TMF Project
Legal basis of EU-wide biobanking cooperation
(BMB-EUCOOP, V010-02)

Mustertexte - ***Englisch***
Generic texts – ***English***

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1. Patient information

Dear patient/proband,

As the doctor who will be treating you, within the scope of your treatment/your participation in the study ..... *(description of project in which the person addressed takes part as a proband, with the supplementary sentence "This project has been ethically evaluated and approved by the responsible ethics commission")* I shall be removing human samples. This will entail ...

(specification of the sample material). Such samples can be of great value for clinical research. In so far as the persons whom I shall be treating give their consent for this procedure, I shall make human samples taken from the context of treatment available to the ... *(description and address of the biobank).* This institution, in the following referred to as the "biobank", will observe professional expertise in the investigation of these human samples and document the related medical data. The institution will thus pursue the purpose of making both the samples and the related data available to interested institutions and scientists engaged in research both in this country and abroad.

The biobank does not pursue the purpose of financial gains. The biobank therefore requests only the reimbursement of expenses incurred for the release of sample material and data to third parties sufficient to cover the running operating costs for this function, but not intended to produce a profit.

In the following text I would like to familiarise you with further details of my co-operation with the biobank. Should you find anything unclear or if you would like to know more about this co-operation, please do not hesitate to send me your questions. Should such questions arise at a later point in time, you can also feel free to contact me or the biobank.

- Description of the biobank as an organisation
- Description of the research purposes which the provision of the human samples and the related data will serve
- Categorisation of the recorded and processed personal data for the proband
- Description of the user group able to receive sample material and data from the biobank; emphasis of the international character; countries/country groups
- Elaboration of the prerequisites for furnishing sample material and data to this group of users and to contractors
- Alternatives for donating anonymised or pseudonymised sample material (see also nos. 32 and 35 of the commented check list, TMF series, volume 3)
- Criteria for the examination of prerequisites for donors
- Duration for the investigation of human samples and storage of the related data
- Naming of a contact person at the biobank for data protection matters (see also no. 31 of the commented check list, TMF series, volume 3)
- Possible reference to third parties having the legally founded right to make use of the sample material (see no. 37 of the above check list).

Your data will of course be treated confidentially if made available for uses going beyond the user group and purposes described.

You can freely decide whether to allow me to make the human samples taken available to the biobank to keep and use for the purposes described above. The same applies for your relevant personal data. No costs will arise as a result of this. Should you decide in favour of the biobank making use of your samples and data, this will be done only on the basis of your express declaration of approval. You shall give this to me; it will then be kept together with your medical record. If you do not wish to approve this, no disadvantages will ensue in respect of your further treatment.

You can revoke your declaration of consent in writing through me or the biobank at any time without giving reasons. No disadvantages will result for you.

Your declaration of approval applies to the samples taken from your body and your relevant personal data. In order to furnish a secure legal basis for me to pass your sample material on to the biobank and their release for research purposes, with your declaration of approval you transfer the ownership of these human samples to me. The reason for this is that, without this transfer of ownership, extremely complicated legal precautions must be taken for the case that you revoke your approval.

Remark: If no transfer of ownership is to take place, but only rights of use are to be granted, this section must be modified!

Nevertheless, the subsequent revoking of approval does not mean that the process ends here: from this point in time, the samples taken from your body are anonymised and knowledge gained with the aid of this sample material can no longer be related to you from this time on. Alternatively, at your request the samples can also be destroyed.

In respect of your personal data, you can contact me or the biobank at any time if you wish to be informed about which data about you have been stored. Should you determine that errors have occurred, you can demand that these be corrected. Should you revoke your declaration of approval, the data will be blocked for further use from this time on.

Should you approve the use of the samples taken from your body and personal data, at the same time you can freely decide whether you wish to be informed if research groups have obtained new medical knowledge of relevance or possible of relevance for your health with the help of these human samples. Should you decide in favour of such information, this will then be made known by me or the biobank as soon as such knowledge is made known there.

In order to be able to contact you in this case, your address data will be stored at the biobank. With the release of results, I shall send you a written invitation to inform you of the results, answer questions that you may have, and discuss the procedure to be followed in future with you. I would like to make you aware that the results may be disclosed to insurance companies at their request, provided that you release me from my professional obligation to maintain secrecy. Furthermore, the results of the study may also furnish information of importance for your relatives.

Should you decide to waive the information about new medical knowledge of relevance for you, this will of course not take place.

Since the investigation of the samples taken from your body and your relevant personal data is fundamentally intended for an indefinite time, it can not be excluded that the objectives of the biobank and/or the research purposes for which your samples and data could be utilised dramatically change. As soon as this is the case, the responsible ethics commission will decide whether your samples and data may be used further for these purposes as well.

Remark: Certain objections have been raised to the inclusion of the ethics commission in this process (due to lack of authority). For this case, the following alternative formulation is proposed:

As soon as this is the case, the biobank will inform you accordingly. The biobank will then inform you about the changed functions and purposes and give you the opportunity to renew your approval in respect of the changes or to revoke your approval.

2. Declaration of consent

of the patient / proband
.....

Address

.....

on behalf of .....
(biobank)

in the presence of the doctor signing below.....

Address:

.....

- in the following: doctor -

concerning the investigation of human samples and the collection and processing of personal data for research purposes

I have been sufficiently informed by the doctor about the basic structure, the purposes and the fundamentally unlimited duration for the investigation of my human samples and the storage of my relevant personal data. In particular, he has informed me in respect of who, and under what prerequisites, can make use of or access my human samples and personal data. I am also aware that ... (biobank) is, along with the doctor, my contact for all matters concerning data protection. My rights in regard to data protection have been explained to me.

The doctor has informed me that I can freely decide whether the human samples taken from my body be investigated for research purposes and my personal data stored and made accessible to others. Moreover, he has made clear that I can revoke my approval in writing at any time through him or ... (biobank) without giving any reasons, without any disadvantages whatever. My revocation also applies to partners in co-operation with the biobank. I am aware that such revocation applies only for future investigations.

In the case of revocation, I would like to have my sample material anonymised. I am aware that, from this time on, any knowledge gained with the aid of this sample material can no longer be attributed to me.

My personal data will be deleted from the time of revocation.

It is my wish that the biobank be the legal owner of the human samples taken from my body. I hereby waive all recourse, for whatever legal reasons, to revoke this right. In the case of revoking my declaration of consent, the samples taken will be anonymised.

Remark: If only rights of use are to be granted, this section must be modified!

For a fundamental change of the research purpose described in the patient information sheet constituting the basis for this approval

- the responsible ethics commission may decide whether my sample material and data may be used further for these purposes
- I shall be informed by the doctor or the biobank and have the opportunity to give my consent again or to revoke my consent.

Should medical knowledge of relevance for maintaining or restoring my health be obtained based on the human samples taken from my body, I would like to be informed about this knowledge.

- yes ☐ - no ☐

I have understood the detailed information in the patient information constituting the basis for this declaration of approval. My questions have been answered completely and to my satisfaction.

I have received a copy of the patient information sheet and a copy of the declaration of consent.

- **Declaration for persons of full legal age**

  I herewith declare my consent

  that human samples taken from my body and data concerning my person, as well as medical data obtained from this sample material, may be utilised for the purposes described in the above-mentioned patient information sheet for keeping and storing, respectively, over a period of unlimited duration and made available to the group of users described therein for use and access, respectively. I hereby transfer the ownership of this sample material without right of revocation to ... (biobank).

  ....
  Place, date Signature of patient/proband

- **Supplementary declaration for persons below full legal age**

  The person described is still below full legal age. The above explanations and information were presented in the presence of his/her parent or guardian. Explanations were given in accordance with the level of comprehension of the patient/proband.

  ....
  Place, date Signature of patient/proband

  .....
  Signature of parent/guardian

- **Supplementary declaration for persons under care**

  The patient/proband described is under my care, i.e. under the care of .....

  (*enter name and address of the person caring for the patient/proband).* As proof, I herewith enclose a copy of the ..... *(power of attorney, appointment as legal representative for health care, advance directive or court order)* of ..... *(date)* together with this declaration.

  The above-mentioned explanations and information were presented to me

  ☐ in the presence of the patient/proband.

  I hereby submit the declaration of consent as his/her representative.

.....	.....
Place, date	Signature of person caring for the patient/proband
.....	.....
Place, date	Signature of doctor

3. Co-operation agreement

- in the following: agreement -

between

the biomaterial bank .....,

represented by ..... (managing director, head, etc.)

..... (address)

- in the following: BMB -

and

the biomaterial bank .....,

... (description of the co-operation partner),

represented by ..... (managing director, head, etc.)

..... (address)

- in the following: co-operation partner -

concerning the supply of human sample material and related data

Preamble

(1) **....** ***(Description of German BMB activities)***

(2) **....** ***(Description of foreign BMB activities)***

§ 1 Object of the agreement

(1) The object of this agreement concerns the samples under the ownership of the BMB in accordance with Annex 1 to this agreement.

Remark: Annex 1 must describe the samples in detail, i.e. the sample type, number of samples, specific characteristics of the samples, sample storage, related data, etc. This information is given in a separate annex, as this obviates the need to change the text of the agreement in each individual case.

(2) The BMB shall supply the samples described in Annex 1 at the request of the co-operation partner in the following form:

- anonymised
- pseudonymised
- person-related

(3) The delivery shall enable the co-operation partner to make the samples described in Annex 1 available to third parties in his own country within the scope of the intended research purposes permitted.

(4) Annex 2 to this agreement gives a binding definition of the intended purposes for passing on the delivery as permitted in accordance with Paragraph 3.

