**SCHEDULE 1 TO THE MSBASE REGISTRY PARTICIPATION AGREEMENT**

**- MSBASE DATA PROCESSING AGREEMENT**

**Prepared for: [centre code], [centre name]**

# INTRODUCTION

This data processing agreement (the “Data Processing Agreement”) sets forth the Centre's rights and obligations as data controller ("Data Controller") and MSBase's rights and obligations as data processor ("Data Processor") when MSBase processes personal data on the Centre's behalf when providing the Services and forms part of the MSBase Participation Agreement. All capitalised but undefined terms in this Data Processing Agreement shall have the meaning given to them in the Agreement.

In this Data Processing Agreement, the terms:

* "Data Controller", "Data Subject", "processing", "Data Processor" and "personal data" bear the respective meanings given to them in the applicable data protection laws. For clarity, a reference to "personal data" shall for the purposes of this Schedule be deemed to be a reference to personal data provided by the Data Controller or its users pursuant to the Agreement; and
* "data protection laws" means all laws, regulations and decisions by competent authorities as well as authority guidance in each Centre’s jurisdiction, or in the EU/EEA as well as the European Data Protection Board's binding regulations and decisions as applicable, that apply to the processing of personal data in the context of the Data Processing Agreement.

This Data Processing Agreement include the following appendices:

* Appendix 1A – Data processing Instructions
* Appendix 1B – Sub-processors
* Appendix 1C – Standard Contractual Clauses for third party transfers

# PROCESSING OF PERSONAL DATA

Data Processor undertakes to only process personal data in accordance with documented instructions from the Data Controller, unless required to act otherwise according to applicable data protection laws; in such event, the Data Processor shall notify the Data Controller of that legal requirement before processing, unless that law prohibits such notification. The Data Controller's initial instructions to the Data Processor regarding the subject-matter and duration of the processing, the nature and purpose of the processing, the type of personal data and categories of data subjects are set forth in this Data Processing Agreement and in Appendix 1A. Any changes to the Data Controller's instructions shall be negotiated separately and, to be valid, documented in writing.

The Data Controller warrants to the Data Processor that:

* it has the right to lawfully supply the data (including any personal data) and has obtained and will maintain all necessary rights, licences, consents and authorisations to transmit the personal data to the Data Processor and to permit it to be processed and used for the purposes contemplated by the Agreement;
* any data (including personal data) which it transmits to the Data Processor will be accurate and up to date and that the Data Controller shall have sole responsibility for the legality, reliability, integrity, accuracy and quality of that data;
* it shall comply with all applicable data protection laws (including ensuring that the instructions it provides to the Data Processor in relation to the processing and collecting of such personal data also complies with data protection laws).

The Data Controller confirms that, except for any written instruction provided in specific cases, the obligations of Data Processor set out in this Data Processing Agreement, including Appendices 1A, 1B and 1C, constitutes the full and complete instructions to be carried out by Data Processor. Any changes to the Data Controller's instructions shall be negotiated separately and, to be valid, documented in writing in Appendix 1A, and duly signed by both parties.

The Data Processor shall, to the extent required under applicable data protection laws and in accordance with the Data Controller's written instruction in each case, assist the Data Controller in fulfilling its legal obligations under such laws.

# EXERCISE OF ACCESS RIGHTS ETC

If data subjects, competent authorities or any other third parties request information from Data Processor regarding the processing of personal data, Data Processor shall refer such request to the Data Controller. Subject to clause 3.2 (disclosure) and 4.7 (standard contractual clauses), Data Processor may not in any way act on behalf of or as a representative of the Data Controller and may not, without prior instructions from the Data Controller, transfer or in any other way disclose personal data or any other information relating to the processing of personal data to any third party except in accordance with this Data Processing Agreement.

In the event Data Processor, according to applicable laws and regulations, is required to disclose personal data that Data Processor processes on behalf of the Data Controller, Data Processor shall be obliged to inform the Data Controller thereof immediately and request confidentiality in conjunction with the disclosure of requested information.

