



# Template: Data Transfer Agreement (DTA) for Personal Data

## How to use this template

This template governs the transfer and use of human personal data that is made available by a provider to the entity that wishes to use this research data for its own research purposes (recipient). It is designed for cases, where no cooperation agreement exists between the contractors.

A DTA must be concluded between legal entities which are to be bound by the contractual provisions, not between individual scientists involved in the transfer and the related research, since they would not be able to guarantee the implementation of the contractual obligations.

The template assumes that human personal data are only transferred after the recipient has gone through an application process, since open access to data or data which have not been fully anonymized are critical due to the fact that informed consent to the use for a specified purpose from the donor/data subject would be needed.

The scope of applicability of the suggested clauses may depend on the distribution policies of the provider using this template. Especially the provisions concerning charges, credits, assignment of intellectual property etc. should be assessed carefully and changed/deleted where appropriate with regard to the policies of the user.

The scope of the template is limited to the transfer of material/data within the EU.

This template is based on a survey of a number of European and national MTA's. Especially the collection of instructions and contractual models of the The Biobanking and Biomolecular Resources Research Infrastructure (BBMRI) has proved to be very useful and should be contacted at any time for further information:

[http://www.bbmri-wp4.eu/wiki/index.php/Main\\_Page](http://www.bbmri-wp4.eu/wiki/index.php/Main_Page)



## Data Transfer Agreement (DTA)

### Preamble

This agreement governs the transfer of human personal data. It is designed for cases, where no cooperation agreement exists between the contractors.

### 1. Parties

The undersigned, the provider X [fill in official name of legal entity that is authorized to enter into this agreement], a [fill in type of legal entity, e.g. foundation, charitable trust, corporation (Ltd. Inc.)], incorporated, organized and duly existing under the laws of the [fill in appropriate jurisdiction], with its principal office at [insert address], hereby legally represented by [insert name of legal representative],

and

Institution Y [fill in official name of legal entity that is authorized to enter into this agreement], a [fill in type of legal entity, e.g. foundation, charitable trust, corporation (Ltd. Inc.)] incorporated, organized and duly existing under the laws of the [fill in appropriate jurisdiction], with its principal office at [insert address], hereby legally represented by [insert name of legal representative],

and/or

Company Z [fill in official name of legal entity that is authorized to enter into this agreement], a [fill in type of legal entity, e.g. corporation (Ltd., inc.)], incorporated, organized and duly existing under the laws under the laws of the [fill in appropriate jurisdiction], with its principal office at [insert address], hereby legally represented by [insert name of legal representative], and/or [..]

[Add any other party which is to be a party to the DTA],

Whereas, the Provider X is a [ e.g. populations biobank] established with the aim to facilitate research on its collection of human biological data; Institution Y (hereinafter: Recipient ) is a [for profit or non-profit] research institute willing to conduct research on certain Data from the provider; The provider is willing to transfer certain Data to the Recipient;

have agreed to be bound by the provisions set out in this Agreement.



## 2. Scope of Supply

The Provider provides to the Recipient the following data: ... [fill in precisely or point to an attachment where the provision is described].

The Recipient acknowledges that the data are provided on an “as is” basis without any warranty of satisfactory quality or fitness for a particular purpose or use or any other warranty, express or implied.

## 3. Data Protection

Annex A summarises the data and/or data that the Provider will make available to the Recipient in accordance with their approved Application [reference number]. The timeframe and methodology by which the data and/or data will be dispatched is also set out in Annex A.

The Provider confirms that for the purposes of this DTA it is entitled to supply the data/and or personal data to the Recipient and that consent covering the intended use has been obtained from the relevant donors/data subjects.

The Recipient will use data for purposes of the analyses set forth and within the limits set by the Research protocol only. The Recipient confirms that the Approved Research Project has been subject to independent scientific review by a recognised body in the manner described in the Application and that the planned use of the data/data has approval of the appropriate ethics and scientific committees. The Recipient confirms that all work using the data will be carried out in compliance with all applicable laws, regulations, guidelines and approvals.

The Recipient will retain the data in a secure network system at such standard as would be reasonably expected for the storage of valuable and proprietary for sensitive/confidential data. The Recipient shall refrain from tracing or identifying the identity of any donors who provided the data. Recipient agrees to preserve, at all times, the confidentiality of information pertaining to identifiable donors. The Recipient agrees not to give access to data, in whole or part, or any identifiable data derived from the data, to any third party. The Recipient shall limit access to and processing of the data to those employees or other authorized representatives of Recipient who: (i) need to process such data in order to conduct their work in connection with the data and the Protocol and (ii) have signed agreements with the Recipient obligating them to maintain the confidentiality of the data and any information to be derived thereof or disclosed to them.