Remark: The research purposes pursued with the samples constituting the object of this agreement must be described in detail as an annex.

§ 2 Transfer of ownership, retention of ownership

(1) The parties are agreed that the ownership of the object of this agreement shall be transferred to the co-operation partner.

(2) The BMB, however, shall retain ownership of the object of this agreement until remunerated in full in accordance with § 5 of this agreement.

Alternative:

§ 2 Transfer of ownership, retention of ownership

(1) The parties are agreed that the co-operation partner shall be accorded only the rights of use of the samples as required in order to fulfil the purposes agreed.

(2) The ownership by the BMB of the object of this agreement in accordance with § 1, Paragraph 1, shall remain unaffected.

§ 3 Assurance of legal propriety on the part of the BMB

(1) The BMB has convinced its suppliers that the taking of all human samples constituting the object of this agreement has been performed only following comprehensive explanations on the part of the doctor and printed information given to the proband and furthermore on the basis of the written consent of the proband.

Remark: In foreign countries, it is sometimes the case that express consent is required only for the use of identifiable human sample material. However, with coded or anonymised material it is sufficient to grant the donor the right of revocation. However, a declaration of consent for all sample types makes the process uniform and easier to oversee.

(2) The BMB attests that it is the legal owner of the samples referred to in § 1, Paragraph 1.

(3) The BMB furthermore attests that the object of the agreement, notwithstanding the exceptions elaborated in § 11, Paragraph 3, are free of the rights of third parties, in particular that there are no conflicting rights of the proband or other third parties in respect of the transfer of rights concerning the samples constituting the object of this agreement to the co-operation partner. The BMB offers this assurance in so far as such conflicting rights have up to now not been asserted.

§ 4 Quality assurance, standards

(1) The BMB attests that the samples its suppliers have properly handled these samples immediately following their removal professionally, in accordance with the quality directive "Removal, storage and transport of human sample material" in the version valid at the time of conclusion of this agreement. This means, in particular, that the samples have at no time, neither during processing nor during storage nor during transport, been exposed to free air longer than ... minutes with a temperature of greater than ... degrees Celsius. The BMB attests that, within its area of responsibility, the samples have also been handled in accordance with the provisions of the above-mentioned quality directive. The corresponding documentation and the quality directive referred to are appended to this agreement as Annex 3.

(2) The BMB attests that, within the area of responsibility of its suppliers, the samples have not been contaminated by any foreign substances either during or following their removal. The BMB also attests that, within its own area of responsibility, no contamination of the samples has occurred.

§ 5 Remuneration, proceeds

(1) The remuneration is in the amount of … EURO, plus the relevant legal value added tax. It is due with the signing of the agreement. The BMB shall invoice the co-operation partner with a corresponding request for payment.

Alternative for the provision of material without remuneration, e.g. for research purposes:

(1) The BMB shall transfer the object of the agreement in accordance with § 1, Paragraph 1 without remuneration to the co-operation partner. For the costs arising in connection with the acquisition and holding of the object of the agreement, the BMB shall receive compensation in the amount of … EURO. The BMB shall have no further claim to payment relating to the context of the object of the agreement. The regulations of Paragraph 2 remain unaffected.

Remark: Within the framework of co-operations, compensation in the form of a mutual supply with samples from the foreign BMB in the same amount or other forms of compensation might, for example, be conceivable.

(2) The shipping of the samples is the responsibility of the BMB, in so far as no other agreement has been reached with the co-operation partner. The costs of packaging are not included in the remuneration of Paragraph 1 and shall be invoiced separately to the co-operation partner, in so far as the partner has not made suitable transport containers available.

(3) The proceeds from the contract-compliant transfer of the object of the agreement to third parties are due solely the co-operation partner.

§ 6 Shipping, packaging, passing of risk

(1) The place of performance is the seat of the BMB. The loading and shipping of the samples take place in the absence of insurance at the cost and risk of the co-operation partner. Unless the co-operation partner expresses other wishes, shipping shall take place by a forwarder or carrier to be determined by the BMB. The BMB shall obligate the forwarder/carrier to undertake the transport in accordance with the provisions of the quality directive, as described in Annex 3 to this agreement and document compliance with the obligations described therein.

(2) The risk of accidental destruction, theft and accidental spoiling of the samples, when the samples to be shipped are given to the forwarder, carrier or other person named to carry out the shipping, is transferred with the turn-over to the co-operation partner.

(3) Should the shipping be delayed at the wish or due to the fault of the co-operation partner, the BMB shall store the object of the agreement at the cost and risk of the co-operation partner. In this case, the notice of readiness to ship is equivalent to shipping.

§ 7 Delivery and performance time, delay

(1) Delivery dates or time limits not expressly agreed as binding are not binding.

(2) For the case that the BMB is at fault in the matter of not meeting an expressly agreed time limit or falls behind schedule for other reasons, the co-operation partner shall grant a reasonable period of grace. Should the delivery still not be carried out after this time has elapsed, the co-operation partner shall be entitled to withdraw from the agreement.

(3) The remaining legal claims and rights of the co-operation partner in respect of delayed delivery remain unaffected.

(4) The BMB is entitled to undertake partial deliveries and partial performance, in so far as this can reasonably be expected of the co-operation partner.

§ 8 Responsibility for violations of obligations

(1) The co-operation partner is obligated to inspect the object of the agreement following delivery from the BMB without undue delay in respect of deviations in quality and amount, as well as inspect the materials for possible damage in transport, and notify the BMB of any such defects. Should the co-operation partner fail to notify the BMB, the object of the agreement delivered shall then be regarded as accepted, unless the deviations of quality and amount were not recognizable during the inspection. Should such a concealed defect emerge at a later point in time, it is the responsibility of the co-operation partner to immediately notify the BMB after its discovery. The object of the agreement shall otherwise also be regarded as accepted.

(2) Claims concerning defects shall not apply in cases of only insignificant deviations between the actual and the agreed quality or only insignificant restriction of use.

(3) The BMB is not obligated to rectify defects when the co-operation partner has not served notification punctually in writing.

(4) In so far as sample defects occur for which the BMB is at fault and the co-operation partner has served notification punctually in writing, the BMB is obligated to rectify the defect, unless the BMB is entitled to invoke legal regulations for refusal to rectify the defect. For each defect found, the co-operation partner shall set a reasonable time limit for the BMB to rectify the defect.

(5) The BMB shall be liable for damages in relation to the co-operation partner in so far as the damages are the result of intent or gross negligence on the part of the BMB, its employees, legal representatives or other vicarious agents. In other respects, the BMB is liable only for predictable damage caused by the violation of essential contractual obligations by the BMB. Liability for lost profits of the co-operation partner, unrealised savings for the co-operation partner, consequential damages, damages resulting from defects, and damages ensuing from the application environment made available by third parties is excluded. The BMB shall furthermore not be liable for damage due to force majeure. This includes, in particular, damage resulting from natural disasters, the effects of war, wage conflicts and other operational disturbances.

(6) The BMB is not obligated to guarantee the suitability of the object of the agreement for the purposes pursued by third parties in the sense of § 1, Paragraph 3.

(7) The above limitations of liability do not apply for the case of compulsory product liability, as well as injury to life, body or health.

(8) Quality defect claims of the co-operation partner shall be subject to a limitation period of 12 months from having received the object of the agreement. The legal time limits remain unaffected for a premeditated or grossly negligent violation of obligations by the BMB, as well as in cases of injury to life, body or health.

§ 9 Observance of national and international law

(1) The parties are obligated for the preparation and use of the object of the agreement to observe all relevant national and international regulations. For the BMB, this obligation concerns the relevant regulations in Germany for sample preparation; for the co-operation partner this obligation concerns the relevant regulations in Germany and the country of the co-operation partner for the use of the material constituting the object of the agreement, in particular in respect of passage to third parties.

(2) Directives, conventions, recommendations and similar sets of rules and regulations from supra-international and international institutions, relevant professional organisations and professional associations are also regulations in the sense of Paragraph 1, in so far as these are regarded as generally recognised.

(3) For the case that one party is guilty of violating the obligations of Paragraph 1 with resulting damages to the other party, the party at fault is liable to provide compensation for these damages in so far as this is not a matter of consequential or indirect damage.

(4) For the case that a third party acquires claims against the other party as a result of a violation in accordance with Paragraph 1, following taking of notice the party at fault shall release the other party without undue delay from all claims of the third party arising from this violation.

§ 10 Return of the samples

(1) In so far as a legitimate interest of the BMB exists, the cooperation partner is obligated at the request of the BMB to return samples named by the BMB transferred to the cooperation partner or made available for use to the cooperation partner by the BMB or to destroy these samples.

(2) A legitimate interest in the sense of Paragraph 1 exists when

- the co-operation partner violates obligations of this agreement repeatedly or seriously
- a proband can legally demand the return or destruction of his sample material from the BMB, in particular when the BMB is obligated by a court decision to return this material

(3) For the case of a dispute between the BMB and the co-operation partner in the matter of whether a legitimate interest in accordance with Paragraph 1 exists, the parties agree on a conciliation process before the national ethics commission *(Remark: This is only a specimen text!)*. The decision of the national ethics committee shall be binding for both parties.

(4) In so far as the return of the sample material is not the result of a violation of obligations on the part of the co-operation partner, the BMB shall compensate the co-operation partner for expenses incurred in connection with the return of the sample material as well as the remuneration paid. Any further claims, in particular damage claims, are not due the co-operation partner.

