



EUROPEAN COMMISSION
DIRECTORATE-GENERAL JUSTICE

Directorate C: Fundamental rights and Union citizenship

Unit C.3: Data protection

Commission Decision C(2004)5721

SET II

**Standard contractual clauses for the transfer of personal data from the Community to third countries
(controller to controller transfers)**

Data transfer agreement

between

Name: Stichting Hartwig Medical Foundation

Address: Sciencepark 408, (1098 XH) Amsterdam, the Netherlands

Tel: +31 (0)20 235 2640

e-mail: info@hartwigmedicalfoundation.nl

hereinafter “**data exporter**”

and

Name: [●]

Address: [●]

Tel: [●]

e-mail: [●]

hereinafter “**data importer**”

each a “**party**”; together “**the parties**”.

Definitions

For the purposes of the clauses:

- a) “personal data”, “special categories of data/sensitive data”, “process/processing”, “controller”, “processor”, “data subject” and “supervisory authority/authority” shall have the same meaning as in Directive 95/46/EC of 24 October 1995 (whereby “the authority” shall mean the competent data protection authority in the territory in which the data exporter is established);
- b) “the data exporter” shall mean the controller who transfers the personal data;
- c) “the data importer” shall mean the controller who agrees to receive from the data exporter personal data for further processing in accordance with the terms of these clauses and who is not subject to a third country’s system ensuring adequate protection;
- d) “clauses” shall mean these contractual clauses, which are a free-standing document that does not incorporate commercial business terms established by the parties under separate commercial arrangements.

The details of the transfer (as well as the personal data covered) are specified in Annex B, which forms an integral part of the clauses.

I. Obligations of the data exporter

The data exporter warrants and undertakes that:

- a) The personal data have been collected, processed and transferred in accordance with the laws applicable to the data exporter.
- b) It has used reasonable efforts to determine that the data importer is able to satisfy its legal obligations under these clauses.
- c) It will provide the data importer, when so requested, with copies of relevant data protection laws or references to them (where relevant, and not including legal advice) of the country in which the data exporter is established.
- d) It will respond to enquiries from data subjects and the authority concerning processing of the personal data by the data importer, unless the parties have agreed that the data importer will so respond, in which case the data exporter will still respond to the extent reasonably possible and with the information reasonably available to it if the data importer is unwilling or unable to respond. Responses will be made within a reasonable time.
- e) It will make available, upon request, a copy of the clauses to data subjects who are third party beneficiaries under clause III, unless the clauses contain confidential information, in which case it may remove such information. Where information is removed, the data exporter shall inform data subjects in writing of the reason for removal and of their right to draw the removal to the attention of the authority. However, the data exporter shall abide by a decision of the authority regarding access to the full text of the clauses by data subjects, as long as data subjects have agreed to respect the confidentiality of the confidential information removed. The data exporter shall also provide a copy of the clauses to the authority where required.

II. Obligations of the data importer

The data importer warrants and undertakes that:

- a) It will have in place appropriate technical and organisational measures to protect the personal data against accidental or unlawful destruction or accidental loss, alteration, unauthorised disclosure or access, and which provide a level of security appropriate to the risk represented by the processing and the nature of the data to be protected.
- b) It will have in place procedures so that any third party it authorises to have access to the personal data, including processors, will respect and maintain the confidentiality and security of the personal data. Any person acting under the authority of the data importer, including a data processor, shall be obligated to process the personal data only on instructions from the data importer. This provision does not apply to persons authorised or required by law or regulation to have access to the personal data.
- c) It has no reason to believe, at the time of entering into these clauses, in the existence of any local laws that would have a substantial adverse effect on the guarantees provided for under these clauses, and it will inform the data exporter (which will pass such notification on to the authority where required) if it becomes aware of any such laws.
- d) It will process the personal data for purposes described in Annex B, and has the legal authority to give the warranties and fulfil the undertakings set out in these clauses.
- e) It will identify to the data exporter a contact point within its organisation authorised to respond to enquiries concerning processing of the personal data, and will cooperate in good faith with the data

exporter, the data subject and the authority concerning all such enquiries within a reasonable time. In case of legal dissolution of the data exporter, or if the parties have so agreed, the data importer will assume responsibility for compliance with the provisions of clause I(e).