The Recipient shall not attempt to contact any data subject.

Recipient shall take reasonable steps to delete data for a given subject when the provider deems that subject to have withdrawn his or her consent. The Recipient confirms that it will deal promptly and appropriately with any withdrawals by donors/data subjects which the Provider notify to the Recipient.



On the Completion of the Research Project or on the termination of this agreement, the Recipient will delete the data and confirm to the provider (in writing) that this has taken place.

On reasonable notice to the Recipient, and in order to confirm or investigate compliance with the provisions of this DTA, the provider may itself or via appropriate third parties:

- choose to inspect the premises and other relevant facilities of the Recipient, in order to review the security, storage or other arrangements for the data;
- request such additional information about the Approved Research Project and/or its progress as the provider may, from time to time, reasonably require.
- the provider will bear the costs of such audits unless a data default within the procedures and processes of the Recipient is discovered, in which case the Recipient will be obliged to re-imburse the reasonable costs of the provider and any relevant third parties.

Any provisions of this agreement intended to protect the rights of human donors/data subjects shall survive the expiry or termination of this agreement.

#### 4. Intellectual Property

Title to the data is and remains in the ownership of the Provider and the data are made available to the Recipient as a service to the research community.

The Recipient shall be entitled to any inventions to the extent that these result from his own independent use of the data. He shall grant the Provider a worldwide non-exclusive royalty-free irrevocable research licence with respect to any such inventions. If the Recipient elects not to seek any intellectual property protection with respect to such inventions he shall transfer any such rights to the provider at no cost.

To the extent that the Provider and the Recipient have each contributed to an invention with respect to the material, they shall jointly own any rights to such an invention. Inventions made solely by the employees or agents of one party shall be owned by that party.

Except as expressly set forth in this Section, nothing herein shall be deemed to grant to either the Provider or Recipient any rights under the other party's patents, patent applications, trademarks, copyrights, trade secrets, know how (whether patentable or unpatentable) or other intellectual property rights.

#### 5. Return and publication of Results

The Recipient agrees that the Provider will publish - at a time not before the date of publication of a paper that describes the results of any analyses of the Material - via the Provider's website:

- General information about the analysis to the public.
- Summary data about the results to registered users of the Provider's website.



- De-identified subject-specific data about the results to registered users of the Provider's website.

## 6. Credits

The Recipient agrees to acknowledge the source of the data in any publications or other public disclosures reporting use of it. The following form of words should be used: "We acknowledge THE PROVIDER, funded by [...] for the supply of the Data".

## 7. Reports/Notification

The Recipient shall provide a copy of any report of its Results that derive from use of the Resource to the Provider in any format (e.g. paper journal, on-line report, meeting abstract).

Notices required under this DTA will be in writing and will be delivered by email to the addresses set out below or (in the event of a failure to deliver an email) by post to the Provider or the Recipient and will be deemed to be given, in the case of delivery by email, upon receipt at the Recipient's email server (unless an automatic response indicating an undeliverable message is received) and, in the case of delivery by post, on the date of delivery (or, if not a business day, on the first business day thereafter).

## 8. Expiry/Termination

This agreement shall expire ...[fill in date], unless earlier terminated by the mutual written agreement of the parties.

The Provider will be entitled to terminate this DTA forthwith by written notice to the Recipient if:

- The Recipient commits any breach of a data provision of this DTA and, in the case of a breach capable of remedy, fails to remedy the same within 20 days after receipt of a written notice giving particulars of the breach and requiring it to be remedied; a breach will be considered capable of remedy if the Recipient can comply with the provision in question in all respects other than as to the time of performance, provided that time of performance is not of the essence.
- The Recipient PI ceases to be employed (or otherwise engaged by) the Recipient Institution; or
- The Recipient Institution ceases, is likely to cease, or threatens to cease carrying on business.



The rights to terminate this DTA given by this clause will be without prejudice to any other right or remedy of either party in respect of the breach concerned, if any, or any other breach.

Upon expiry or termination of this Agreement:

- The grant of rights to the Recipient will be automatically terminated;
- The Recipient shall delete the data.

## 9. Charges/Payment

In consideration for the Provider's entering into this Agreement, the Recipient agrees to pay the Provider an amount of [specify fee and VAT, if applicable] by wire transfer to the Provider, account Number [..], swiftcode [..].

This DTA is conditional on the Access Charges being paid and so, for the avoidance of doubt, no biodata/data will be provided to the Recipient until or unless the access charges are received in full.

