



Brussels, 4.6.2021
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ANNEX

ANNEX

to the

COMMISSION IMPLEMENTING DECISION

**on standard contractual clauses for the transfer of personal data to third countries
pursuant to Regulation (EU) 2016/679 of the European Parliament and of the Council**

SCHEDULE 1
STANDARD CONTRACTUAL CLAUSES
Data Processor to Data Processor and Data Controller to Data Processor

RECITALS

The terms and conditions in this Standard Contract Clauses ("SCCs"), are entered into between ICON CLINICAL RESEARCH LIMITED on behalf of itself and any Affiliates that are procuring services from Supplier ("You", "Your", "Vendor" or "Supplier"), pursuant to the terms of any and all Master Services or originating Agreement. Any reference to "ICON" or "exporter" or "us" refers to ICON CLINICAL RESEARCH LIMITED and all of its affiliates.

These SCCs together with the Agreement, constitute a legally binding agreement and governs the transfer of data during the use of the Services provided to ICON. Supplier agrees that these SCCs is like any written negotiated agreement signed by Supplier and agrees to enter into these SCCs on behalf of itself and, to the extent required under applicable Data Protection Laws, in the name and on behalf of its Supplier Affiliates (defined below). For the purposes of these SCCs only, and except where indicated otherwise, the term "Supplier" shall include Supplier and Supplier Affiliates. All capitalized terms not defined herein shall have the meaning set forth in the Agreement.

The following SCCs include terms that relate to transfers from ICON as controller and ICON as processor to Supplier. Where ICON is exporting personal data as a controller the terms detailed under any heading entitled Module 2 will apply. Where ICON is exporting personal data as a processor to Supplier, the terms detailed under any heading entitled Module 3 will apply. At all material times, Supplier is acting as a processor and importer of personal data provided by ICON. The terms and conditions governing the transfer of data during the use of the Services provided to ICON from the UK are set out in schedule 2 below. Those terms and conditions governing the transfers from Switzerland and set out in schedule 3.

DEFINITIONS

"Affiliates" means an entity that directly or indirectly controls, is controlled by, or is under common control with another entity.

"Agreement" means the Master Services Agreement or any originating agreement entered into by the Parties of which this Addendum forms part.

"Data Protection Laws" means all applicable national, federal, state, regional and international laws, statutes, decrees, directives, declarations, legislative enactments, regulations, orders, court rulings, and binding industry codes of conduct/practice, as modified or replaced from time to time, relating to the protection of individuals with regard to privacy or the Processing of Personal Data, to the extent that they apply to either Party in relation to the Processing of Personal Data pursuant to this Agreement.

"Supplier Affiliates" means any of Supplier Affiliate(s): (a) (i) that are subject to Data Protection Laws of the European Union, the European Economic Area and/or their member states, Switzerland and/or the United Kingdom, and (ii) permitted to supply the Services pursuant to the Agreement between Supplier and ICON CLINICAL RESEARCH LIMITED but have not signed their own agreement and are not a "Supplier" as defined under the Agreement, (b) if and to the extent Supplier processes data for which such Affiliate(s) qualify as the Importers.

SECTION I

Clause 1

Purpose and scope

- (a) The purpose of these standard contractual clauses is to ensure compliance with the requirements of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation)¹ for the transfer of personal data to a third country.
- (b) The Parties:
 - (i) the natural or legal person(s), public authority/ies, agency/ies or other body/ies (hereinafter “entity/ies”) transferring the personal data, as listed in Annex I.A. (hereinafter each “data exporter”), and
 - (ii) the entity/ies in a third country receiving the personal data from the data exporter, directly or indirectly via another entity also Party to these Clauses, as listed in Annex I.A. (hereinafter each “data importer”)have agreed to these standard contractual clauses (hereinafter: “Clauses”).
- (c) These Clauses apply with respect to the transfer of personal data as specified in Annex I.B.
- (d) The Appendix to these Clauses containing the Annexes referred to therein forms an integral part of these Clauses.