§ 11 Further use, passage to third parties, personal rights

(1) The co-operation partner is aware that the object of the agreement is intended solely for research purposes. The object of the agreement is not intended for the purpose of manufacturing medicines or substances.

(2) The passing of the object of the agreement or parts thereof to third parties by the co-operation partner is permitted in accordance with the purposes described in Annex 2 to this agreement. The BMB attests that no conflicting rights have been accorded a proband or another third party.

(3) The co-operation partner is obligated to observe the personal rights of the proband. In particular, he is obligated to observe the following rights guaranteed to the proband by the BMB:

- Disclosure to third parties for advertising purposes is not permitted.
- The use of the object of the agreement is limited to the research purposes described in Annex 2 to this agreement.
- The probands named (pseudonymsised) in Annex 4 to this agreement wish to be informed for the case that new medical knowledge of relevance for their health is obtained from the human samples removed from them. The cooperation partner is obligated to inform the BMB in writing about such knowledge without undue delay.

(4) The co-operation partner is obligated to inform the BMB in writing concerning all accesses of third parties, in particular of foreclosure measures as well as other injuries to its property. The co-operation partner is liable to the BMB for all damages and costs arising as a result of a violation of this obligation and measures of intervention required against access on the part of third parties.

§ 12 Form of agreements with third parties

The co-operation partner is obligated to include the rights of the BMB and its probands described above in all agreements with third parties concerning samples constituting the object of the present agreement, in particular deriving from the regulations of § 10 and § 11 of the present agreement, are not jeopardised and can be realised in relation to the third parties as well.

§ 13 Anonymisation, traceability

The co-operation partner is entitled to anonymise the samples, in so far as the proband has not retained the right to demand the destruction or return of their sample material or to be informed of medical knowledge gained of relevance for his or her health. These probands are named in Annex 4 and Annex 6 to this agreement. Should a proband exercise the right to have sample material returned or destroyed, the co-operation partner shall be obligated to turn over or destroy all samples from this proband at the request of the BMB in accordance with § 10. This does not apply in so far as the samples have already been anonymised.

§ 14 Data protection, anonymity

(1) The co-operation partner is obligated to observe the relevant data protection stipulations and principles of good scientific practice at all times while making use of the samples.

(2) Re-establishing or attempting to re-establish the connection to specific persons with anonymised or pseudonymised samples on the part of the co-operation partner is forbidden.

(3) The co-operation partner is obligated to protect the medical data entrusted to him by a suitable data protection concept. The separate data protection declaration in Annex 5 to this agreement defines this more exactly.

§ 15 Data protection/Confidentiality

(1) It is hereby drawn to the attention of the co-operation partner that personal data are stored and processed at the BMB to the extent necessary within the scope of the contractual relationship. With the exception of legal obligations, the disclosure of personal data to third parties may not take place.

(2) Both parties to the agreement are obligated to treat all documents, data inventories and information concerning the other party to the agreement as strictly confidential in so far as these have not already been disclosed publicly.

§ 16 Violations of the agreement, stipulated penalty

(1) Should the co-operation partner be guilty of violating any of the obligations deriving from the regulations of § 9 to § 13 of this agreement, for each violation of the agreement - excluding the objection of the continuation context - he shall be liable for a penalty in the amount of 10,000 Euros to the BMB.

(2) The BMB retains the right to separately claim damages attributable to the violation of the agreement in excess of this amount.

(3) Should the co-operation partner give the object of this agreement to a third party for purposes other than those defined in Annex 2 to this agreement, the BMB shall be entitled to terminate this agreement with immediate effect. All remaining claims of the BMB remain unaffected.

§ 17 Claims by the proband/third parties, release

(1) The co-operation partner releases the BMB from any claims by the proband or other third parties - in particular damages and compensation for pain and suffering - raised in connection with the use of the object of the agreement in accordance with the stipulations agreed or by non-compliance with the obligations of the co-operation partner.

(2) The costs reimbursed in accordance with Paragraph 1 also include reasonable costs of prosecution and legal defence incurred by the BMB for the enforcement of the rights transferred with this agreement or defence against claims of third parties.

(3) The BMB shall inform the cooperation partner without undue delay of prosecution and defence measures to be undertaken and give the cooperation partner the opportunity to conduct the process against the third party or parties. Furthermore, the cooperation partner shall be obligated to support the BMB with the defence against these claims.

§ 18 Transfer of rights to third parties

A party to the agreement is not entitled to assign individual rights or the entire rights of this agreement to third parties without the previous approval of the other party. Approval may not be denied without good cause.

§ 19 Contact persons

(1) Each party to the agreement shall name a contact person, who will be responsible for all explanations, questions and information relating to this agreement and, for the case that this person is unavailable, a deputy contact person.

(2) The parties to the agreement are obligated to empower the contact persons with the necessary authority.

§ 20 Concluding regulation, annexes

(1) The present agreement, including the annexes thereto, contains all regulations of the parties in respect of the object of the agreement. Verbal agreements do not exist. Previous agreements and definitions in respect of the object of the agreement are no longer valid with the taking effect of this agreement.

(2) The annexes appended before the signature part of this agreement are part of the agreement.

(3) For the case that the annexes to this agreement incorporate more specific regulations than the stipulations of the principal part of the agreement, these specific regulations shall take precedence over the regulations in the principal part of the agreement.

§ 21 Term, termination

(1) The present agreement takes force after being signed by both parties. It is for an unlimited time.

(2) The present agreement can be terminated with notice of ... as per ... .

(3) The right of the parties to terminate the agreement with good cause remains unaffected. Good cause exists on the part of the BMB in particular for the case of a violation against the regulations of § 9, § 10, § 11 and § 12 of this agreement.

§ 22 Consequences of terminating the agreement

The regulations of § 10, § 11, § 13, § 14 and § 15 of this agreement remain valid in the case that the agreement is terminated.

§ 23 Language of the agreement

(1) The original language of the agreement is German.

(2) Translations of this agreement and its annexes to other languages than the original language of the agreement serve solely to simplify reading the agreement for the co-operation partner.

§ 24 Applicable law, place of jurisdiction

(1) The law of the Federal Republic of Germany applies exclusively for the present contractual relationship. The application of the Vienna UN Convention on Contracts for the International Sale of Goods of 11 April 1980 (BGBl.* 1989 II, page 588) is excluded.

(2) For all legal disputes in connection with or deriving from this agreement the parties agree on the seat of the BMB as the place of jurisdiction.

§ 25 Conciliation

(1) For all legal disagreements ensuing from this agreement, the parties have recourse to the conciliation body of the ... in the interest of partially or entirely, temporarily or permanently clearing up the dispute before initiating court procedures.

Remark: In the text the national ethics commission was given as an example; however, this could also be any other suitable committee.

(2) The parties proceed on the assumption that the conciliation process of ... in Annex 7 to this agreement is fair and impartial, the conciliators are neutral, the result of the conciliation process is not bound to ascertaining facts, and legal recourse to public courts remains open. The version of the conciliation process circulated via the website of the ... referred to in Paragraph 1 shall constitute the basis for the conciliation process; this applies correspondingly for the costs arising from the conciliation process.

* Federal legal gazette

(3) With the day of its opening, the conciliation process suspends the time limits for the statute of limitations and for all claims arising from the facts of the dispute. This suspension ends in accordance with § 203 of the German Civil Code three months after the conclusion of the conciliation process.

§ 26 Concluding provisions

(1) The co-operation partner is not entitled to assign claims deriving from this agreement to other parties or to dispose of these in any other way without the approval of the BMB.

(2) Should a provision of this agreement be or become invalid, this shall not affect the validity of the remaining provisions of the agreement.

(3) Amendments or supplements to this agreement require the written form. This applies for changing the requirement for the written form as well.

Annexes:

1. ***Description of samples and data***
2. ***Research purposes***
3. ***Documentation of sample treatment (quality directive)***
4. ***Probands wishing to be informed***
5. ***Data protection declaration***
6. ***Probands with anonymity prohibition due to right of sample return or destruction***
7. ***Conciliation process***

.....	.....
Place, date	Signature of BMB
.....	.....
Place, date	Signature of co-operation partner

4. Material transfer agreement (MTA)

between

the biomaterial bank .....,

represented by ..... *(managing director, head, etc.)*

..... (address)

- in the following: BMB -

and

.... *(Description of the institution to which the*

biomaterial is to be given),

represented by ..... *(managing director, head, etc.)*

..... (address)

- in the following: institution -

concerning the one-time supply of human sample material and related data

§ 1 Object of the agreement

(1) The object of this agreement concerns the samples under the ownership of the BMB in accordance with Annex 1 to this agreement.

Remark: Annex 1 must describe the samples in detail, i.e. the sample type, number of samples, specific characteristics of the samples, sample storage, related data, etc. This information is given in a separate annex, as this obviates the need to change the text of the agreement in each individual case.

(2) The BMB shall supply the samples described in Annex 1 to the above institution in

- anonymised
- pseudonymised
- person-related

form.

(3) Delivery shall take place exclusively for the purposes described in this MTA.

Remark: The research purposes pursued with the samples constituting the object of this agreement must be described in detail as an annex. A kind of testing plan, such as used for clinical studies, would appear to be appropriate here. The question remains, however, whether the BMB should control this plan before concluding this agreement in order to determine that the samples turned over may be used only for this research purpose or whether the plan should serve only the function of limiting the purposes for which the samples constituting the object of the agreement are to be used. This question requires further discussion.

§ 2 Transfer of ownership, retention of ownership

(1) The parties are agreed that the institution shall be accorded the ownership of the object constituting the object of the agreement.