## 10. Assignment and sub-contracting

Neither party will be entitled to assign this DTA or any of its rights or obligations hereunder without first having received the written approval of the other party, which approval not to be unreasonably withheld or delayed. The Recipient will not sub-contract the performance of any of its obligations under the DTA or any part thereof without having first obtained the prior written consent of the Provider, such consent not to be unreasonably withheld. In the event that consent is granted, the Recipient shall be responsible for the acts, defaults and omissions of its sub-contractors as if they were the Recipient's own, and any consent given will not relieve the Recipient of any of its obligations under this DTA.

## 11. Limitation of Liability and Indemnity

The Recipient will indemnify the Provider against all losses (whether direct or indirect, reasonably foreseeable or specifically contemplated by the parties), damages, costs, expenses (including but not limited to reasonable legal costs and expenses) that it incurs as a result of: (i) the use, storage or disposal of human personal data by the Recipient; or (ii) any negligence or wilful default of the Recipient, provided that the Provider agrees to use its reasonable endeavours to mitigate any loss.

BOTH PARTIES ACKNOWLEDGE AND AGREE THAT THE MATERIALS ARE BEING SUPPLIED WITH NO WARRANTIES, EXPRESS OR IMPLIED, AND BIOBANK



EXPRESSLY DISCLAIMS ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT OR THAT THE DATA WILL NOT DEGRADE IN RECIPIENT'S SAFE KEEPING. NEITHER PARTY MAKES ANY REPRESENTATION THAT THE USE OF THE MATERIALS WILL NOT INFRINGE THE PATENT OR PROPRIETARY RIGHTS OF ANY THIRD PARTY.

IN NO EVENT SHALL EITHER PARTY BE LIABLE FOR ANY INDIRECT, INCIDENTAL, SPECIAL OR CONSEQUENTIAL DAMAGES ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT WHETHER OR NOT THAT PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF OR IS OTHERWISE ON NOTICE OF SUCH POSSIBILITY.

## 12. Force majeure

If any party is prevented from, hindered or delayed in performing any of its obligations under this DTA by reason of a Force Majeure Event, such party will promptly notify the other of the date of its commencement and the effects of the Force Majeure Event on its ability to perform its obligations under this DTA. If mutually agreed by the parties, then the obligations of the party so affected will thereupon be suspended for so long as the Force Majeure Event may continue. The party affected by a Force Majeure Event will not be liable for any failure to perform such of its obligations as are prevented by the Force Majeure Event provided that such party will use every reasonable effort to minimise the effects thereof and will resume performance as soon as possible after the removal of such Force Majeure Event. If the period of non-performance exceeds 28 days from the start of the Force Majeure Event then the non-affected party will have the option, by written notice to the other party, to terminate this DTA. For the purpose of this clause, Force Majeure Event means any event beyond the reasonable control of a party including, without limitation, acts of God, war, terrorism, riot, civil commotion, malicious damage, compliance with any law or governmental order, rule, regulation or direction, accident, fire, flood or storm. For the avoidance of doubt, strike, industrial action, failure of technology systems, third party insolvency and failure of the Provider or any other third party will not be considered to be Force Majeure Events. The provisions of this clause will not affect any other right which either party may have to terminate this DTA.

## 13. Applicable law and jurisdiction

This DTA will be governed by and construed in accordance with the laws of [insert appropriate jurisdiction]; parties agree that the [fill in nationality] courts will have exclusive jurisdiction over any suit, action, proceedings or dispute arising out of, or in connection with, this Agreement.



#### 14. General

This DTA governs the relationship between the parties to the exclusion of any other terms and conditions and, together with any other document referred to in this Agreement, constitutes the whole agreement between the parties in relation to the subject matter hereof.

If there is any conflict between the provisions of this DTA and any of the annexes and related documents (including, but without limitation, the provisions of the Access Procedures) then the provisions of this DTA will apply.

A waiver, delay or forbearance by either party, whether express or implied, in enforcing or exercising any of its rights or remedies hereunder will not constitute a waiver of such right or remedy.

No provision of this DTA is intended to be enforceable by any person who is not a party to this Agreement and nor are any rights granted to any third party under statute or otherwise.

Nothing in this DTA will create a partnership, joint venture or relationship of agency between the parties.

All variations to this DTA must be agreed, set out in writing and signed on behalf of the parties before they take effect.

#### 15. Attachments

This Agreement incorporates the attached terms and conditions (including any documents and/or data that are referred to in them), the Annexes and where applicable the contents of the Preliminary and Main Application Forms [reference number].

Signatures

Yours faithfully Accepted and agreed

For and on behalf of THE PROVIDER For and on behalf of Recipient Institution

For and on behalf of the Recipient Principal Investigator.