Clause 2

Effect and invariability of the Clauses

- (a) These Clauses set out appropriate safeguards, including enforceable data subject rights and effective legal remedies, pursuant to Article 46(1) and Article 46 (2)(c) of Regulation (EU) 2016/679 and, with respect to data transfers from controllers to processors and/or processors to processors, standard contractual clauses pursuant to Article 28(7) of Regulation (EU) 2016/679, provided they are not modified, except to select the appropriate Module(s) or to add or update information in the Appendix. This does not prevent the Parties from including the standard contractual clauses laid down in these Clauses in a wider contract and/or to add other clauses or additional safeguards, provided that they do not contradict, directly or indirectly, these Clauses or prejudice the fundamental rights or freedoms of data subjects.
- (b) These Clauses are without prejudice to obligations to which the data exporter is subject by virtue of Regulation (EU) 2016/679.

Clause 3

Third-party beneficiaries

- (a) Data subjects may invoke and enforce these Clauses, as third-party beneficiaries, against the data exporter and/or data importer, with the following exceptions:
 - (i) Clause 1, Clause 2, Clause 3, Clause 6, Clause 7;

- (ii) Clause 8 - Module One: Clause 8.5 (e) and Clause 8.9(b); Module Two: Clause 8.1(b), 8.9(a), (c), (d) and (e); Module Three: Clause 8.1(a), (c) and (d) and Clause 8.9(a), (c), (d), (e), (f) and (g); Module Four: Clause 8.1 (b) and Clause 8.3(b);
 - (iii) Clause 9 - Module Two: Clause 9(a), (c), (d) and (e); Module Three: Clause 9(a), (c), (d) and (e);
 - (iv) Clause 12 - Module One: Clause 12(a) and (d); Modules Two and Three: Clause 12(a), (d) and (f);
 - (v) Clause 13;
 - (vi) Clause 15.1(c), (d) and (e);
 - (vii) Clause 16(e);
 - (viii) Clause 18 - Modules One, Two and Three: Clause 18(a) and (b); Module Four: Clause 18.
- (b) Paragraph (a) is without prejudice to rights of data subjects under Regulation (EU) 2016/679.

Clause 4

Interpretation

- (a) Where these Clauses use terms that are defined in Regulation (EU) 2016/679, those terms shall have the same meaning as in that Regulation.
- (b) These Clauses shall be read and interpreted in the light of the provisions of Regulation (EU) 2016/679.
- (c) These Clauses shall not be interpreted in a way that conflicts with rights and obligations provided for in Regulation (EU) 2016/679.

Clause 5

Hierarchy

In the event of a contradiction between these Clauses and the provisions of related agreements between the Parties, existing at the time these Clauses are agreed or entered into thereafter, these Clauses shall prevail.

Clause 6

Description of the transfer(s)

The details of the transfer(s), and in particular the categories of personal data that are transferred and the purpose(s) for which they are transferred, are specified in Annex I.B.

Clause 7 - Optional

Docking clause

- (a) An entity that is not a Party to these Clauses may, with the agreement of the Parties, accede to these Clauses at any time, either as a data exporter or as a data importer, by completing the Appendix and signing Annex I.A.

- (b) Once it has completed the Appendix and signed Annex I.A, the acceding entity shall become a Party to these Clauses and have the rights and obligations of a data exporter or data importer in accordance with its designation in Annex I.A.
- (c) The acceding entity shall have no rights or obligations arising under these Clauses from the period prior to becoming a Party.

SECTION II – OBLIGATIONS OF THE PARTIES

Clause 8

Data protection safeguards

The data exporter warrants that it has used reasonable efforts to determine that the data importer is able, through the implementation of appropriate technical and organisational measures, to satisfy its obligations under these Clauses.

MODULE TWO: Transfer controller to processor

8.1 Instructions

- (a) The data importer shall process the personal data only on documented instructions from the data exporter. The data exporter may give such instructions throughout the duration of the contract.
- (b) The data importer shall immediately inform the data exporter if it is unable to follow those instructions.

8.2 Purpose limitation

The data importer shall process the personal data only for the specific purpose(s) of the transfer, as set out in Annex I.B, unless on further instructions from the data exporter.

8.3 Transparency

On request, the data exporter shall make a copy of these Clauses, including the Appendix as completed by the Parties, available to the data subject free of charge. To the extent necessary to protect business secrets or other confidential information, including the measures described in Annex II and personal data, the data exporter may redact part of the text of the Appendix to these Clauses prior to sharing a copy, but shall provide a meaningful summary where the data subject would otherwise not be able to understand the its content or exercise his/her rights. On request, the Parties shall provide the data subject with the reasons for the redactions, to the extent possible without revealing the redacted information. This Clause is without prejudice to the obligations of the data exporter under Articles 13 and 14 of Regulation (EU) 2016/679.

