed or covered by the general personality rights of the donor and the more so the more conclusions one may draw as to the person of the donor.\(^{30}\)

In recent literature, this general personality right is defined in more detail as being a right to bio-ethic or bio-material self-determination, as compared with the right to a self-image or the right to informal self definition.\(^{31}\)

In which manner one describes it in more detail, the general personality right of the donor on principle is a law of a third party to be infringed. Since the general personality right as such may not be waived, one may not assume that consent is a complete waiver.

In this context the question arises whether in a transferral of ownership one needs to distinguish between entirely anonymous, only factual anonymous, pseudo-anonymous samples or those where the person-related information may not be reduced.

**6.1. Data protection infringement**

In research with human body substances, person-related data are collected, processed and used. Therefore, data protection regulations apply on principle. These regulations are stipulated in the federal data protection laws (BDSG), in the particular state data protection laws and in various special regulations such as the law for doctors, the cancer registry law etc. (Arztrecht, KrebsRegisterGesetz). Since the specific state data protection laws include mainly the same basic principles and regulations as the BDSG/federal law, we shall refer mainly to the federal regulations in the following. For the question whether data protection regulations apply, we need to distinguish between the tissue sample as such and the data gathered from it.

**6.2 Tissue sample**


With regard to tissue samples, we are dealing on principle with non-person related data (§ 3 Abs. 1).\textsuperscript{32}

\textbf{a) Anonymous sample}

If the tissue samples are completely anonymous, i.e. the reference sample does not show a person's name either, data protection regulations do not apply.\textsuperscript{33} If one represents the opinion that tissue samples must be considered data carriers from which genetic and other medically individualized information may be deduced, this does not oppose this opinion. Some of these genetic and other medically individualized findings are person-related data, but only until or as long as the sample itself has not yet been anonymized.

In objection it is argued that an absolute and secure anonymization may hardly be achieved. By means of an identified reference tissue sample or results from other genome analyses a tissue could be related again to a particular person or to a family related person, even if otherwise no information is known about the respective person. The first version of objection requires that the sample itself is personalized. Should that not be the case, relating it to a particular person does not happen.

It is correct that results from other genome analyses in theory allow for classifying the sample. However, this is considered at present to be too much of an effort so that we may assume that a relationship to a person is not possible as per § 3 Abs. 6 BDSG.

In Germany, we understand a purely factual anonymization when we speak about "anonymization". Therefore, § 3 Abs. 6 BDSG shows a definition by law of an anonymization: Anonymizing means changing person-related data such that individual information about personal or material relationships may not or only with unproportionately large efforts of time, cost and labour be linked to a determined or determinable natural person.

Samples which are only factually anonymized do not usually allow as per this definition – at least for the time being– conclusion as to the donor.\textsuperscript{34} Therefore, it is highly improbable that the data protection rights of the donor are violated.\textsuperscript{35}

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\textsuperscript{32} Halász, S. 263; Breyer, S. 660.
\textsuperscript{33} Breyer, S. 660.
\textsuperscript{34} Vgl. hierzu auch Wellbrock, Datenschutzrechtliche Aspekte des Aufbaus von Biobanken, in: MedR 2003, S. 78.
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With regard to the option of transferral of ownership to a third party this means that a sample which was anonymized as per § 3 Abs. 6 BDSG, i.e. which cannot be personalized in any way, may have its ownership rights transferred to a third party at any time and without limitations from a data protection point of view.

**b) Person-related sample**

Should the sample be labeled for the purposes of identifying it with personal data of the donor, a personal reference is given as per § 3 Abs. 9 BDSG. Since the tissue sample is considered a carrier of highly sensitive information, the personalized sample must fully comply with data-protection regulations as do the person-related data gathered from the sample. Thus, the following applies:

On principle, collecting person-related data is only permissible if it is permitted by a legal stipulation (f.ex. KrebRegG /CancerRegistryLaw) or by a consent given by the person in question.