# SUB-PROCESSORS AND THIRD COUNTRY TRANSFERS

Subject to clause 4.2, the Data Processor may engage additional or replacement sub-processors to process the personal data on behalf of the Data Processor without obtaining any further written, specific authorisation from the Data Controller. Prior to Data Processor engaging any new sub-processor to carry out processing activities of the personal data on behalf of the Data Controller, the Data Processor will notify the Data Controller of such change ("Initial Notice"). If the Data Controller initially objects to an additional or replacement sub-processor:

* the Data Processor shall provide the Data Controller with any additional information reasonably requested by the Data Controller to enable the Data Controller to assess whether the use of the proposed sub-processor will ensure the Data Controller's compliance with this Data Processing Agreement and the data protection laws;
* subsequently, if the Data Controller (acting reasonably) can demonstrate to Data Processor that such compliance will not be maintained through the proposed sub-processor, the Data Controller shall be entitled to terminate the Agreement on 28 days' written notice provided such notice is given within 14 days of the Initial Notice.

Where Data Processor authorises any sub-processor as described in clause 4.1, the Data Processor shall:

* restrict the sub-processor's access to Data Controller's data (including any personal data) only to what is necessary to maintain the Services or to provide the Services to Data Controller in accordance with Appendix 1A and Data Processor will prohibit the sub-processor from accessing the data (including any personal data) for any other purpose;
* enter into a written contract with the sub-processor that requires it to comply with the same data processing obligations to those contained in this Data Processing Agreement, and, upon the Data Controller's written request, provides the Data Controller with copies of such contracts; and
* be accountable to the Data Controller for the acts or omissions of any sub-processor as if such acts or omissions were acts or omission of the Data Processor.

Appendix 1B contains a list of pre-approved sub-processors as of the date of entry into force of the Data Processing Agreement.

The Data Controller recognises and accepts that the Data Processor, in accordance with what is stated in Appendix 1B, is engaging Microsoft Azure Australia (“Microsoft”) as an approved sub-processor, and that the Data Processor has entered into a data processing agreement with Microsoft based on Microsoft’s standards for data processing agreements. Provided that and to the extent it does not cause Data Controller or Data Processor to be in breach of any applicable data protection laws, Data Processor shall not be obligated to enforce on Microsoft other obligations regarding the processing of personal data other than what is contained in the Microsoft standard data processing agreement that has been entered into between Microsoft and the Data Processor.

The Data Controller agrees to the transfer of personal data to, or access to personal data from, sub-processor(s) in Australia or other locations outside of the EU/EEA, as provided in Appendix 1B.

Through this Data Processing Agreement, the parties agree to the standard contractual clauses in Appendix 1C.

Through this Data Processing Agreement, the Data Processor is authorised to enter into standard contractual clauses in Appendix 1C with sub-processors.

The Data Processor shall inform the Data Controller if an adequate level of protection can no longer be guaranteed for the transfer of personal data to, or access from, a country outside the EU/EEA. Furthermore, in such situation, the Data Processor shall immediately take relevant measures to ensure that the personal data is processed in accordance with the applicable data protection laws and inform the Data Controller on what measures have been taken.

# InFORMATION SECURITY AND CONFIDENTIALITY

Data Processor shall be obligated to fulfil any legal obligations imposed on it regarding information security under applicable data protection laws and shall in any case take appropriate technical and organizational measures to protect the personal data which is processed.

The MSBase Information Security Policy is provided as part of the MSBase governance package and details the technical and organisational security measures implemented by the Data Processor.

The Data Processor undertakes not to, without the Data Controller's prior written consent, disclose or otherwise make personal data processed under this Data Processing Agreement available to any third party, except for approved sub-processors engaged in accordance with this data processing agreement.

The Data Processor shall be obliged to ensure that only such staff and other Data Processor representatives that directly require access to personal data in order to fulfil the Data Processor's obligations in accordance with this Data Processing Agreement have access to such information. The Data Processor shall ensure that such staff and other Data Processor representatives are bound by a confidentiality obligation concerning this information to the same extent as the Data Processor in accordance with this data processing agreement.