(2) The BMB, however, shall retain ownership of the object of this agreement until remunerated in full in accordance with § 5 of this MTA.

§ 3 Assurance of legal propriety on the part of the BMB

(1) The BMB has convinced its suppliers that the taking of all human samples constituting the object of this agreement has been performed only following comprehensive explanations on the part of the doctor and printed information given to the proband and furthermore on the basis of the written consent of the proband.

Remark: In foreign countries, it is sometimes the case that express consent is required only for the use of identifiable human sample material. However, with coded or anonymised material it is sufficient to grant the donor an opt-out solution and the donor not make use of this right. However, a declaration of consent for all sample types makes the process uniform and easier to oversee.

(2) The BMB attests that it is the legal owner of the samples referred to in § 1, Paragraph 1.

(3) The BMB furthermore attests that the object of the agreement, notwithstanding the exceptions elaborated in § 11, Paragraph 3, are free of the rights of third parties, in particular that there are no conflicting rights of the proband or other third parties in respect of the transfer of rights concerning the samples constituting the object of this agreement to the institution. The BMB offers this assurance in so far as such conflicting rights have up to now not been asserted.

§ 4 Quality assurance, standards

(1) The BMB attests that the samples its suppliers have properly handled these samples immediately following their removal professionally, in accordance with the quality directive "Removal, storage and transport of human sample material" in the version valid at the time of conclusion of this agreement. This means, in particular, that the samples have at no time, neither during processing nor during storage nor during transport, been exposed to free air longer than ... minutes with a temperature of greater than ... degrees Celsius. The BMB attests that, within its area of responsibility, the samples have also been handled in accordance with the provisions of the above-mentioned quality directive. The corresponding documentation and the quality directive referred to are appended to this agreement as Annex 2.

(2) The BMB attests that, within the area of responsibility of its suppliers, the samples have not been contaminated by any foreign substances either during or following their removal. The BMB also attests that, within its own area of responsibility, no contamination of the samples has occurred.

Remark: The "Model Transfer Agreement" of the Netherlands-based Federatie van medisch wetenschappelijke Vereningen proposes completely excluding the biobankfrom the safety and non-contamination of the human samples. Moreover, the biobank should accordingly not be liable for any damages in so far as this has not been expressly agreed otherwise. However, a specimen text of the agreement intended for widespread use can be judged in accordance with standard business terms, such far-reaching liability and warranty exclusions are forbidden, as these could not be effectively agreed

§ 5 Remuneration

(1) The remuneration is in the amount of ... EURO, plus the relevant legal value added tax. It is due with the signing of the agreement. The BMB shall invoice the institution with a corresponding request for payment.

Alternative for the provision of material without remuneration, e.g. for research purposes:

(1) The BMB shall transfer the object of the agreement in accordance with § 1, Paragraph 1 without remuneration to the co-operation partner. For the costs arising in connection with the acquisition and holding of the object of the agreement, the BMB shall receive compensation in the amount of ... EURO. The BMB shall have no further claim to payment relating to the context of the object of the agreement. The regulations of Paragraph 2 remain unaffected.

(2) The shipping of the samples is the responsibility of the BMB, in so far as no other agreement has been reached with the institution. The costs of packaging are not included and shall be invoiced separately to the institution, in so far as the partner has not made suitable transport containers available.

§ 6 Shipping, packaging, passing of risk

(1) The place of performance is the seat of the BMB. The loading and shipping of the samples take place in the absence of insurance at the cost and risk of the institution. Unless the co-operation partner expresses other wishes, shipping shall take place by a forwarder or carrier to be determined by the BMB. The BMB shall obligate the forwarder/carrier to undertake the transport in accordance with the provisions of the quality directive, as described in Annex 2 to this MTA and document compliance with the obligations described therein.

(2) The risk of accidental destruction, theft and accidental spoiling of the samples, when the samples to be shipped are given to the forwarder, carrier or other person named to carry out the shipping, is transferred with the turn-over to the institution.

(3) Should the shipping be delayed at the wish or due to the fault of the co-operation partner, the BMB shall store the object of the agreement at the cost and risk of the institution. In this case, the notice of readiness to ship is equivalent to shipping.

§ 7 Delivery and performance time, delay

(1) Delivery dates or time limits not expressly agreed as binding are not binding.

(2) For the case that the BMB is at fault in the matter of not meeting an expressly agreed time limit or falls behind schedule for other reasons, the institution shall grant a reasonable period of grace. Should the delivery still not be carried out after this time has elapsed, the institution shall be entitled to withdraw from the agreement.

(3) The remaining legal claims and rights of the institution in respect of delayed delivery remain unaffected.

(4) The BMB is entitled to undertake partial deliveries and partial performance, in so far as this can reasonably be expected of the institution.

§ 8 Responsibility for violations of obligations

(1) The institution is obligated to inspect the object of the agreement following delivery from the BMB without undue delay in respect of deviations in quality and amount, as well as inspect the materials for possible damage in transport, and notify the BMB of any such defects. Should the institution partner fail to notify the BMB, the object of the agreement delivered shall then be regarded as accepted, unless the deviations of quality and amount were not recognizable during the inspection. Should such a concealed defect emerge at a later point in time, it is the responsibility of the institution to immediately notify the BMB after its discovery. The object of the agreement shall otherwise also be regarded as accepted.

(2) Claims concerning defects shall not apply in cases of only insignificant deviations between the actual and the agreed quality or only insignificant restriction of use.

(3) The BMB is not obligated to rectify defects when the institution has not served notification punctually in writing.

(4) In so far as sample defects occur for which the BMB is at fault and the institution has served notification punctually in writing, the BMB is obligated to rectify the defect, unless the BMB is entitled to invoke legal regulations for refusal to rectify the defect. For each defect found, the institution shall set a reasonable time limit for the BMB to rectify the defect. Should the BMB still not fulfil its responsibility to supply defect-free materials a second time after having been duly notified, the institution shall be entitled to withdraw from the agreement or to appropriately take this into account in relation to remuneration.

(5) The BMB shall be liable for damages in relation to the institution in so far as the damages are the result of intent or gross negligence on the part of the BMB, its employees, legal representatives or other vicarious agents. In other respects, the BMB is liable only for predictable damage caused by the violation of essential contractual obligations by the BMB. Liability for lost profits of the institution, unrealised savings for the institution, consequential damages, damages resulting from defects, and damages ensuing from the application environment made available by third parties is excluded. The BMB shall furthermore not be liable for damage due to force majeure. This includes, in particular, damage resulting from natural disasters, the effects of war, wage conflicts and other operational disturbances.

(6) The institution is solely responsible for determining the suitability of the samples for the purposes which it pursues.

(7) The above limitations of liability do not apply for the case of compulsory product liability, as well as injury to life, body or health.

(8) Quality defect claims of the institution partner shall be subject to a limitation period of 12 months from having received the object of the agreement. The legal time limits remain unaffected for a premeditated or grossly negligent violation of obligations by the BMB, as well as in cases of injury to life, body or health.

Remark: The remarks of § 4 apply here correspondingly.

§ 9 Observance of national and international law

(1) The parties are obligated for the preparation and use of the object of the agreement to observe all relevant national and international regulations. For the BMB, this obligation concerns the relevant regulations in Germany for sample preparation; for the institution this obligation concerns the relevant regulations in Germany and the country of the institution for the use of the material constituting the object of the agreement.

(2) Directives, conventions, recommendations and similar sets of rules and regulations from supra-international and international institutions, relevant professional organisations and professional associations are also regulations in the sense of Paragraph 1, in so far as these are regarded as generally recognised.

(3) For the case that one party is guilty of violating the obligations of Paragraph 1 with resulting damages to the other party, the party at fault is liable to provide compensation for these damages in so far as this is not a matter of consequential or indirect damage.

(4) For the case that a third party acquires claims against the other party as a result of a violation in accordance with Paragraph 1, following taking of notice the party at fault shall release the other party without undue delay from all claims of the third party arising from this violation.

§ 10 Return of the samples

(1) In so far as a legitimate interest of the BMB exists, the institution is obligated at the request of the BMB to return samples named by the BMB transferred to the institution or made available for use to the institution by the BMB or to destroy these samples.

(2) A legitimate interest in the sense of Paragraph 1 exists when

- the institution violates obligations of this agreement repeatedly or seriously
- a proband can legally demand the return or destruction of his sample material from the BMB, in particular when the BMB is obligated by a court decision to return this material

(3) For the case of a dispute between the BMB and the institution in the matter of whether a legitimate interest in accordance with Paragraph 1 exists, the parties agree on a conciliation process before the national ethics commission *(Remark: This is only a specimen text!)*. The decision of the national ethics committee shall be binding for both parties.

(4) In so far as the return of the sample material is not the result of a violation of obligations on the part of the institution, the BMB shall compensate the institution for expenses incurred in connection with the return of the sample material as well as the remuneration paid. Any further claims, in particular damage claims, are not due the institution.

§ 11 Further use, passage to third parties, personal rights

(1) The institution is aware that the object of the agreement is intended solely for research purposes. The object of the agreement is not intended for the purpose of manufacturing medicines or substances.

(2) The passing of the object of the agreement or parts thereof to third parties by the institution, in particular, the passage of their ownership to third parties, is not permitted.

Remark: If the institution is not a single legal entity, but a consortium for example, a clarification would be required here as to who fits the definition of the "third party".

Alternative:

(2) The passing of the object of the agreement or parts thereof to third parties is permitted on the part of the institution. The BMB attests that no conflicting rights exist on the part of a proband or another third party.