Person-related data generally must be deleted according to §§ 20 Abs. 2, 35 Abs. 2 BDSG if their storage is not permissible or if their information is not/not any longer required by the data processing office. An unpermissible storage is given if the purpose requiring the information had been achieved.

Within the scope of medical treatment or diagnosis measures this point in time is the end of the medical measures,- unless there is an obligation for maintenance. With research projects this point in time would be the end of the research project. Even if a consent of the donor was given as per § 4a BDSG, this consent is usually limited to a particular research project, thus the person-related data must be deleted according to the same principles.

Data collected for research purposes are bound completely to this purpose. They must not be used for other purposes than research according to § 40 Abs. 1 BDSG. Under certain circumstances, further processing may be permissible for another than the original research purpose. However, this requires either a new consent of the donor or a positive answer when weighing the interests of research against the protection of the personality. Here, we are faced with a high level of preconditions.

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36 Breyer, S.660.
37 Breyer, S.660.
38 Breyer, S. 660.
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42 Deutsch / Spickhoff, Rdnr.194 m.w.Nw.; LG Köln, NJW 1995, 1621.
Further must be observed to anonymize data, but as a minimum to pseudomize them as per § 40 BSG as soon as the research purpose permits this. Pseudomizing is permitted only if anonymizing is not possible. Handing over person-related data constitutes a form of transmittal in the sense of § 3 Abs. 4 Nr. 3 BDSG. Corresponding regulations are found in state data protection laws.

6.3. Opposing rights of the donor

a) Anonymized sample

Should a sample be completely, or at least factually anonymized, it appears impossible at first sight that general personality rights of the donor be infringed. Since the general personality right is expressed in particular by the right to informal self-determination, an infringement in the case of anonymization is not possible.

However, recent literature represents the opinion that without exception even in cases of anonymization a consent must be given, independent of the data-protection question.\(^{43}\) This means that whenever a donor has not consented to a particular form of use and utilization, the same is not permissible.\(^{44}\) Should the donor for example in the declaration of consent be given the right to request return or destruction of his sample without indication of reasons, an anonymization is not permissible, thus also passing on the anonymous sample is not permissible. If the sample were to be anonymized in order to pass it on to a third party, the will of the donor could not be met.

Even if the donor gives his express consent to the utilization of his body materials for particular research goals, a transmission of ownership to a third party is not permissible if the third party has deviating research goals or purposes or even aims at commercial purposes.\(^{45}\) The same applies if the donor expressly stipulates in his declaration of consent that a passing on of his materials is not permissible or only permissible to a particular recipient. In all of these cases, the "right of personal body self-determination" (Recht auf personal-leibliche Selbstverfügung) would be infringed.\(^{46}\) A transferral of ownership to third parties with good intentions will be possible, thus leaving the donor at best a right to damages. There may be a case of penal offence on the part of the acting or responsible party. Therefore, the declaration of consent should include a passage indicating that a right to return or destruction of completely or factually anonymized samples does not exist. Further, the consent to the passing on of

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\(^{43}\) Freier, in: MedR S. 324 m.w.Nw.

\(^{44}\) Deutsch / Spickhoff, RdNr 613 m.w.Nw.

anonymized samples to third parties should be included – independent of the person or research purpose of the third party

b) Pseudomized samples
Pseudomized samples are stored under pseudonym or assumed name, thus, at first are not linkable to an identifiable person by the recipient. Transferral of ownership of these samples to a third party appears to be possible on principle. However, since the donor may still be identified, the risk of having his data protection rights infringe upon remains. With regard to pseudomized samples, person-related data are processed. Any passing on of pseudomized samples to third parties, therefore, may be done only under observation of the known data protection regulations. Moreover, in dealing with samples which are only pseudomized, the general personality right of the donor, in particular his right to informal self-determination is effected.