# DATA BREACH NOTIFICATIONS

 Data Processor shall inform the Data Controller without undue delay after becoming aware of any accidental or unauthorized access to personal data or any other security incidents (personal data breach).

 Data Processor shall assist Data Controller with any information reasonably required to fulfil its data breach notification requirements.

# AUDIT RIGHTS

 The Data Controller shall be entitled to take measures necessary to verify that Data Processor is able to comply with its obligations under this Data Processing Agreement, and that Data Processor has in fact undertaken the measures to ensure such compliance. Data Processor undertakes to make available to the Data Controller all information and all assistance necessary to demonstrate compliance with the obligations laid down in this data processing agreement and allow for and contribute to audits, including on-site inspections, conducted by the Data Controller or another auditor mandated by the Data Controller.

 The Data Processor shall immediately inform the Data Controller if, in its opinion, an instruction provided to Data Processor when Data Controller exercises its rights under clause 7.1 above, infringes applicable data protection laws.

# MEASURES UPON COMPLETION OF PROCESSING OF PERSONAL DATA

 Upon expiry of the Agreement and this Data Processing Agreement, the Data Processor will, if not instructed otherwise in writing by the Data Controller, erase any personal data processed under this data processing agreement 90 days after the expiry date.

 Upon request by the Data Controller, Data Processor shall provide a written notice of the measures taken regarding the personal data set out in clause 8.1.

# COMPENSATION

 In light of the formulation of the Services, the Data Processor shall be entitled to compensation for processing of personal data required by the Data Controller in accordance with what is stated in this clause 9.

 The Data Processor will be entitled to reasonable compensation on a time and materials basis in accordance with the then hourly rates in Data Processor's rate card to the extent the Data Controller

1. requires the Data Processor to assist the Data Controller in accordance with clauses 2.4, 3.1 and/or 6.2,
2. requires any audit in accordance with clause 7, and/or
3. requires measures to be made following upon completion of processing in accordance with clause 8. The right to compensation only applies to the extent the measure is not already part of the Services or the Services' functionality.

 In case of changed instructions in accordance with clause 2.1 the Data Processor shall be entitled to compensation for any documented additional costs for the performance of the Services which are due to the change, unless the change is caused by general demands on the Services that cannot be specifically attributed to the Data Controller, e.g. amendments or changes to applicable legislation or industry standards. The Data Processor shall further not be entitled to compensation to the extent the change otherwise corresponds to the obligations that a supplier of similar services as the Services normally can be expected to offer to its Centres on reasonable terms and conditions.

# LIABILITY

A party shall be fully liable for and indemnify the other party for any claims attributable to any damage caused by and losses incurred as a result of the other party not fulfilling its obligations under this Data Processor Agreement or data protection laws.

In case of claims from data subjects arising from a breach by the other party of this Data Processor Agreement or breach of data protection laws, the party who has been held liable for (or otherwise incurred liability in relation to) the claim shall be entitled to regressively recover the share of such losses which, according to applicable data protection laws, is attributable to the other party, and a fair share of the litigation costs which that party has incurred in relation to such dispute with the Data Subjects.

A party who is subject to claims from a Data Subject shall:

1. without undue delay notify the other party in writing of stated claims, if it is probable that claims against the other party pursuant to this clause 10 may be made,
2. under negotiation or trial in court and before any settlement or other arrangement with the Data Subject allow the other party
	1. to get access to the Data Subject’s and the party’s pleadings and any other correspondence; and
	2. to comment on these, which are also reasonably taken into account to the extent that the comments may have an impact on the size of the claim for damage.

A party’s liability for other types of damages other than those expressly regulated by this Data Processor Agreement shall, unless otherwise stated in the Agreement, annually be limited to direct damage and an amount corresponding to a maximum amount of AUD 10,000.00.