(3) The institution is obligated to observe the personal rights of the proband. In particular, it is obligated to observe the following rights guaranteed to the proband by the BMB:

- Disclosure to third parties for advertising purposes is not permitted.
- The use of the object of the agreement is limited to the research purposes described in Annex 3 to this agreement.
- The probands named (pseudonymised) in Annex 4 to this agreement wish to be informed for the case that new medical knowledge of relevance for their health is obtained from the human samples removed from them. The institution is obligated to inform the BMB in writing about such knowledge without undue delay.

(4) The co-operation partner is obligated to inform the BMB in writing concerning all accesses of third parties, in particular of foreclosure measures as well as other injuries to its property. The co-operation partner is liable to the BMB for all damages and costs arising as a result of a violation of this obligation and measures of intervention required against access on the part of third parties.

§ 12 Rights deriving from research results

(1) The institution shall have sole rights to the research results obtained in accordance with the contracted use defined in § 1, Paragraph 1 of this MTA in relation to the BMB.

(2) For the evaluation of the research results, it is the responsibility of the institution to observe possible effects arising from § 10 of this MTA.

§ 13 Anonymisation, traceability

The institution is entitled to anonymise the samples, in so far as the proband has not retained the right to demand the destruction or return of their sample material or to be informed of medical knowledge gained of relevance for his or her health. These probands are named in Annex 4 and Annex 6 to this agreement. Should a proband exercise the right to have sample material returned or destroyed, the institution shall be obligated to turn over or destroy all samples from this proband at the request of the BMB in accordance with § 10. This does not apply in so far as the samples have already been anonymised.

§ 14 Data protection, re-identification

(1) The institution is obligated to observe the relevant data protection stipulations and principles of good scientific practice at all times while making use of the samples.

(2) Re-establishing or attempting to re-establish the connection to specific persons with anonymised or pseudonymised samples on the part of the institution is forbidden.

(3) The institution is obligated to protect the medical data entrusted to him by a suitable data protection concept. The separate data protection declaration in Annex 5 to this agreement defines this more exactly.

§ 15 Data protection/Confidentiality in relation to the partner to the agreement

(1) It is hereby drawn to the attention of the institution that personal data are stored and processed at the BMB to the extent necessary within the scope of the contractual relationship. With the exception of legal obligations, the disclosure of personal data to third parties may not take place.

(2) Both parties to the agreement are obligated to treat all documents, data inventories and information concerning the other party to the agreement as strictly confidential in so far as these have not already been disclosed publicly.

§ 16 Violations of the agreement, stipulated penalty

(1) Should the institution be guilty of violating any of the obligations deriving from the regulations of this agreement, for each violation of the agreement - excluding the objection of the continuation context - it shall be liable for a penalty in the amount of 10,000 Euros to the BMB.

(2) The BMB retains the right to separately claim damages attributable to the violation of the agreement in excess of this amount.

§ 17 Claims by the proband/third parties, release

(1) The institution releases the BMB from any claims by the proband or other third parties - in particular damages and compensation for pain and suffering - raised in connection with the use of the object of the agreement in accordance with the stipulations agreed or by non-compliance with the obligations of the institution.

(2) The costs reimbursed in accordance with Paragraph 1 also include reasonable costs of prosecution and legal defence incurred by the BMB for the enforcement of the rights transferred with this agreement or defence against claims of third parties.

(3) The BMB shall inform the institution without undue delay of prosecution and defence measures to be undertaken and give the institution the opportunity to conduct the process against the third party or parties. Furthermore, the institution shall be obligated to support the BMB with the defence against these claims.

§ 18 Applicable law, place of jurisdiction

(1) The law of the Federal Republic of Germany applies exclusively for the present contractual relationship. The application of the Vienna UN Convention on Contracts for the International Sale of Goods of 11 April 1980 (BGBl.* 1989 II, page 588) is excluded.

(2) For all legal disputes in connection with or deriving from this agreement the parties agree on the seat of the BMB as the place of jurisdiction.

§ 19 Conciliation

(1) For all legal disagreements ensuing from this agreement, the parties have recourse to the conciliation body of the ... in the interest of partially or entirely, temporarily or permanently clearing up the dispute before initiating court procedures.

Remark: In the text the national ethics commission was given as an example; however, this could also be any other suitable committee.

(2) The parties proceed on the assumption that the conciliation process of ... in Annex 7 to this agreement is fair and impartial, the conciliators are neutral, the result of the conciliation process is not bound to ascertaining facts, and legal recourse to public courts remains open. The version of the conciliation process circulated via the website of the ... referred to in Paragraph 1 shall constitute the basis for the conciliation process; this applies correspondingly for the costs arising from the conciliation process.

(3) With the day of its opening, the conciliation process suspends the time limits for the statute of limitations and for all claims arising from the facts of the dispute. This suspension ends in accordance with § 203 of the German Civil Code three months after the conclusion of the conciliation process.

§ 20 Concluding provisions

(1) The institution is not entitled to assign claims deriving from this agreement to other parties or to dispose of these in any other way without the approval of the BMB. The regulations of § 354a of the German Commercial Code (HGB) remain unaffected.

(2) Should a provision of this agreement be or become invalid, this shall not affect the validity of the remaining provisions of the agreement.

(3) Amendments or supplements to this agreement require the written form. This applies for changing the requirement for the written form as well.

* Federal legal gazette

Annexes:
1 Description of samples and data
2 Documentation of sample treatment (quality directive)
3 Research purposes
4 Probands wishing to be informed
5 Data protection declaration
6 Probands with anonymity prohibition due to right of sample return or destruction
7 Conciliation process

.....	.....
Place, date	Signature of BMB
.....	.....
Place, date	Signature of institution

5. Agreement for commissioning the investigation of samples

Preliminary general remark

The agreement is intended for cases in which a German biobank commissions a service provider in a foreign country

- to investigate biomaterial and maintain the material in an immediately accessible form (e.g. properly frosted and stored)
- to process the personal data relating to these materials
- to derive medical knowledge from these materials (e.g. performing certain analyses).

The content of the commission may vary and must not exist in cumulative form.

Preliminary remark concerning data protection law

For the case that a German biobank makes personal data available to a foreign service provider, the question constantly arises of whether a data communication in the sense of § 3, Paragraph 4, No. 3 of the German Federal Data Protection Act (BDSG) exists for which special prerequisites apply. When the party receiving these data is a contracted data processor in the sense of § 11 of the BDSG, then in accordance with § 3, Paragraph 8, Sentence 3 of the BDSG this party is no longer a "third party" if this is located within Germany, in a member state of the EU or a contracting state of the European Economic Area (EEA). In this case, according to data processing law no such communication exists and the passage of data between the customer and the contractor within the framework of the contracted data processing relationship is regarded as an internal process.

Therefore, for the group of foreign cooperation partners in Great Britain, the Netherlands and Austria referred to here: Commissioned data processors in these countries are not "third parties" in the sense of the BDSG and the passage of personal data to these parties is no "communication" subject to approval following examination by the German biobank. For the data processing and the rights of those affected the German data protection regulations apply; in respect of the technical organisational measures, the regulations of the contractor's country apply.

For the case of Switzerland, which is neither an EU member state nor "another contracting state" in the sense of the agreement concerning the European Economic Area, the legal situation is somewhat more complicated. In relation to the German biobank, a commissioned data processor in Switzerland is always a "third party" and the transmission of personal data to this party constitutes a "communication".

The permissibility of this communication must be examined on the basis of the provisions of § 4b of the BDSG (communication of personal data to a foreign country). Thus, in accordance with § 4b, Paragraph 2, Sentence 2 of the BDSG, such a communication is not permissible in particular when an adequate level of data protection cannot be ensured in the receiving country.

For Switzerland, however, the EU Commission recognises an adequate level of data protection (Official Gazette of the EU Nr. L 215/1 of 25 August, 2000), so that only the general prerequisites for approval for the communication of data must be fulfilled. In the present context, the consent of the parties affected will in any case be obtained. If these are preceded by information also relating to the data processing situation in Switzerland, it is to be assumed that the consent, and therefore the legal basis for the communication of personal data to a service provider in Switzerland, has taken effect.

Preliminary remark concerning personal rights

The right of self determination in respect of information covered by the data protection regulations is only one special formulation of the personal right derived from Article 2, Paragraph 1 in conjunction with Article 1, Paragraph 1 of fundamental law. For this reason, the data protection regulations do not cover all further aspects of personal rights.

In the present context, this emerges in the following manner: In so far as this is a matter of the processing of personal data according to commission, one can draw, in particular, upon the regulations of § 11 of the BDSG and a corresponding contractual incorporation of these stipulations can be implemented on a "secure basis". If, however, the commissioned service provider - as assumed here - assumes other duties entailing handling of the human samples from which the

personal data derive in addition to pure data processing, these obligations require the additional express regulation in the form of an agreement furthermore oriented towards the data protection aspects.

Here, it is necessary to recall the "Three-level model" expounded within the scope of the TMF expert assessment "Biomaterials - Legal framework" (TMF series, volume 2). This differentiates in the legal evaluation of human sample material between

- the property rights level, which concerns the questions of ownership, possession and use (ownership level)
- the level of personal data and the handling thereof (data protection level) and
- the level of commitments and obligations which the donor assigns to the biomaterial (personal rights level).

The data protection level, however, reveals considerable similarities and, in part, also overlapping with the personal rights level. It is therefore legitimate to orient contractual relationships for commissioned data processing to agreement models tested in terms of data protection law and supplement these only to take into account such aspects as cannot be solely or in any case not clearly or not sufficiently defined by data protection regulations.