The transferral of ownership of only pseudomized samples is, therefore, only permissible under observation of the respective data protection regulations, and usually only if the donor has given his consent to the transferral of ownership of his pseudomized sample. This means that samples which were received due to a dereliction on the part of the donor (if this is even possible based on the above explanations), may usually be passed on only in an anonymized version. The reason is that personality rights may absolutely not be given up or abandoned by way of dereliction. In this respect, there must always be an express declaration of the donor. Therefore, the data protection law and the general personality right of the donor, which superimposes the object ownership of the sample, do limit the absolute right of disposition of the biobank as the sample owner.

c) Samples which may not be reduced in their person-relationship
Samples which may not be reduced in their person-relationship on principle may only be transmitted to third parties with the express consent of the donor and under observation of the relevant data protection regulations. This far the above applies.

6.4 Summary (transferral of ownership
According to this opinion, ownership of samples owned by a biobank may be transferred to third parties for certain if the samples have first been anonymized in
the sense of the BDSG, i.e. have been factually anonymized, and if an express and opposing intention of the donor – which may be seen also in the declaration of intent – is not notable.
Thus, a transferral of ownership of samples which have not been reduced in their person-relationship or have only been pseudomized is permissible only under observation of the relevant data protection regulations and only with the consent of the donor.

6.5. Transferral of utilization rights
In light of the opinion represented here to the fact that no transferral of ownership takes place, the question arises whether the biobank is permitted to transfer the right of utilization to third parties. If we assume usufruct, we find first of all that as per § 1059 S. 1 BGB an usufruct as such may not be transferred. According to § 1059 S. 2 BGB the practical application of usufruct may be left to a third party.
The bio materials bank may transfer the utilization rights to a third party (other biobanks for example), provided and only as far it has the utilization rights itself and has the permission to transfer such rights to third parties. The permission for transferral of utilization rights may be given in the declaration of intent. For reasons of legal clearness, the phrasing should be included that the donor transfers to the biobank all known utilization rights. It is recommended to include a very detailed listing of all commercial and non-commercial types of use.

7. What are the circumstances allowing a donor to request the return or the destruction of his sample?
7.1 Contract for treatment and diagnosis
As discussed above, after termination of contract (or after early termination) the donor may request the return or destruction of the collected samples provided that the body materials have been collected within the scope of a contract for treatment or diagnosis with a doctor.
A limitation arises only if the doctor or the clinic is obligated to destroy the sample for other reasons (for example a contaminated sample).

7.2 Contractual agreement
The contractual basis for the rights of the biobank may be either a donation contract or usufruct, if a transferral of ownership was not planned.

If the ownership of the sample moves to the biobank, it has an unlimited right to utilization. A legal recall right usually does not apply here (the collection of the body materials will hardly lead to poverty of the donor).

Only if the obligational contract (schuldrechtlicher Vertrag) must be retro-acted upon due to a right of withdrawal or valid contesting by the donor, the donor may request the return of his body materials in the course of this retro-action. If the donor— as provided for in the declarations of intent discussed here – was permitted by the collecting agency that he "…may request at any time the return or destruction of the sample …", then we are dealing with a contractual right of return or destruction.

7.3 Abuse

In the case of abuse of the sample, the rights thereto having been legally and with intent/willingly transferred to the biobank, the donor may file a claim for cease and desist as per §§ 823, 1004 BGB. This claim to cease and desist may even be converted to a claim for destruction or return, if the abuse may not be prevented by other means.

6.4 Change of purpose

As shown above, the principle of earmarking a purpose applies also to the area of research. Thus, if the purpose of a research project permits or if the project is finished, the donor will have the right to request the destruction of the sample.

6.5 Real claims

If the owner lost the sample, the ownership herein did not necessarily transfer to a third party. A bona fide purchase will not be possible. In this case, the donor may request return of the sample according to § 985 BGB.

7. What are the consequences for the already stored data and research results?

7.1 Return request for samples so far used properly

Should the request of the donor to destroy the sample apply only for the future, there will be no effect on the already stored data and research results. The evaluation and processing executed up to the date of the recall was legally proper. However, this will
usually entail the obligation of the research institute to anonymize the person-related data as far as possible.