A party’s liability to pay for damages under this clause 10 also applies after the Agreement otherwise has been terminated.

APPENDIX 1A – DATA PROCESSING INSTRUCTIONS

**Purposes**

1. Provisioning of the web-based MSBase Registry and the locally installed MSBase Data-entry Software (MDS), and to provide operational and administrative support, enabling Centers and its Principal Investigators to conduct analyses and studies using the MSBase Registry Platform.
2. System development and testing to ensure quality of Services provided in accordance with a) above.
3. Maintenance and care of registry platform.
4. Transfer of data to third parties as part of any research project or other relevant data sharing initiative that the Data Controller wishes to pursue, as further instructed on a case-by-case basis in relation to the specific recipient and purpose of the transfer.

**Categories of data**

**Centre Patients – MSBase Registry Minimum Dataset**

Patient profile information (Patient GUID, Gender, Birth date, Date of MS onset), Centre visits (Visit Date, KFS, EDSS), Paraclinical tests (Test date, Test type), Relapses (Relapse Date, CNS region, Information on corticosteroids), Treatments (Treatment ID, Start date, End date)

**Centre Patients – MSBase Registry Comprehensive Data Dictionary (optional data fields)**

<https://www.msbase.org/media/1197/mds-data-dictionary.pdf>

**MSBase Member’s User Profile Data Fields**

Title, First name, Last name, Email, Birth year, Gender, Country of practice, Preferred phone, Profession/Role, University/Medical School, Year of highest medical degree, EDSS certification, Affiliation for publication purposes

**MSBase Member’s Centre Profile Data Fields**

Centre name, Hospital, Department, Street Address, City, Country, Postal code, Primary phone, Fax

**Categories of Data Subjects**

Centre Patients

 MSBase Members

**Processing Operations**

Registration, collection, storing, processing and distribution.

**Location of Processing Operations**

Processing operations are located in the jurisdiction of respective Centre and in Australia, with hosting through Microsoft Azure South East Australia datacentre.

**Information Security**

The MSBase Information Security policy is available upon request from the MSBase Operations Team.

APPENDIX 1B – SUB-PROCESSORS

1. Approved Sub-Processors

The following sub-processors shall be considered approved by the Data Controller at the time of entering into the Agreement:

1. Microsoft Azure

Australia Southeast Datacentre

Australian Business Number: 29 002 589 460

1. Kiandra IT

28/570 Bourke Street

Melbourne VIC 3000, Australia

Australian Business Number: 15 070 937 656

iii. Icometrix

Kolonel Begaultlaan 1b / 12

3012 Leuven

Belgium

iiii. ProSynergie Sàrl

Rue Alexandre Gavard, 16

1227 Carouge

Switzerland

Swiss Commercial Register Number: CHE-113.526.430

APPENDIX 1C – STANDARD CONTRACTUAL CLAUSES

1. STANDARD CONTRACTUAL CLAUSES (PROCESSORS)

For the purposes of Article 26(2) of Directive 95/46/EC for the transfer of personal data to processors established in third countries which do not ensure an adequate level of data protection:

**Name of the data exporting organisation (i.e. MSBase Centre):** Centre name, Centre code

**Centre Address:** xxx

**Telephone:** xxx

**Fax:** xxx

**Email(s):** xxx

**Other information needed to identify the organisation** (data **exporter):** N/A

**and**

**Name of the data importing organisation:** MSBase Foundation Ltd

**Address:** Central Clinical School, Level 6, The Alfred Centre

 99 Commercial Road

 Melbourne VIC 3004, AUSTRALIA

**Telephone:** +61 3 9903 8264;

**Email:** info@msbase.org

**Other information needed to identify the organisation** (the data **importer**)**:**

<https://www.msbase.org/>

each a ‘party’; together ‘the parties’,

HAVE AGREED on the following Contractual Clauses (the Clauses) in order to adduce adequate safeguards with respect to the protection of privacy and fundamental rights and freedoms of individuals for the transfer by the data exporter to the data importer of the personal data specified in Subappendix 1.