- f) At the request of the data exporter, it will provide the data exporter with evidence of financial resources sufficient to fulfil its responsibilities under clause III (which may include insurance coverage).
- g) Upon reasonable request of the data exporter, it will submit its data processing facilities, data files and documentation needed for processing to reviewing, auditing and/or certifying by the data exporter (or any independent or impartial inspection agents or auditors, selected by the data exporter and not reasonably objected to by the data importer) to ascertain compliance with the warranties and undertakings in these clauses, with reasonable notice and during regular business hours. The request will be subject to any necessary consent or approval from a regulatory or supervisory authority within the country of the data importer, which consent or approval the data importer will attempt to obtain in a timely fashion.
- h) It will process the personal data, at its option, in accordance with:
 - i. the data protection laws of the country in which the data exporter is established, or
 - ii. the relevant provisions of any Commission decision pursuant to Article 25(6) of Directive 95/46/EC, where the data importer complies with the relevant provisions of such an authorisation or decision and is based in a country to which such an authorisation or decision pertains, but is not covered by such authorisation or decision for the purposes of the transfer(s) of the personal data, or
 - iii. the data processing principles set forth in Annex A.

Data importer to indicate which option it selects: iii

Initials of data importer:.....

- i) It will not disclose or transfer the personal data to a third party data controller located outside the European Economic Area (EEA) unless it notifies the data exporter about the transfer and
 - i. the third party data controller processes the personal data in accordance with a Commission decision finding that a third country provides adequate protection, or
 - ii. the third party data controller becomes a signatory to these clauses or another data transfer agreement approved by a competent authority in the EU, or
 - iii. data subjects have been given the opportunity to object, after having been informed of the purposes of the transfer, the categories of recipients and the fact that the countries to which data is exported may have different data protection standards, or
 - iv. with regard to onward transfers of sensitive data, data subjects have given their unambiguous consent to the onward transfer

III. Liability and third party rights

- a) Each party shall be liable to the other parties for damages it causes by any breach of these clauses. Liability as between the parties is limited to actual damage suffered. Punitive damages (i.e. damages intended to punish a party for its outrageous conduct) are specifically excluded. Each party shall be liable to data subjects for damages it causes by any breach of third party rights under these clauses. This does not affect the liability of the data exporter under its data protection law.
- b) The parties agree that a data subject shall have the right to enforce as a third party beneficiary this clause and clauses I(b), I(d), I(e), II(a), II(c), II(d), II(e), II(h), II(i), III(a), V, VI(d) and VII against the

data importer or the data exporter, for their respective breach of their contractual obligations, with regard to his personal data, and accept jurisdiction for this purpose in the data exporter's country of establishment. In cases involving allegations of breach by the data importer, the data subject must first request the data exporter to take appropriate action to enforce his rights against the data importer; if the data exporter does not take such action within a reasonable period (which under normal circumstances would be one month), the data subject may then enforce his rights against the data importer directly. A data subject is entitled to proceed directly against a data exporter that has failed to use reasonable efforts to determine that the data importer is able to satisfy its legal obligations under these clauses (the data exporter shall have the burden to prove that it took reasonable efforts).

IV. Law applicable to the clauses

These clauses shall be governed by the law of the country in which the data exporter is established, with the exception of the laws and regulations relating to processing of the personal data by the data importer under clause II(h), which shall apply only if so selected by the data importer under that clause.