7.2 Return request for samples illegally processed
7.3 Person-related data
Should person-related data be gained from a sample, these must be deleted at the request of the donor. No data may be stored against the will of the donor. This is already stipulated as per the BDSG. This applies even more so if the data have been collected unlawfully.

7.4 Research results
Should the research results have commercial value, the donor may have a claim to gain from the point of view of unjustified enrichment.
The research results themselves may not be requested to be handed over. One may have to consider the claim of the donor for preventing publication of the research results.

8. What is the role of anonymization with regard to the right of return or destruction?
If a sample is completely or even only factually anonymized in the sense of § 3 Abs. 6 BDSG, a return or destruction of the sample is impossible. This applies also in case of a factual anonymization, because the effort for identification would be so high as to make it unreasonable for a biobank to make this effort. Since a link from the sample to a person is not given any longer, the rights of the donor are hardly touched by it. Therefore, the donor may at best make a claim for damages. Differing from the sperm case decision by the BGH, the donor will not have a claim for compensation for personal suffering. Since the sample is separated for good from the body and was not intended to be reunited with it, any personality rightful link is missing.

9. Under which circumstances may anonymize samples be transferred to third parties?
Anonymized samples may be transferred to third parties at any time, provided the donor has not explicitly forbidden it or provided the donor has not expressly been given the right to request return or destruction of the sample at any time.
10. What are the consequences for claiming a possible right to return or destruction of samples already transferred?

10.1. Consequences as to ownership
In the case of an anonymized transferral of the sample there are no consequences as to ownership since the sample cannot be identified any longer.
If the ownership of the sample has been transferred, the question arises whether the third party has acquired the ownership in good faith. If that is the case, the donor may request its return.

10.2. Consequences as to data protection
In this case, the donor may request deletion of the data relating to himself.

11. Do ownership and recall rights depend on whether a sample was collected in connection with some treatment or for research purposes?
This question was already answered above. The donor has the ownership of a sample gathered in connection with treatment. It may not be used for research purposes without a new consent by the donor/patient.
If the patient agrees to have his materials used for research purposes after proper information, the same applies as if the sample had been originally collected for research purposes. In this respect, the above comments apply.

12. What are the consequences as to ownership upon the death of a donor/patient?
Should a patient/donor die, the heirs receive the right to dispose of the body and former body materials of the deceased ad lib within the scope of legal regulations and under observation of the personality rights of the deceased lasting beyond his death. This usually results in a "disposal" of the body by means of cremation or burial. Should the body be wanted for medical research, the consent of the next of kin is required who have observe the supposed or actual will of the deceased. The ownership of the samples does not automatically get transferred.

13. Do ownership rights entail rights to the utilization of a BB or to research results produced by its means?
The question aims at finding whether monetary advantages resulting from the utilization of research results may be claimed by the donor or the BB. This question
has caused great interest worldwide since the court case John More vs. Regents of University of California et al.\textsuperscript{47}.

\section*{13.1. Civil Code Claims}

Should a doctor receive more than a small remuneration for his efforts when transferring the sample, one will generally assume that this must be reprimanded as unpermitted commercialization.\textsuperscript{48}. Whether and to what degree this applies to a biobank remains a question, because in this case the specific ethics of doctors do not apply in that manner. However, this may interfere with principle of research freedom connected with non-profit research which should not be confused with the freedom to make profit.

According to Taupitz, contractual concerns of the patient he is entitled to may be affected by a commercial utilization "...if the body materials of the patient are of extraordinary high value, because they may be of a particularly rare type."\textsuperscript{49}. This might make it necessary to consider claims for damages or even compensation for personal suffering. The amounts payable would be low, because they would be set according to the level of effort compensation which is paid for the collection of body materials.

With regard to a participation in the gain from utilization of the sample we should state "that a marketable product is based mostly on the substantial contribution made by participating doctors and research institutes. Thus, the contribution by the materials' donor to the marketable product is usually quite low."\textsuperscript{50}.