8.4 Accuracy

If the data importer becomes aware that the personal data it has received is inaccurate, or has become outdated, it shall inform the data exporter without undue delay. In this case, the data importer shall cooperate with the data exporter to erase or rectify the data.

8.5 Duration of processing and erasure or return of data

Processing by the data importer shall only take place for the duration specified in Annex I.B. After the end of the provision of the processing services, the data importer shall, at the choice of the data exporter, delete all personal data processed on behalf of the data exporter and certify to the data exporter that it has done so, or return to the data exporter all personal data processed on its behalf and delete existing copies. Until the data is deleted or returned, the data importer shall continue to ensure compliance with these Clauses. In case of local laws applicable to the data importer that prohibit return or deletion of the personal data, the data importer warrants that it will continue to ensure compliance with these Clauses and will only process it to the extent and for as long as required under that local law. This is without prejudice to Clause 14, in particular the requirement for the data importer under Clause 14(e) to notify the data exporter throughout the duration of the contract if it has reason to believe that it is or has become subject to laws or practices not in line with the requirements under Clause 14(a).

8.6 Security of processing

- (a) The data importer and, during transmission, also the data exporter shall implement appropriate technical and organisational measures to ensure the security of the data, including protection against a breach of security leading to accidental or unlawful destruction, loss, alteration, unauthorised disclosure or access to that data (hereinafter “personal data breach”). In assessing the appropriate level of security, the Parties shall take due account of the state of the art, the costs of implementation, the nature, scope, context and purpose(s) of processing and the risks involved in the processing for the data subjects. The Parties shall in particular consider having recourse to encryption or pseudonymisation, including during transmission, where the purpose of processing can be fulfilled in that manner. In case of pseudonymisation, the additional information for attributing the personal data to a specific data subject shall, where possible, remain under the exclusive control of the data exporter. In complying with its obligations under this paragraph, the data importer shall at least implement the technical and organisational measures specified in Annex II. The data importer shall carry out regular checks to ensure that these measures continue to provide an appropriate level of security.
- (b) The data importer shall grant access to the personal data to members of its personnel only to the extent strictly necessary for the implementation, management and monitoring of the contract. It shall ensure that persons authorised to process the personal data have committed themselves to confidentiality or are under an appropriate statutory obligation of confidentiality.
- (c) In the event of a personal data breach concerning personal data processed by the data importer under these Clauses, the data importer shall take appropriate measures to address the breach, including measures to mitigate its adverse effects. The data importer shall also notify the data exporter without undue delay after having become aware of the breach. Such notification shall contain the details of a contact point where more information can be obtained, a description of the nature of the breach (including, where possible, categories and approximate number of data subjects and personal data records concerned), its likely consequences and the measures taken or proposed to address the breach including, where appropriate, measures to mitigate its possible adverse effects. Where, and in so far as, it is not possible to provide all information

at the same time, the initial notification shall contain the information then available and further information shall, as it becomes available, subsequently be provided without undue delay.

- (d) The data importer shall cooperate with and assist the data exporter to enable the data exporter to comply with its obligations under Regulation (EU) 2016/679, in particular to notify the competent supervisory authority and the affected data subjects, taking into account the nature of processing and the information available to the data importer.

8.7 Sensitive data

Where the transfer involves personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, genetic data, or biometric data for the purpose of uniquely identifying a natural person, data concerning health or a person's sex life or sexual orientation, or data relating to criminal convictions and offences (hereinafter "sensitive data"), the data importer shall apply the specific restrictions and/or additional safeguards described in Annex I.B.

8.8 Onward transfers

The data importer shall only disclose the personal data to a third party on documented instructions from the data exporter. In addition, the data may only be disclosed to a third party located outside the European Union (in the same country as the data importer or in another third country, hereinafter "onward transfer") if the third party is or agrees to be bound by these Clauses, under the appropriate Module, or if:

- (i) the onward transfer is to a country benefitting from an adequacy decision pursuant to Article 45 of Regulation (EU) 2016/679 that covers the onward transfer;
- (ii) the third party otherwise ensures appropriate safeguards pursuant to Articles 46 or 47 Regulation of (EU) 2016/679 with respect to the processing in question;
- (iii) the onward transfer is necessary for the establishment, exercise or defence of legal claims in the context of specific administrative, regulatory or judicial proceedings; or
- (iv) the onward transfer is necessary in order to protect the vital interests of the data subject or of another natural person.