***Clause 1***

**Definitions**

For the purposes of the Clauses:

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| (a) | ‘personal data’, ‘special categories of data’, ‘process/processing’, ‘controller’, ‘processor’, ‘data subject’ and ‘supervisory authority’ shall have the same meaning as in Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data[[1]](#footnote-1); |

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| (b) | ‘the data exporter’ means the controller who transfers the personal data; |

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| (c) | ‘the data importer’ means the processor who agrees to receive from the data exporter personal data intended for processing on his behalf after the transfer in accordance with his instructions and the terms of the Clauses and who is not subject to a third country’s system ensuring adequate protection within the meaning of Article 25(1) of Directive 95/46/EC; |

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| (d) | ‘the sub-processor’ means any processor engaged by the data importer or by any other sub-processor of the data importer who agrees to receive from the data importer or from any other sub-processor of the data importer personal data exclusively intended for processing activities to be carried out on behalf of the data exporter after the transfer in accordance with his instructions, the terms of the Clauses and the terms of the written subcontract; |

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| (e) | ‘the applicable data protection law’ means the legislation protecting the fundamental rights and freedoms of individuals and, in particular, their right to privacy with respect to the processing of personal data applicable to a data controller in the Member State in which the data exporter is established; |

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| (f) | ‘technical and organisational security measures’ means those measures aimed at protecting personal data against accidental or unlawful destruction or accidental loss, alteration, unauthorised disclosure or access, in particular where the processing involves the transmission of data over a network, and against all other unlawful forms of processing. |

***Clause 2***

**Details of the transfer**

The details of the transfer and in particular the special categories of personal data where applicable are specified in Subappendix 1 which forms an integral part of the Clauses.

***Clause 3***

**Third-party beneficiary clause**

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| 1. | The data subject can enforce against the data exporter this Clause, Clause 4(b) to (i), Clause 5(a) to (e), and (g) to (j), Clause 6(1) and (2), Clause 7, Clause 8(2), and Clauses 9 to 12 as third-party beneficiary. |

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| 2. | The data subject can enforce against the data importer this Clause, Clause 5(a) to (e) and (g), Clause 6, Clause 7, Clause 8(2), and Clauses 9 to 12, in cases where the data exporter has factually disappeared or has ceased to exist in law unless any successor entity has assumed the entire legal obligations of the data exporter by contract or by operation of law, as a result of which it takes on the rights and obligations of the data exporter, in which case the data subject can enforce them against such entity. |

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| 3. | The data subject can enforce against the sub-processor this Clause, Clause 5(a) to (e) and (g), Clause 6, Clause 7, Clause 8(2), and Clauses 9 to 12, in cases where both the data exporter and the data importer have factually disappeared or ceased to exist in law or have become insolvent, unless any successor entity has assumed the entire legal obligations of the data exporter by contract or by operation of law as a result of which it takes on the rights and obligations of the data exporter, in which case the data subject can enforce them against such entity. Such third-party liability of the sub-processor shall be limited to its own processing operations under the Clauses. |

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| 4. | The parties do not object to a data subject being represented by an association or other body if the data subject so expressly wishes and if permitted by national law. |

***Clause 4***

**Obligations of the data exporter**

The data exporter agrees and warrants:

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| (a) | that the processing, including the transfer itself, of the personal data has been and will continue to be carried out in accordance with the relevant provisions of the applicable data protection law (and, where applicable, has been notified to the relevant authorities of the Member State where the data exporter is established) and does not violate the relevant provisions of that State; |

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| (b) | that it has instructed and throughout the duration of the personal data-processing services will instruct the data importer to process the personal data transferred only on the data exporter’s behalf and in accordance with the applicable data protection law and the Clauses; |

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| (c) | that the data importer will provide sufficient guarantees in respect of the technical and organisational security measures specified in Subappendix 2 to this contract; |