The draft of the agreement is therefore oriented to a specimen agreement for commissioned data processing of the Gesellschaft für Datenschutz und Datensicherung (Association for data protection and data security), which normally finds approval on the part of the supervisory authorities, and introduces further elements specifically tailored to the handling of biomaterials.

Agreement

between

..... *(biobank)*

- in the following: customer -

and

..... (service provider)

- in the following: contractor -

§ 1 Object of the agreement

The contractor shall assume . . . *(brief description of the services which the contractor is to perform in respect of the biomaterials)* and process the related personal data as instructed by the customer in accordance with the description of responsibilities in Annex 1, which is part of this agreement.

§ 2 Responsibility for legal permissibility

(1) The customer attests that he is the rightful owner of the biomaterials constituting the object of this agreement and that the persons from whom these materials have been removed have legally consented to the use of these materials for the purposes defined in the agreement.

Remark: If the biobank has only rights of use for the sample material, Paragraph 1 must be accordingly modified!

(2) The customer is, notwithstanding the regulations of § 7 of this agreement, solely responsible for assessing the legal permissibility of the collection, processing and use of data within the scope of this contractual relationship by the contractor in respect of the regulations of the Federal Data Protection Act and other provisions concerning data protection.

(3) The customer is solely responsible for assessing the legal permissibility of compliance with the legal provisions governing personal rights to be observed for the handling of human biomaterial.

§ 3 Accountability of the contractor for the handling of biomaterials

(1) The contractor shall use the biomaterials handed over by the customer exclusively for the purposes described in the agreement, within the scope of the description of responsibilities given in Annex 1 to this agreement.

(2) For the fulfilment of his responsibilities, the contractor is bound to comply with the instructions of the customer. Instructions from the customer require the written form.

§ 4 Accountability of the contractor for data processing

(1) The contractor shall collect, process and use the personal data made available by the customer exclusively within the scope of this agreement and possible individual instructions of the customer. The accountability of the contractor also covers the necessary collaboration for the preparation of the register of data processing and the controls for conformity with regulations on the part of the customer. Data and documents relating to personal data and no longer required may be destroyed only after approval by the customer.

(2) The instructions of the customer require the written form, in so far as another form is not more appropriate due to special circumstances.

§ 5 Variants for processing and use

(1) The contractor is entitled to make use of all technical processing steps and uses of the biomaterials and data required for the fulfilment of the object of the agreement (e.g. freezing sample material, preparation of new tissue sections, duplication of inventories for safeguarding against loss, creation of log files, intermediate data records and work areas, etc.). In addition, he is entitled to correct errors of technical origin, in connection with which he must accordingly inform the customer without undue delay. The processing of data for purposes other than the purposes defined in the agreement on the part of the contractor is forbidden.

(2) The removal of the reference to the name of the donor of biomaterials and the anonymisation of personal data, as well as the deleting of personal data, require the written approval of the customer. This also applies for the destruction of biomaterials and data storage media containing personal data.

§ 6 Contact persons for the parties to the agreement

(1) The customer and the contractor hereby name the following contact persons, who will be responsible for issuing instructions and receiving instructions, respectively, for ongoing developments:

For the customer:

_____ (Name, function, telephone)

For the contractor:

_____ (Name, function, telephone)

(2) In the case of a change in or hindrance of the responsible contact person, the respective party to the agreement shall inform the other party of a deputy/new contact person in writing without undue delay.

§ 7 Obligations of the parties to the agreement in respect of information concerning the handling of biomaterials

(1) The contractor shall inform the customer of contradictions in these contractual agreements and individual instructions in respect of statutory and other legal provisions to be observed for the handling of biomaterials. This also applies for other recognised provisions in the country of the contractor, such as recommendations and/or directives of professional organisations and ethics commissions.

(2) Should the customer determine that the contractor deviates from the stipulations of this agreement or the stipulations defined in Annex 1 to this agreement in the conduct of his investigations, he shall inform the contractor of this without undue delay. In this case, the parties to the agreement shall jointly define a solution in conformance with the legal provisions.

§ 8 Obligations of the parties to the agreement in respect of data processing

(1) Should the contractor be of the opinion that an instruction of the customer constitutes a violation of the Federal Data Protection Act or other provisions concerning data protection, he shall inform the customer of this without undue delay. The contractor is entitled to suspend performance of the respective instruction until this is confirmed or corrected by the responsible representative of the customer.

(2) The contractor shall inform the customer without undue delay of disturbances, suspected violations of data protection, or other irregularities concerning the investigation of the personal data relating to the object of the agreement.

(3) The contractor shall inform the customer without undue delay concerning the determination of errors or irregularities which he, in particular makes during the checking of results. Should the errors determined lead to necessary process changes, the parties shall agree on these prior to their implementation.

§ 9 Confidentiality

(1) The contractor is obligated during the processing of personal data in accordance with the contractual relationship to safeguard the personal data of the customer in respect of maintaining data secrecy in accordance with § 5 of the BDSG. In this respect, he shall employ only persons obligated to maintaining data secrecy in accordance with § 5 of the BDSG for the collection, processing and use of these data. In particular, he is responsible for exercising the necessary circumspection to ensure that all persons entrusted with the processing and fulfilment of this agreement observe the legal stipulations concerning data protection and do not disclose information obtained from the customer without authorisation to third parties or otherwise exploit such information.

(2) Both parties to the agreement are obligated to treat all knowledge of operational and business secrets obtained within the framework of the contractual relationship as strictly confidential.

§ 10 Data protection representative for the contractor

(1) The contractor shall appoint a data security representative prior to the beginning of the responsibilities defined in the agreement.

(2) The data security representative is responsible for ensuring compliance with the Federal Data Protection Act and other provisions concerning data protection, as well as stipulations in respect of general personal rights of the persons affected, within the scope of the agreed relationship as well.

(3) In the case of a change of the responsible contact person, the contractor shall inform the customer without undue delay.

§ 11 Rights of the donor

(1) The customer is responsible for ensuring the rights of the donor.

(2) The contractor shall support the customer in ensuring compliance with these rights, in particular in respect of notifications (including new medical knowledge of relevance for the donor, in case the donor wishes this), furnishing information, rectification, blockage, deleting and destruction.

(3) Should the contractor violate the rights of the donor, the customer shall support the donor in a suitable manner with the enforcement of his or her rights.

§ 12 Liability

(1) The contractor is liable to the customer for damages resulting from fault on the part of the contractor, his employees and persons whom he entrusts with the fulfilment of the services defined in the agreement.

(2) For the compensation of damages which the party affected suffers due to inadmissible or incorrect collection, processing or use of data in accordance with the Federal Data Protection Act or other stipulations within the framework of the contractual relationship, the customer is responsible to the donor. For the case of fault on the part of the contractor, the customer reserves the right of recourse.

(3) The regulations of Paragraph 2 shall apply for the inadmissible or incorrect handling of biomaterials.

§ 13 Controlling compliance with the agreement

(1) The customer is entitled to perform controlling of compliance with the agreement as described in No. 6 of the annex to § 9 of the BDSG in consultation with the contractor or to have these controls performed. He is entitled to convince himself of compliance with this agreement in the form of random sampling by the contractor in his operational activity, which in the normal case must be announced 48 hours beforehand.

(2) The contractor is obligated to give the customer the required information for controlling compliance with the agreement on request and to furnish proof in support of this information, as well as ensuring entry of the customer to control-relevant rooms.

§ 14 Sub-contracted relationships

Entering into sub-contracted relationships on the part of the contractor is forbidden.

Alternative:

(1) Except for the case of express written approval of the customer, the contractor is not authorised to enter into agreements with sub-contractors for the fulfilment of his responsibilities ensuing from the agreement.

(2) Agreements with sub-contractors shall be submitted to the customer to obtain his approval. The customer shall examine the agreements in respect of conflicts with his interests in connection with the principal agreement.

§ 15 Definition of technical and organisational measures

(1) The contractor shall observe the principles of orderly electronic bookkeeping and guarantee the security measures required within the framework of the orderly performance of responsibilities. The technical and organisational measures required for this in accordance with § 9 of the BDSG and the annex to this are separately defined in Annex 2 of this agreement and are part of the agreement.

(2) ***Reference to technical specifications for the handling of biomaterial, Annex 3! Orientation to the quality assurance specifications of TP 4 of the first BMB project.***

(3) The technical and organisational measures can be continuously updated over the course of the contractual relationship in accordance with further technical and organisational developments in the area of responsibility of the contractor. These measures must be agreed with the customer prior to their implementation.

§ 16 Obligations following the termination of the agreement

(1) With the termination of the contractual relationship, the contractor shall be obligated to return all biomaterials, data and documents relating to the agreement or present proof of the orderly destruction thereof if the parties have agreed on this.

(2) The contractor shall retain documentation serving for the proof of orderly data and sample processing in accordance with the respective retention periods following the termination of the agreement. He may be relieved of this obligation by giving these to the customer following the termination of the agreement.

(3) For the case of recourse, the contractor shall also furnish the still existing documentation for proof of relief from obligation for safekeeping by the customer, following the termination of the agreement as well.

(4) The parties to the agreement shall be obligated to observe the regulations of § 9 of this agreement analogously after termination of the agreement as well.

§ 17 Applicable law, place of jurisdiction

(1) The law of the Federal Republic of Germany applies exclusively for the present contractual relationship.

(2) For all legal disputes deriving from this agreement, the place of jurisdiction shall be the seat of the customer.

§ 18 Conciliation

(1) For all legal disagreements ensuing from this agreement, the parties have recourse to the conciliation body of the ... *(name of the body)* in the interest of partially or entirely, temporarily or permanently clearing up the dispute before initiating court procedures.