Any onward transfer is subject to compliance by the data importer with all the other safeguards under these Clauses, in particular purpose limitation.

8.9 Documentation and compliance

- (a) The data importer shall promptly and adequately deal with enquiries from the data exporter that relate to the processing under these Clauses.
- (b) The Parties shall be able to demonstrate compliance with these Clauses. In particular, the data importer shall keep appropriate documentation on the processing activities carried out on behalf of the data exporter.

- (c) The data importer shall make available to the data exporter all information necessary to demonstrate compliance with the obligations set out in these Clauses and at the data exporter's request, allow for and contribute to audits of the processing activities covered by these Clauses, at reasonable intervals or if there are indications of non-compliance. In deciding on a review or audit, the data exporter may take into account relevant certifications held by the data importer.
- (d) The data exporter may choose to conduct the audit by itself or mandate an independent auditor. Audits may include inspections at the premises or physical facilities of the data importer and shall, where appropriate, be carried out with reasonable notice.
- (e) The Parties shall make the information referred to in paragraphs (b) and (c), including the results of any audits, available to the competent supervisory authority on request.

MODULE THREE: Transfer processor to processor

8.1 Instructions

- (a) The data exporter has informed the data importer that it acts as processor under the instructions of its controller(s), which the data exporter shall make available to the data importer prior to processing.
- (b) The data importer shall process the personal data only on documented instructions from the controller, as communicated to the data importer by the data exporter, and any additional documented instructions from the data exporter. Such additional instructions shall not conflict with the instructions from the controller. The controller or data exporter may give further documented instructions regarding the data processing throughout the duration of the contract.
- (c) The data importer shall immediately inform the data exporter if it is unable to follow those instructions. Where the data importer is unable to follow the instructions from the controller, the data exporter shall immediately notify the controller.
- (d) The data exporter warrants that it has imposed the same data protection obligations on the data importer as set out in the contract or other legal act under Union or Member State law between the controller and the data exporter.

8.2 Purpose limitation

The data importer shall process the personal data only for the specific purpose(s) of the transfer, as set out in Annex I.B., unless on further instructions from the controller, as communicated to the data importer by the data exporter, or from the data exporter.

8.3 Transparency

On request, the data exporter shall make a copy of these Clauses, including the Appendix as completed by the Parties, available to the data subject free of charge. To the extent necessary to protect business secrets or other confidential information, including personal data, the data exporter may redact part of the text of the Appendix prior to sharing a copy, but shall provide a meaningful summary where the data subject would otherwise not be able to understand its

content or exercise his/her rights. On request, the Parties shall provide the data subject with the reasons for the redactions, to the extent possible without revealing the redacted information.

8.4 Accuracy

If the data importer becomes aware that the personal data it has received is inaccurate, or has become outdated, it shall inform the data exporter without undue delay. In this case, the data importer shall cooperate with the data exporter to rectify or erase the data.

8.5 Duration of processing and erasure or return of data

Processing by the data importer shall only take place for the duration specified in Annex I.B. After the end of the provision of the processing services, the data importer shall, at the choice of the data exporter, delete all personal data processed on behalf of the controller and certify to the data exporter that it has done so, or return to the data exporter all personal data processed on its behalf and delete existing copies. Until the data is deleted or returned, the data importer shall continue to ensure compliance with these Clauses. In case of local laws applicable to the data importer that prohibit return or deletion of the personal data, the data importer warrants that it will continue to ensure compliance with these Clauses and will only process it to the extent and for as long as required under that local law. This is without prejudice to Clause 14, in particular the requirement for the data importer under Clause 14(e) to notify the data exporter throughout the duration of the contract if it has reason to believe that it is or has become subject to laws or practices not in line with the requirements under Clause 14(a).