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| (d) | that after assessment of the requirements of the applicable data protection law, the security measures are appropriate to protect personal data against accidental or unlawful destruction or accidental loss, alteration, unauthorised disclosure or access, in particular where the processing involves the transmission of data over a network, and against all other unlawful forms of processing, and that these measures ensure a level of security appropriate to the risks presented by the processing and the nature of the data to be protected having regard to the state of the art and the cost of their implementation; |

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| (e) | that it will ensure compliance with the security measures; |

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| (f) | that, if the transfer involves special categories of data, the data subject has been informed or will be informed before, or as soon as possible after, the transfer that its data could be transmitted to a third country not providing adequate protection within the meaning of Directive 95/46/EC; |

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| (g) | to forward any notification received from the data importer or any sub-processor pursuant to Clause 5(b) and Clause 8(3) to the data protection supervisory authority if the data exporter decides to continue the transfer or to lift the suspension; |

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| (h) | to make available to the data subjects upon request a copy of the Clauses, with the exception of Subappendix 2, and a summary description of the security measures, as well as a copy of any contract for sub-processing services which has to be made in accordance with the Clauses, unless the Clauses or the contract contain commercial information, in which case it may remove such commercial information; |

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| (i) | that, in the event of sub-processing, the processing activity is carried out in accordance with Clause 11 by a sub-processor providing at least the same level of protection for the personal data and the rights of data subject as the data importer under the Clauses; and |

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| (j) | that it will ensure compliance with Clause 4(a) to (i). |

***Clause 5***

**Obligations of the data importer**[[2]](#footnote-2)

The data importer agrees and warrants:

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| (a) | to process the personal data only on behalf of the data exporter and in compliance with its instructions and the Clauses; if it cannot provide such compliance for whatever reasons, it agrees to inform promptly the data exporter of its inability to comply, in which case the data exporter is entitled to suspend the transfer of data and/or terminate the contract; |

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| (b) | that it has no reason to believe that the legislation applicable to it prevents it from fulfilling the instructions received from the data exporter and its obligations under the contract and that in the event of a change in this legislation which is likely to have a substantial adverse effect on the warranties and obligations provided by the Clauses, it will promptly notify the change to the data exporter as soon as it is aware, in which case the data exporter is entitled to suspend the transfer of data and/or terminate the contract; |

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| (c) | that it has implemented the technical and organisational security measures specified in Subappendix 2 before processing the personal data transferred; |

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| (d) | that it will promptly notify the data exporter about:

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| (i) | any legally binding request for disclosure of the personal data by a law enforcement authority unless otherwise prohibited, such as a prohibition under criminal law to preserve the confidentiality of a law enforcement investigation; |

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| (ii) | any accidental or unauthorised access; and |

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| (iii) | any request received directly from the data subjects without responding to that request, unless it has been otherwise authorised to do so; |

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| (e) | to deal promptly and properly with all inquiries from the data exporter relating to its processing of the personal data subject to the transfer and to abide by the advice of the supervisory authority with regard to the processing of the data transferred; |

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| (f) | at the request of the data exporter to submit its data-processing facilities for audit of the processing activities covered by the Clauses which shall be carried out by the data exporter or an inspection body composed of independent members and in possession of the required professional qualifications bound by a duty of confidentiality, selected by the data exporter, where applicable, in agreement with the supervisory authority; |

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| (g) | to make available to the data subject upon request a copy of the Clauses, or any existing contract for sub-processing, unless the Clauses or contract contain commercial information, in which case it may remove such commercial information, with the exception of Subappendix 2 which shall be replaced by a summary description of the security measures in those cases where the data subject is unable to obtain a copy from the data exporter; |

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| (h) | that, in the event of sub-processing, it has previously informed the data exporter and obtained its prior written consent; |

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| (i) | that the processing services by the sub-processor will be carried out in accordance with Clause 11; |

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| (j) | to send promptly a copy of any sub-processor agreement it concludes under the Clauses to the data exporter. |