(2) The procedure of Paragraph 1 is oriented to the conciliation process appended to this agreement as Annex 4.

(3) With the day of its opening, the conciliation process suspends the time limits for the statute of limitations and for all claims arising from the facts of the dispute. This suspension ends three months after the conclusion of the conciliation process.

§ 19 Written form

Amendments to, supplements to, termination of and annulment of this agreement, as well as changing the requirement for the written form, require the written form. The regulation of § 4, Paragraph 2 remains unaffected.

§ 20 Separability clause

Should a provision of this agreement be or become invalid, this shall not affect the validity of the remaining provisions of the agreement.

Annexes: ***1 Definition of responsibilities***

2 Technical and organisational measures - data

3 Technical and organisational measures - biomaterial

4 Conciliation process

.....	.....
Place, date	Signature of Customer
.....	.....
Place, date	Signature of Contractor

Annex 1 to the agreement of .....

Definition of responsibilities

The contractor shall perform the following responsibilities for the customer in accordance with the regulations of the agreement.

- Acceptance, treatment and safekeeping of biomaterials from the customer, in particular . . . . . *(description of the biomaterial categories, technical methods for treatment and storage)*
- Processing and maintaining the related personal data, in particular . . . . . *(description of the data types, the processing method, the data security methods, control routines, etc.)* in accordance with the specifications of the customer, in consideration of the regulations of Annex 2.
- The contractor is obligated to document the collection, processing and use of data in detail, on the basis of which the customer can give proof of the orderly use of the data. The basis for this documentation is the principles of orderly bookkeeping and orderly electronic bookkeeping (see Official Gazette of the Federal Ministry of Finance 1995 I, page 738).
- The contractor is obligated to document the acceptance, processing and use of the biomaterials in detail, on the basis of which the customer can give proof of the orderly use of the biomaterials. This documentation shall be on the basis of the quality assurance specifications in accordance with . . . . . *(correctly name the TP 4 of the first BMB project!).*
- Performing . . . . . *(description of analyses, etc., procedures for the communication of results, procedures for informing patients/probands for the case that they wish to be informed about knowledge obtained)* at the request of the customer.

Annex 2 to the agreement of .....

Technical and organisational measures – data
(§ 9 of the BDSG and annex to this)

Remark: ***Commissioned data processors are also required to meet technical and organisational measures in accordance with § 9 of the BDSG required to fulfil the specifications of the BDSG. Which measures are required is decided on an individual basis. The lists are therefore to be regarded only as examples.***

Organisational measures can, for example, be

- the organisational, spatial and personnel delimitation of data processing from other company areas
- determination of the function, competences and responsibility for data processing
- regulations for the secure and orderly handling of data processing tasks (monitoring of compliance with the regulations), examination of the effectiveness of the regulations and measures, as well as continuous adjustment thereof
- Other.

Remark: ***The control elements and separation regulation in the following are taken from the annex to § 9, Sentence 1 of the BDSG. The respective individual measures names are once again only examples.***

1) Control of entry

Measures suitable for preventing access by unauthorised persons to data processing systems on which personal data are processed could be:

- Securing the entrance ways (alarm system, electric door openers)
- Establishing authorisation regulations for entry, including documentation, for employees and external persons (maintenance personnel, visitors)
- Keys, code cards
- Control/documentation of entry
- Plant security, doorkeeper
- Other.

2) Control of admission

Measures according to which unauthorised persons are prevented from using data processing systems and methods. This refers to the admission of unauthorised persons to the EDP system itself in contrast to the (physical) control of entry.

- Password protection
- Securing monitor stations by screen savers, blockage and password-controlled reactivation (English command: on resume, password-protect)
- Securing the network against access from outside
- Securing the network (internally)
- Other.

3) Control of access

It must be ensured that the persons authorised to use the data processing method can access the system only on the basis of the personal data underlying their access rights and that, during the handling of such data, no unauthorised persons are able to read, copy, change or remove such data, e.g. by

- Establishing different access rights for access to data for automatic equipment, e.g. online terminals and connected PCs
- Legitimation of authorised persons (passwords, admission codes)
- Control of access
- Possibilities for partial access to databases and functions, e.g. deleting
- Other.

4) Control of data passed to others

Here, it must be ensured with the electronic transfer of personal data or during transport or storing to data storage media that no unauthorised persons are able to read, copy, change or remove such data.

The transport of data storage media containing personal data to a file shredder may be carried out only in closed containers and in closed vehicles (orderly attached plans etc. or containers), so that no material can be lost.

Conceivable are

- Defining areas in which data storage media must be kept or may be kept
- Defining the persons who may remove data storage media from these areas
- Controlling the removal of data storage media
- Securing the areas in which the data storage media are kept
- Defining authorisation for data interchange and transport
- Legitimation of the authorised persons (e.g. data storage media covering letter)
- Generation of handover reports/acknowledgements of receipt
- Other.

5) Control of data entry

This must ensure that subsequent controlling is possible and that it can be determined whether and by whom personal data have been entered in, changed, or removed from the data processing systems.

This can be realised by

- Labelling the acquired data
- Creating data acquisition protocols for the entry of, change to and deleting of personal data
- The regulation of access rights
- The control and evaluation of the protocols

6) Job control

Commissioned data processing may take place only in accordance with the instructions of the customer. The customer must ensure that he is able to control this. This shall be contractually defined.

Examples are

- An unequivocally formulated agreement governing this
- An order form
- Criteria for the selection of the contractor
- Controls of performance by the customer for compliance with the stipulations of the agreement

7) Control of availability

Personal data must be protected against accidental destruction or loss. This prerequisite can be fulfilled by

- Data security and backup concepts
- Uninterrupted power supply
- Catastrophe or emergency plans (water, fire, explosion, threat of attacks, crash, earthquake)
- Virus protection, firewall
- Weak-point analysis (security on the premises, building protection, computer and computer network intrusions)
- Safekeeping of data in data security cabinets, safes

8) Separation regulation

It must be ensured that collected personal data intended for different purposes can be separately processed.

There is, however, no need for physical separation. A logical separation is sufficient.

6. BMB conciliation procedure

§ 1 Scope of application

The conciliation process is available for the case of disputes arising from matters originating in the co-operation of the biomaterial banks (BMBs) and service providers in Germany and in foreign countries, as well as from contractual relationships between the German BMB and foreign research institutions. In particular, this includes disputes

(a) between the German BMB and the foreign BMB

(b) between the German BMB and German/foreign service providers

(c) between the German BMB and German/foreign research institutions

(d) arising from other legal relationships between a German BMB and other German/foreign contractual partners.

§ 2 Initiating the process

(1) The conciliation process begins with the day on which the conciliation body receives a written request from one party to conduct the process (application for conciliation). The application must be submitted four-fold. The following information must be contained in the application for conciliation:

(a) Name, address, telephone, fax or other communication references of the parties, the legal representative and, if possible, legal counsel for the party making application for the conciliation process, as well as the legal representative and, if possible, legal counsel for the other parties concerned in so far as this is known

(b) A brief summary of the object of dispute

(c) The documents required for an understanding of the facts (agreements, written correspondence, technical documentation, etc.)

(2) The conciliation body shall inform the other parties named in the application for conciliation in the form of a copy of the application for conciliation and grant these parties a reasonable period of time, which however may not exceed three weeks, to declare its readiness to proceed with the conciliation process. A non-recurrent extension of this period is possible when each party formally requests this.

(3) Furthermore, the conciliation body shall inform all parties of the day on which the conciliation procedure begins.

(4) For the case that the other parties do not punctually declare their readiness, the conciliation process shall be regarded as concluded.

(5) The language of the conciliation procedure is German. However, by agreement with the parties the conciliation body can determine that another language be used.

§ 3 Constitution of the conciliation team

(1) The conciliation body shall inform the parties about the planned members of the conciliation team and appoints these persons.

(2) In the normal case, the conciliation team is comprised of a legal expert qualified to exercise a judicial office and having experience with counsel in the area of medical research, a medical specialist with BMB knowledge or experience in the performance of clinical studies or molecular-genetic research projects, as well as a specialist in medical ethics. The legal expert is the presiding judge of the conciliation team and is in charge of conducting the process.

(3) The conciliators shall be neutral, impartial and independent. They may not represent or counsel (or have counselled) any of the parties in connection with the subject of conciliation, neither in court nor out of court. With the exception of an activity in accordance with § 6, Paragraph 4, they may also not take part as judge or conciliator in a process in any way related to the object of dispute of the conciliation process.

(4) At the wish of both parties, the conciliators can request that the parties agree to a declaration of neutrality before beginning the process, in which all circumstances are disclosed which could place the impartiality or independence of the team in doubt.

(5) The conciliation body shall decide in the matter of bias appeals. Should it become necessary to name another person to the position of a conciliator, this shall take place in accordance with Paragraph 1.

§ 4 General maxima for the process

(1) **Suspension of the statute of limitations:** In respect of all claims arising from the subject of conciliation, the parties shall waive a plea based on the statute of limitations until one of the parties refuses to resume the proceedings.

(2) **Confidentiality:** The conciliation process shall be closed to the public unless otherwise agreed by the parties. All persons taking part in the conciliation process, including the conciliation team, the parties, legal counsel, expert witnesses and other persons present during the conciliation dates shall observe confidentiality in respect of the conciliation procedure and may not make use of or disclose information relating to or deriving from the conciliation procedure in relation to a third party. At the request of a party, each of the persons named shall submit a corresponding declaration of obligation to observe confidentiality in writing before taking part in the conciliation process. Following the conclusion of the conciliation process, all persons taking part shall return documents obtained from one of the parties during the conciliation process to the party introducing these to the process without retaining a copy thereof.