8.6 Security of processing

- (a) The data importer and, during transmission, also the data exporter shall implement appropriate technical and organisational measures to ensure the security of the data, including protection against a breach of security leading to accidental or unlawful destruction, loss, alteration, unauthorised disclosure or access to that data (hereinafter “personal data breach”). In assessing the appropriate level of security, they shall take due account of the state of the art, the costs of implementation, the nature, scope, context and purpose(s) of processing and the risks involved in the processing for the data subject. The Parties shall in particular consider having recourse to encryption or pseudonymisation, including during transmission, where the purpose of processing can be fulfilled in that manner. In case of pseudonymisation, the additional information for attributing the personal data to a specific data subject shall, where possible, remain under the exclusive control of the data exporter or the controller. In complying with its obligations under this paragraph, the data importer shall at least implement the technical and organisational measures specified in Annex II. The data importer shall carry out regular checks to ensure that these measures continue to provide an appropriate level of security.
- (b) The data importer shall grant access to the data to members of its personnel only to the extent strictly necessary for the implementation, management and monitoring of the contract. It shall ensure that persons authorised to process the personal data have committed themselves to confidentiality or are under an appropriate statutory obligation of confidentiality.
- (c) In the event of a personal data breach concerning personal data processed by the data importer under these Clauses, the data importer shall take appropriate measures to address the breach, including measures to mitigate its adverse effects. The data

importer shall also notify, without undue delay, the data exporter and, where appropriate and feasible, the controller after having become aware of the breach. Such notification shall contain the details of a contact point where more information can be obtained, a description of the nature of the breach (including, where possible, categories and approximate number of data subjects and personal data records concerned), its likely consequences and the measures taken or proposed to address the data breach, including measures to mitigate its possible adverse effects. Where, and in so far as, it is not possible to provide all information at the same time, the initial notification shall contain the information then available and further information shall, as it becomes available, subsequently be provided without undue delay.

- (d) The data importer shall cooperate with and assist the data exporter to enable the data exporter to comply with its obligations under Regulation (EU) 2016/679, in particular to notify its controller so that the latter may in turn notify the competent supervisory authority and the affected data subjects, taking into account the nature of processing and the information available to the data importer.

8.7 Sensitive data

Where the transfer involves personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, genetic data, or biometric data for the purpose of uniquely identifying a natural person, data concerning health or a person's sex life or sexual orientation, or data relating to criminal convictions and offences (hereinafter "sensitive data"), the data importer shall apply the specific restrictions and/or additional safeguards set out in Annex I.B.

8.8 Onward transfers

The data importer shall only disclose the personal data to a third party on documented instructions from the controller, as communicated to the data importer by the data exporter. In addition, the data may only be disclosed to a third party located outside the European Union (in the same country as the data importer or in another third country, hereinafter "onward transfer") if the third party is or agrees to be bound by these Clauses, under the appropriate Module, or if:

- (i) the onward transfer is to a country benefitting from an adequacy decision pursuant to Article 45 of Regulation (EU) 2016/679 that covers the onward transfer;
- (ii) the third party otherwise ensures appropriate safeguards pursuant to Articles 46 or 47 of Regulation (EU) 2016/679;
- (iii) the onward transfer is necessary for the establishment, exercise or defence of legal claims in the context of specific administrative, regulatory or judicial proceedings; or
- (iv) the onward transfer is necessary in order to protect the vital interests of the data subject or of another natural person.

Any onward transfer is subject to compliance by the data importer with all the other safeguards under these Clauses, in particular purpose limitation.

8.9 Documentation and compliance

- (a) The data importer shall promptly and adequately deal with enquiries from the data exporter or the controller that relate to the processing under these Clauses.
- (b) The Parties shall be able to demonstrate compliance with these Clauses. In particular, the data importer shall keep appropriate documentation on the processing activities carried out on behalf of the controller.
- (c) The data importer shall make all information necessary to demonstrate compliance with the obligations set out in these Clauses available to the data exporter, which shall provide it to the controller.
- (d) The data importer shall allow for and contribute to audits by the data exporter of the processing activities covered by these Clauses, at reasonable intervals or if there are indications of non-compliance. The same shall apply where the data exporter requests an audit on instructions of the controller. In deciding on an audit, the data exporter may take into account relevant certifications held by the data importer.
- (e) Where the audit is carried out on the instructions of the controller, the data exporter shall make the results available to the controller.
- (f) The data exporter may choose to conduct the audit by itself or mandate an independent auditor. Audits may include inspections at the premises or physical facilities of the data importer and shall, where appropriate, be carried out with reasonable notice.
- (g) The Parties shall make the information referred to in paragraphs (b) and (c), including the results of any audits, available to the competent supervisory authority on request.