***Clause 6***

**Liability**

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| 1. | The parties agree that any data subject, who has suffered damage as a result of any breach of the obligations referred to in Clause 3 or in Clause 11 by any party or sub-processor is entitled to receive compensation from the data exporter for the damage suffered. |

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| 2. | If a data subject is not able to bring a claim for compensation in accordance with paragraph 1 against the data exporter, arising out of a breach by the data importer or his sub-processor of any of their obligations referred to in Clause 3 or in Clause 11, because the data exporter has factually disappeared or ceased to exist in law or has become insolvent, the data importer agrees that the data subject may issue a claim against the data importer as if it were the data exporter, unless any successor entity has assumed the entire legal obligations of the data exporter by contract of by operation of law, in which case the data subject can enforce its rights against such entity.The data importer may not rely on a breach by a sub-processor of its obligations in order to avoid its own liabilities. |

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| 3. | If a data subject is not able to bring a claim against the data exporter or the data importer referred to in paragraphs 1 and 2, arising out of a breach by the sub-processor of any of their obligations referred to in Clause 3 or in Clause 11 because both the data exporter and the data importer have factually disappeared or ceased to exist in law or have become insolvent, the sub-processor agrees that the data subject may issue a claim against the data sub-processor with regard to its own processing operations under the Clauses as if it were the data exporter or the data importer, unless any successor entity has assumed the entire legal obligations of the data exporter or data importer by contract or by operation of law, in which case the data subject can enforce its rights against such entity. The liability of the sub-processor shall be limited to its own processing operations under the Clauses. |

***Clause 7***

**Mediation and jurisdiction**

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| 1. | The data importer agrees that if the data subject invokes against it third-party beneficiary rights and/or claims compensation for damages under the Clauses, the data importer will accept the decision of the data subject:

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| (a) | to refer the dispute to mediation, by an independent person or, where applicable, by the supervisory authority; |

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| (b) | to refer the dispute to the courts in the Member State in which the data exporter is established. |

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| 2. | The parties agree that the choice made by the data subject will not prejudice its substantive or procedural rights to seek remedies in accordance with other provisions of national or international law. |

***Clause 8***

**Cooperation with supervisory authorities**

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| 1. | The data exporter agrees to deposit a copy of this contract with the supervisory authority if it so requests or if such deposit is required under the applicable data protection law. |

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| 2. | The parties agree that the supervisory authority has the right to conduct an audit of the data importer, and of any sub-processor, which has the same scope and is subject to the same conditions as would apply to an audit of the data exporter under the applicable data protection law. |

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| 3. | The data importer shall promptly inform the data exporter about the existence of legislation applicable to it or any sub-processor preventing the conduct of an audit of the data importer, or any sub-processor, pursuant to paragraph 2. In such a case the data exporter shall be entitled to take the measures foreseen in Clause 5(b). |

***Clause 9***

**Governing law**

The Clauses shall be governed by the law of the Member State in which the data exporter is established, namely [insert country].

***Clause 10***

**Variation of the contract**

The parties undertake not to vary or modify the Clauses. This does not preclude the parties from adding clauses on business related issues where required as long as they do not contradict the Clause.

***Clause 11***

**Sub-processing**

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| 1. | The data importer shall not subcontract any of its processing operations performed on behalf of the data exporter under the Clauses without the prior written consent of the data exporter. Where the data importer subcontracts its obligations under the Clauses, with the consent of the data exporter, it shall do so only by way of a written agreement with the sub-processor which imposes the same obligations on the sub-processor as are imposed on the data importer under the Clauses.[[3]](#footnote-3) Where the sub-processor fails to fulfil its data protection obligations under such written agreement the data importer shall remain fully liable to the data exporter for the performance of the sub-processor’s obligations under such agreement. |

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| 2. | The prior written contract between the data importer and the sub-processor shall also provide for a third-party beneficiary clause as laid down in Clause 3 for cases where the data subject is not able to bring the claim for compensation referred to in paragraph 1 of Clause 6 against the data exporter or the data importer because they have factually disappeared or have ceased to exist in law or have become insolvent and no successor entity has assumed the entire legal obligations of the data exporter or data importer by contract or by operation of law. Such third-party liability of the sub-processor shall be limited to its own processing operations under the Clauses. |