\section*{13.2. Claims to patent rights}

One might consider the case of a missing consent prior to the collection of the sample. In such a case, no patent rights may be granted as per § 2 Nr. 1 Patent Law (PatG) if the publication or utilization of the invention would offend public order or is against good manners. In literature, we find this opinion also to apply to achieving the invention in the first place, thus considering the manner of collecting the sample as a severe breach of law.\textsuperscript{51}

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\textsuperscript{47} Supreme Court of California, 51 Cal. 3 d 120, 793 P.2 d 479, 271 Cal. Rptr. 146, July 9, 1990.
\textsuperscript{49} Taupitz, in: ACP 191 (191), 201 (217).
\textsuperscript{50} Spranger, ebenda.
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However, if the donor has given his consent to collecting and processing the sample, he may make any further claims.

Summary and Recommendation

1. Body materials taken from a living person remains usually to be the property of that person according to this opinion. Only if a clear, preferably written declaration of the donor/patient is available showing that he transfers the ownership of the materials to the collecting party (doctor, clinic, BB etc.), a lawful transferral of ownership has in fact taken place.

Even though literature shows a stron opinion that the ownership of the materials transfers on the basis of a conclusive declaration of intent, one may not exclude the possibility that a court of law will not follow this opinion. In order to exclude the risk of punishability or of code of law claims for damages, it is recommendable to include a passage both in the patient information as well as the declarations of intent to the effect that the ownership of the body materials transfers to the collecting party.

As an alternative, the explicit – though limited – usufruct of the body materials may be agreed upon. This may actually be preferable under certain circumstances. This may be the case in particular if the donor/patient is to be granted the right to request the return or destruction of the body materials at any time.

In case of an old sample which was collected during a contract for treatment for the purpose of making a diagnosis or was collected as a "by- or waste product" during treatment, the obligation for the disposal of the body materials is given unless as an exception it is necessary to store the sample for medical-therapeutic reasons. Doing research with these body materials is usually not permitted without prior consent of the donor. Therefore, old samples should not be used for research purposes. One aspect has not been cleared to satisfaction whether a complete anonymization is to be set equal to a destruction, thus allowing research thereafter.

2. Even after the ownership of the body materials has been transferred to the BB, the personality rights of the donor/patient superimpose the ownership rights. Therefore, the BB may not do with the body materials in an unlimited manner. In particular, the general personality rights and the data protections law limit the rights derived from the ownership of the body materials.

A mostly free disposal of the body materials is usually only possible if the sample has been absolute or at factually anonymized.
3. Provided the biobank is the owner of the body materials, it may pass it on to third parties under observation of the rights of the donor and of the data protection stipulations. Therefore, an unlimited passing on to third parties is only possible, if the body materials do not show any further person relationship, i.e. have been anonymized. In this case, a protective conveyance is possible. Passing on pseudomized or body material not at all reduced in it person-relationship is permissible only with the consent of the patient/donor. If the donor objected to the passing on of his body materials, even an anonymized transferral may be prohibited. It is certainly recommendable to include a regulation in the declaration of intent allowing the BB to pass on body materials – at least once it is anonymized.

4. As a precaution, the declaration of intent should include a passage allowing the BB to anonymize body materials at any time. At the same time, the patient information must note that if that were the case, the patient/donor may not make a claim for return or destruction of the materials since it would be impossible after anonymization.

5. The donor/patient, on principle, may not waive his general personality rights. At best, he may consent to interventions in his general personality rights after having been completely and fully informed. Therefore, the information and declaration of consent of the patient play a central role.

6. The donor usually does not have the right to make claims of any kind as to research results, if he has transferred the ownership of his body materials to the BB and has consented properly to research being done thereon. This applies particularly for commercial utilizations. The patient must be informed in this respect by means of the patient information brochure. The declaration of intent should include correspondingly a passage to the effect that the donor agrees to the BB using the research results commercially at their own risk and for their own benefit.