Clause 9

Use of sub-processors

MODULE TWO: Transfer controller to processor

- (a) **OPTION 1: SPECIFIC PRIOR AUTHORISATION** The data importer shall not sub-contract any of its processing activities performed on behalf of the data exporter under these Clauses to a sub-processor without the data exporter's prior specific written authorisation. The data importer shall submit the request for specific authorisation at least 30 days prior to the engagement of the sub-processor, together with the information necessary to enable the data exporter to decide on the authorisation. The list of sub-processors already authorised by the data exporter can be found in Annex III. The Parties shall keep Annex III up to date.
- (b) Where the data importer engages a sub-processor to carry out specific processing activities (on behalf of the data exporter), it shall do so by way of a written contract that provides for, in substance, the same data protection obligations as those binding the data importer under these Clauses, including in terms of third-party beneficiary rights for data subjects. The Parties agree that, by complying with this Clause, the data importer fulfils its obligations under Clause 8.8. The data importer shall ensure that the sub-processor complies with the obligations to which the data importer is subject pursuant to these Clauses.

- (c) The data importer shall provide, at the data exporter's request, a copy of such a sub-processor agreement and any subsequent amendments to the data exporter. To the extent necessary to protect business secrets or other confidential information, including personal data, the data importer may redact the text of the agreement prior to sharing a copy.
- (d) The data importer shall remain fully responsible to the data exporter for the performance of the sub-processor's obligations under its contract with the data importer. The data importer shall notify the data exporter of any failure by the sub-processor to fulfil its obligations under that contract.
- (e) The data importer shall agree a third-party beneficiary clause with the sub-processor whereby - in the event the data importer has factually disappeared, ceased to exist in law or has become insolvent - the data exporter shall have the right to terminate the sub-processor contract and to instruct the sub-processor to erase or return the personal data.

MODULE THREE: Transfer processor to processor

- (a) **OPTION 1: SPECIFIC PRIOR AUTHORISATION** The data importer shall not sub-contract any of its processing activities performed on behalf of the data exporter under these Clauses to a sub-processor without the prior specific written authorisation of the controller. The data importer shall submit the request for specific authorisation at least 30 days prior to the engagement of the sub-processor, together with the information necessary to enable the controller to decide on the authorisation. It shall inform the data exporter of such engagement. The list of sub-processors already authorised by the controller can be found in Annex III. The Parties shall keep Annex III up to date.
- (b) Where the data importer engages a sub-processor to carry out specific processing activities (on behalf of the controller), it shall do so by way of a written contract that provides for, in substance, the same data protection obligations as those binding the data importer under these Clauses, including in terms of third-party beneficiary rights for data subjects. The Parties agree that, by complying with this Clause, the data importer fulfils its obligations under Clause 8.8. The data importer shall ensure that the sub-processor complies with the obligations to which the data importer is subject pursuant to these Clauses.
- (c) The data importer shall provide, at the data exporter's or controller's request, a copy of such a sub-processor agreement and any subsequent amendments. To the extent necessary to protect business secrets or other confidential information, including personal data, the data importer may redact the text of the agreement prior to sharing a copy.
- (d) The data importer shall remain fully responsible to the data exporter for the performance of the sub-processor's obligations under its contract with the data importer. The data importer shall notify the data exporter of any failure by the sub-processor to fulfil its obligations under that contract.
- (e) The data importer shall agree a third-party beneficiary clause with the sub-processor whereby - in the event the data importer has factually disappeared, ceased to exist in law or has become insolvent - the data exporter shall have the right to terminate the sub-processor contract and to instruct the sub-processor to erase or return the personal data.

Clause 10

Data subject rights

MODULE TWO: Transfer controller to processor

- (a) The data importer shall promptly notify the data exporter of any request it has received from a data subject. It shall not respond to that request itself unless it has been authorised to do so by the data exporter.
- (b) The data importer shall assist the data exporter in fulfilling its obligations to respond to data subjects' requests for the exercise of their rights under Regulation (EU) 2016/679. In this regard, the Parties shall set out in Annex II the appropriate technical and organisational measures, taking into account the nature of the processing, by which the assistance shall be provided, as well as the scope and the extent of the assistance required.
- (c) In fulfilling its obligations under paragraphs (a) and (b), the data importer shall comply with the instructions from the data exporter.