V. Resolution of disputes with data subjects or the authority

- a) In the event of a dispute or claim brought by a data subject or the authority concerning the processing of the personal data against either or both of the parties, the parties will inform each other about any such disputes or claims, and will cooperate with a view to settling them amicably in a timely fashion.
- b) The parties agree to respond to any generally available non-binding mediation procedure initiated by a data subject or by the authority. If they do participate in the proceedings, the parties may elect to do so remotely (such as by telephone or other electronic means). The parties also agree to consider participating in any other arbitration, mediation or other dispute resolution proceedings developed for data protection disputes.
- c) Each party shall abide by a decision of a competent court of the data exporter's country of establishment or of the authority which is final and against which no further appeal is possible.

VI. Termination

- a) In the event that the data importer is in breach of its obligations under these clauses, then the data exporter may temporarily suspend the transfer of personal data to the data importer until the breach is repaired or the contract is terminated.
- b) In the event that:
 - i. the transfer of personal data to the data importer has been temporarily suspended by the data exporter for longer than one month pursuant to paragraph (a);
 - ii. compliance by the data importer with these clauses would put it in breach of its legal or regulatory obligations in the country of import;
 - iii. the data importer is in substantial or persistent breach of any warranties or undertakings given by it under these clauses;
 - iv. a final decision against which no further appeal is possible of a competent court of the data exporter's country of establishment or of the authority rules that there has been a breach of the clauses by the data importer or the data exporter; or
 - v. a petition is presented for the administration or winding up of the data importer, whether in its personal or business capacity, which petition is not dismissed within the applicable period for such dismissal under applicable law; a winding up order is made; a receiver is appointed over any of its assets; a trustee in bankruptcy is appointed, if the data importer is

an individual; a company voluntary arrangement is commenced by it; or any equivalent event in any jurisdiction occurs

then the data exporter, without prejudice to any other rights which it may have against the data importer, shall be entitled to terminate these clauses, in which case the authority shall be informed where required. In cases covered by (i), (ii), or (iv) above the data importer may also terminate these clauses.

- c) Either party may terminate these clauses if (i) any Commission positive adequacy decision under Article 25(6) of Directive 95/46/EC (or any superseding text) is issued in relation to the country (or a sector thereof) to which the data is transferred and processed by the data importer, or (ii) Directive 95/46/EC (or any superseding text) becomes directly applicable in such country.
- d) The parties agree that the termination of these clauses at any time, in any circumstances and for whatever reason (except for termination under clause VI(c)) does not exempt them from the obligations and/or conditions under the clauses as regards the processing of the personal data transferred.

VII. Variation of these clauses

The parties may not modify these clauses except to update any information in Annex B, in which case they will inform the authority where required. This does not preclude the parties from adding additional commercial clauses where required.

VIII. Description of the Transfer

The details of the transfer and of the personal data are specified in Annex B. The parties agree that Annex B may contain confidential business information which they will not disclose to third parties, except as required by law or in response to a competent regulatory or government agency, or as required under clause I(e). The parties may execute additional annexes to cover additional transfers, which will be submitted to the authority where required. Annex B may, in the alternative, be drafted to cover multiple transfers.

Dated:.....

FOR DATA IMPORTER

FOR DATA EXPORTER

[●]