(3) **Representation:** Each party may request representation by or the support of legal counsel. The legal counsel shall show proof of legitimation at the request of the conciliation team or another party in the form of written authorisation.

(4) **Services of process:** The application for the initiation of the conciliation process and the decisions of the conciliation team shall be delivered to the parties in the form of a simple letter requiring confirmation of receipt on the part of the addressee. All other statements of the case, summons and decrees (with fixed time limits) shall be communicated without specific form for the purpose of notification as a letter, fax or e-mail. Should a party be represented by legal counsel, the counsel shall also be notified.

(5) **Obligation to work towards concluding the process**: The conciliation team shall work towards concluding the process as quickly as possible. It is therefore the responsibility of the parties to present the statement of facts completely and punctually and present all information requested by the conciliation team in such a manner that the process can be concluded after one hearing.

§ 5 Conduct of the conciliation

(1) The conciliation team shall determine the procedure to follow, in accordance with the following rules.

(2) After conducting hearings with the parties, the conciliation team can firstly carry out a formless verbal discussion (mediation). All parties concerned shall have the opportunity (in writing as well) to present their preliminary position.

(3) Otherwise, the conciliation team shall give the parties the opportunity to present the object of the dispute, the background of the dispute, the respective objective of conciliation, and the arguments for the legal position in written form. Relevant documents and other evidence suitable for submission must also be included. Should the documents be submitted as copies, the conciliation team may request presentation of the original documents if their authenticity is open to dispute. The parties shall also present other evidence (such as by witnesses or judicial inspection).

(4) Furthermore, the conciliation team can request the presentation of supplementary information or documents which it regards as necessary for a comprehensive judgment of the factual and legal situation during any stage of the conciliation process from the parties or one of the parties.

(5) Requests by the conciliation team in accordance with Paragraphs 3 and 4 may be made with a set time limit. A party may apply to have these time limits extended.

(6) Following the submission of written positions in accordance with Paragraph 3, the conciliation team shall indicate the apparent principal points for the process to the parties and furnish the parties with a non-binding estimate of the process costs.

(7) Thereupon, in the normal case the conciliation team shall then fix a verbal hearing which, in so far as this appears to be expedient in view of the circumstances, shall take place at the site of the object of dispute. The conciliation team is empowered to accept the object of the dispute by judicial inspection, as well as to call in competent employees or authorised representatives of the parties or experts. The team may question these persons individually and also in the absence of a party.

(8) The conciliation team shall encourage the readiness of the parties to reach an agreement and, in so far as possible, present proposals for an amicable settlement of the dispute or individual points of dispute in every phase of the process.

(9) Deviations from the process steps described above may be made as agreed with the parties in so far as these appear to be expedient. In particular, the conciliation team may communicate its decision in a written process for cases in which written proceedings are sufficient.

(10) Supplementary to these steps, the provisions of the Code of Civil Procedure are of relevance for the authorities of the conciliation team during the conduct of the conciliation process.

§ 6 Result of the conciliation

(1) **Mediated settlement:** If an agreement is reached between the parties based on a proposal of or through the intermediation of the conciliation team, this shall be documented as a mediated settlement and the transcript of the proceedings presented by the members of the conciliation team to the parties or their legal counsels for signature.

(2) **Provisional ruling:** The conciliation process can also result in agreements on individual issues of dispute or provisional rulings on the basis of a proposal or through the intermediation of the conciliation team and permitting the resumption of procedures in respect of issues still under dispute and not yet concluded.

(3) **Conciliation verdict:** If agreement cannot be reached between the parties, the conciliation team shall present a conciliation verdict in written form with a brief statement of reasons. The conciliation verdict is intended to take account of the scientific and economic interests, the goal of a long-term co-operation, and the putative result of a court process between the parties. The time limit for the acceptance of the conciliation verdict is three weeks. A party may apply to extend this time non-recurrently. If the conciliation verdict is accepted by all parties, it is regarded as a mediated settlement in the sense of Paragraph 1. The conciliation team shall inform the parties of this in writing.

(4) **Arbitration award:** The parties can agree in the form of § 1031 of the Code of Civil Procedure that the conciliation team is empowered to render the final decision regarding the object of the dispute. In this case, § 1025 to § 1062 of the Code of Civil Procedure apply in addition to this conciliation procedure. In particular, the conciliation team may decide as a court of arbitration on provisional rulings in accordance with agreements reached between the parties, for example the provisional payment of money, the establishing of securities, the performing of certain services, or decreeing the performance of acts or omissions. Such a ruling is binding for the parties until replaced by another arbitration award, a different agreement between the parties, or a court decision.

§ 7 Relationship between conciliation and court or arbitration award processes

(1) In the absence of other agreements between the parties, neither proposals for mediation by the parties nor by the conciliation team nor the circumstance that a party indicates its readiness to accept a proposal for a mediated solution or a conciliation verdict nor concessions made during the conciliation process nor other utterances of the parties or the conciliation team may be introduced in the court or arbitration award process. This does not apply for a conciliation verdict in accordance with § 6, Paragraph 3 and its reasons.

(2) A conciliation process in accordance with the provisions of the conciliation procedure and a provisional arbitration award process in accordance with § 6, Paragraph 4, Sentence 3 may also be conducted or resumed when a legal dispute in a regular court is contingent upon or made to depend upon this. Each party and the conciliation team can, however, terminate the process by written declaration when the legal dispute is partly or entirely related to a process in a regular court or a dormant court process by one of the parties is resumed.

§ 8 Terminating the conciliation process

The conciliation process is concluded

(1) when the concurrence for the initiation of the conciliation process is not granted (§ 2, Paragraph 4)

(2) by the decision of the conciliation team that further conciliation efforts hold no promise due to lacking readiness of the parties or one of the parties to work towards an agreement in accordance with § 4, Paragraph 5

(3) with the reaching of a mediated settlement in respect of the object of dispute in accordance with § 6, Paragraph 1

(4) with the expiry of the time limit for the acceptance of a conciliation verdict in accordance with § 6, Paragraph 2, irrespective of whether acceptance follows or not

(5) with the final arbitration award in accordance with § 6, Paragraph 4

(6) with the submission of a declaration in accordance with § 7, Paragraph 2 in respect of a related court process

(7) with the presentation of a corresponding written declaration of a party in each stage of the process.

§ 9 Exclusion of liability

The conciliation team is liable to the parties for acts or omissions in connection with the conciliation process or its initiation or termination only for the case of premeditated behaviour. In individual cases, the conciliation team may conclude a regulation with the parties which deviates from this stipulation. The conciliation body is liable to the parties for acts or omissions in connection with the conciliation process or its initiation or termination only for the case of premeditated or grossly negligent behaviour.

§ 10 Costs

(1) The conciliation team shall decide on the distribution of the costs arising as a result of the conciliation process between the parties, in consideration of the facts of the matter and the status of the dispute as appears just in accordance with § 317 of the German Civil Code. Their decision is binding for the parties. In the normal case, the parties are enjoined to bear the costs arising for themselves and their legal counsel. Exceptions to this require special grounds.

(2) The parties are liable for the costs in accordance with § 11 as co-debtors.

(3) The members of the conciliation team are entitled to their own remuneration from the parties in accordance with the provisions of § 11. A member of the conciliation team retains the right to remuneration even for the case that his or her function ends before the conclusion of the conciliation process, unless this claim is refused with justification due to reproachable misbehaviour.

§ 11 Remuneration for the members of the conciliation team

(1) The members of the conciliation team shall calculate their remuneration on the basis of the expenditure of time in connection with the conciliation process. This also applies when the conciliation team is empowered to function as a court of arbitration. The hourly rate is 210 Euros. The conciliation body may adjust the hourly rate for future conciliation processes to the prevailing economic development; the currently applicable hourly rate can be obtained from the conciliation body and can be found in the Internet on the homepage of the conciliation body under http://www.....de . The costs of telephone, postage, travel and clerical expenditures shall be invoiced in harmony with the solicitors' remuneration law, in place of which a lump sum for expenses can be invoiced in the amount of the hourly rate, plus the value added tax in the respectively valid amount.

(2) In accordance with Paragraph 1, the conciliation body shall be reimbursed in the amount of a lump sum fee of two hours at the hourly rate for the initiation of the process.

(3) Following the initiation of the conciliation process, the conciliation team may demand an equal amount from each party as an advance payment against the remuneration expected for the members of the conciliation team and the other costs of the conciliation process. The amount of the advance payment shall be oriented to the cost estimate of the conciliation team in accordance with § 5, Paragraph 7. Further advance payments may be demanded during the course of the conciliation process. The conciliation team is not obligated to assume (resume) its function.

(4) Following the conclusion of the conciliation process, the conciliation team shall inform the parties of the process costs arising and, in consideration of the costs decided upon in accordance with § 10, Paragraph 1, either reimburse the parties for advance payments exceeding the process costs or demand the payment of cost and remuneration balances still open.

§ 12 Entering into force

This conciliation procedure will be made known via the homepage of the conciliation body and enter into force on ... 2008. With the notification of a new conciliation procedure, the previous conciliation procedure will no longer be in force. Conciliation processes already begun at the time at which the previous conciliation procedure becomes invalid shall be continued to their conclusion in accordance with the previous conciliation procedure.

§ 13 Conciliation body

The conciliation body functioning in the sense of this conciliation procedure is the registrar's office of the ..... (address, communication data).