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| 3. | The provisions relating to data protection aspects for sub-processing of the contract referred to in paragraph 1 shall be governed by the law of the Member State in which the data exporter is established, namely [insert country]. |

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| 4. | The data exporter shall keep a list of sub-processing agreements concluded under the Clauses and notified by the data importer pursuant to Clause 5(j), which shall be updated at least once a year. The list shall be available to the data exporter’s data protection supervisory authority. |

***Clause 12***

**Obligation after the termination of personal data-processing services**

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| 1. | The parties agree that on the termination of the provision of data-processing services, the data importer and the sub-processor shall, at the choice of the data exporter, return all the personal data transferred and the copies thereof to the data exporter or shall destroy all the personal data and certify to the data exporter that it has done so, unless legislation imposed upon the data importer prevents it from returning or destroying all or part of the personal data transferred. In that case, the data importer warrants that it will guarantee the confidentiality of the personal data transferred and will not actively process the personal data transferred anymore. |

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| 2. | The data importer and the sub-processor warrant that upon request of the data exporter and/or of the supervisory authority, it will submit its data-processing facilities for an audit of the measures referred to in paragraph 1. |

**Subappendix 1**

**to the Standard Contractual Clauses**

This Subappendix forms part of the Clauses and must be completed and signed by the parties

The Member States may complete or specify, according to their national procedures, any additional necessary information to be contained in this Subappendix

**Data exporter**

The data exporter is locally collecting and storing patient data. The data exporter can transfer pseudonymised data to the MSBase Registry. The data exporter can request pseudonymised data extracts from the MSBase Registry for collaborative research purposes.

**Data importer**

The data importer is collecting, storing, analysing and distributing pseudonymised data.

**Data subjects**

The personal data transferred concern the following categories of data subjects (please specify):

* Centre Patients
* MSBase Members

**Categories of data**

The personal data transferred concern the following categories of data:

See Appendix 1A – Categories of Data (pg. 7)

**Special categories of data (if appropriate)**

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

N/A

**Processing operations**

The personal data transferred will be subject to the following basic processing activities:

Collection, storage, retrieval, aggregation, analysis, graphing, distribution.

For a detailed description of processing operations, please refer to the following documents:

* MSBase Information Security Policy (available upon request from the MSBase Operations Team)
* MSBase Participation Agreement (part of the MSBase governance package)

**Subappendix 2**

**to the Standard Contractual Clauses**

This Subappendix forms part of the Clauses and must be completed and signed by the parties.

**Description of the technical and organisational security measures implemented by the data importer in accordance with Clauses 4(d) and 5(c) is contained within the MSBase Registry Participation Agreement and the MSBase Information Security Policy, which is available upon request from the Operations Team.**

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1. Parties may reproduce definitions and meanings contained in Directive 95/46/EC within this Clause if they considered it better for the contract to stand alone. [↑](#footnote-ref-1)
2. Mandatory requirements of the national legislation applicable to the data importer which do not go beyond what is necessary in a democratic society on the basis of one of the interests listed in Article 13(1) of Directive 95/46/EC, that is, if they constitute a necessary measure to safeguard national security, defence, public security, the prevention, investigation, detection and prosecution of criminal offences or of breaches of ethics for the regulated professions, an important economic or financial interest of the State or the protection of the data subject or the rights and freedoms of others, are not in contradiction with the standard contractual clauses. Some examples of such mandatory requirements which do not go beyond what is necessary in a democratic society are, inter alia, internationally recognised sanctions, tax-reporting requirements or anti-money-laundering reporting requirements. [↑](#footnote-ref-2)
3. This requirement may be satisfied by the sub-processor co-signing the contract entered into between the data exporter and the data importer under this Decision. [↑](#footnote-ref-3)