Hans van Snellenberg

Signature: _____

Signature: _____

DATA PROCESSING PRINCIPLES

1. Purpose limitation: Personal data may be processed and subsequently used or further communicated only for purposes described in Annex B or subsequently authorised by the data subject.
2. Data quality and proportionality: Personal data must be accurate and, where necessary, kept up to date. The personal data must be adequate, relevant and not excessive in relation to the purposes for which they are transferred and further processed.
3. Transparency: Data subjects must be provided with information necessary to ensure fair processing (such as information about the purposes of processing and about the transfer), unless such information has already been given by the data exporter.
4. Security and confidentiality: Technical and organisational security measures must be taken by the data controller that are appropriate to the risks, such as against accidental or unlawful destruction or accidental loss, alteration, unauthorised disclosure or access, presented by the processing. Any person acting under the authority of the data controller, including a processor, must not process the data except on instructions from the data controller.
5. Rights of access, rectification, deletion and objection: As provided in Article 12 of Directive 95/46/EC, data subjects must, whether directly or via a third party, be provided with the personal information about them that an organisation holds, except for requests which are manifestly abusive, based on unreasonable intervals or their number or repetitive or systematic nature, or for which access need not be granted under the law of the country of the data exporter. Provided that the authority has given its prior approval, access need also not be granted when doing so would be likely to seriously harm the interests of the data importer or other organisations dealing with the data importer and such interests are not overridden by the interests for fundamental rights and freedoms of the data subject. The sources of the personal data need not be identified when this is not possible by reasonable efforts, or where the rights of persons other than the individual would be violated. Data subjects must be able to have the personal information about them rectified, amended, or deleted where it is inaccurate or processed against these principles. If there are compelling grounds to doubt the legitimacy of the request, the organisation may require further justifications before proceeding to rectification, amendment or deletion. Notification of any rectification, amendment or deletion to third parties to whom the data have been disclosed need not be made when this involves a disproportionate effort. A data subject must also be able to object to the processing of the personal data relating to him if there are compelling legitimate grounds relating to his particular situation. The burden of proof for any refusal rests on the data importer, and the data subject may always challenge a refusal before the authority.
6. Sensitive data: The data importer shall take such additional measures (e.g. relating to security) as are necessary to protect such sensitive data in accordance with its obligations under clause II.
7. Data used for marketing purposes: Where data are processed for the purposes of direct marketing, effective procedures should exist allowing the data subject at any time to “opt-out” from having his data used for such purposes.
8. Automated decisions: For purposes hereof “automated decision” shall mean a decision by the data exporter or the data importer which produces legal effects concerning a data subject or significantly affects a data subject and which is based solely on automated processing of personal data intended to evaluate certain personal aspects relating to him, such as his performance at work, creditworthiness, reliability, conduct, etc. The data importer shall not make any automated decisions concerning data subjects, except when:
 - a) i. such decisions are made by the data importer in entering into or performing a contract with the data subject, and

ii. the data subject is given an opportunity to discuss the results of a relevant automated decision with a representative of the parties making such decision or otherwise to make representations to that parties.

or

b) where otherwise provided by the law of the data exporter.

APPENDIX B

DESCRIPTION OF THE TRANSFER

(To be completed by the parties)

Data subjects

The personal data transferred concern the following categories of data subjects:

[● Patients of healthcare institutions in the Netherlands]

Purposes of the transfer(s)

The transfer is made for the following purposes:

[● To enable the data importer to conduct a research as further described in the Data Access Request Form submitted to data exporter, which Data Access Request Form is attached as Annex I to the License Agreement to which these clauses are attached.]

Categories of data

The personal data transferred concern the following categories of data:

[● Depending on what is requested in the Data Request Form and approved by the Data Access Board] [● Encoded patient data (year of birth, gender, previous treatment data, post-biopsy treatment data), encoded tumor data (primary tumor, biopsy location) and encoded genetic data, including somatic, structural variants, copy number regions, purity.]

Recipients

The personal data transferred may be disclosed only to the following recipients or categories of recipients:

[● Persons working for data importer and participate in the research for which the personal data are received by the data importer.]

Sensitive data (if appropriate)

The personal data transferred concern the following categories of sensitive data:

[● Health data and genetic data]

Additional useful information (storage limits and other relevant information):

[● The Parties have agreed upon additional rights and obligations of the data importer in relation to the use of the personal data in the License Agreement to which these clauses are attached.]

Contact points for data protection enquiries

Data importer

[● Name party]

Address: [●]

Attn.: [●]

Telephone: [●]

Email: [●]

Data exporter

Hartwig Medical Foundation

Address: Sciencepark 408, 1098 XH Amsterdam, the Netherlands

Attn.: Hans van Snellenberg

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