MODULE THREE: Transfer processor to processor

- (a) The data importer shall promptly notify the data exporter and, where appropriate, the controller of any request it has received from a data subject, without responding to that request unless it has been authorised to do so by the controller.
- (b) The data importer shall assist, where appropriate in cooperation with the data exporter, the controller in fulfilling its obligations to respond to data subjects' requests for the exercise of their rights under Regulation (EU) 2016/679 or Regulation (EU) 2018/1725, as applicable. In this regard, the Parties shall set out in Annex II the appropriate technical and organisational measures, taking into account the nature of the processing, by which the assistance shall be provided, as well as the scope and the extent of the assistance required.
- (c) In fulfilling its obligations under paragraphs (a) and (b), the data importer shall comply with the instructions from the controller, as communicated by the data exporter.

Clause 11

Redress

- (a) The data importer shall inform data subjects in a transparent and easily accessible format, through individual notice or on its website, of a contact point authorised to handle complaints. It shall deal promptly with any complaints it receives from a data subject.

MODULE TWO: Transfer controller to processor

MODULE THREE: Transfer processor to processor

- (b) In case of a dispute between a data subject and one of the Parties as regards compliance with these Clauses, that Party shall use its best efforts to resolve the issue amicably in a timely fashion. The Parties shall keep each other informed about such disputes and, where appropriate, cooperate in resolving them.
- (c) Where the data subject invokes a third-party beneficiary right pursuant to Clause 3, the data importer shall accept the decision of the data subject to:
 - (i) lodge a complaint with the supervisory authority in the Member State of his/her habitual residence or place of work, or the competent supervisory authority pursuant to Clause 13;
 - (ii) refer the dispute to the competent courts within the meaning of Clause 18.
- (d) The Parties accept that the data subject may be represented by a not-for-profit body, organisation or association under the conditions set out in Article 80(1) of Regulation (EU) 2016/679.
- (e) The data importer shall abide by a decision that is binding under the applicable EU or Member State law.
- (f) The data importer agrees that the choice made by the data subject will not prejudice his/her substantive and procedural rights to seek remedies in accordance with applicable laws.

Clause 12

Liability

MODULE TWO: Transfer controller to processor

MODULE THREE: Transfer processor to processor

- (a) Each Party shall be liable to the other Party/ies for any damages it causes the other Party/ies by any breach of these Clauses.
- (b) The data importer shall be liable to the data subject, and the data subject shall be entitled to receive compensation, for any material or non-material damages the data importer or its sub-processor causes the data subject by breaching the third-party beneficiary rights under these Clauses.
- (c) Notwithstanding paragraph (b), the data exporter shall be liable to the data subject, and the data subject shall be entitled to receive compensation, for any material or non-material damages the data exporter or the data importer (or its sub-processor) causes the data subject by breaching the third-party beneficiary rights under these Clauses. This is without prejudice to the liability of the data exporter and, where the data exporter is a processor acting on behalf of a controller, to the liability of the controller under Regulation (EU) 2016/679 or Regulation (EU) 2018/1725, as applicable.
- (d) The Parties agree that if the data exporter is held liable under paragraph (c) for damages caused by the data importer (or its sub-processor), it shall be entitled to claim back from the data importer that part of the compensation corresponding to the data importer's responsibility for the damage.

- (e) Where more than one Party is responsible for any damage caused to the data subject as a result of a breach of these Clauses, all responsible Parties shall be jointly and severally liable and the data subject is entitled to bring an action in court against any of these Parties.
- (f) The Parties agree that if one Party is held liable under paragraph (e), it shall be entitled to claim back from the other Party/ies that part of the compensation corresponding to its / their responsibility for the damage.
- (g) The data importer may not invoke the conduct of a sub-processor to avoid its own liability.

Clause 13

Supervision

MODULE TWO: Transfer controller to processor

MODULE THREE: Transfer processor to processor

- (a) Where the data exporter is established in an EU Member State: The supervisory authority with responsibility for ensuring compliance by the data exporter with Regulation (EU) 2016/679 as regards the data transfer, as indicated in Annex I.C, shall act as competent supervisory authority.
- (b) The data importer agrees to submit itself to the jurisdiction of and cooperate with the competent supervisory authority in any procedures aimed at ensuring compliance with these Clauses. In particular, the data importer agrees to respond to enquiries, submit to audits and comply with the measures adopted by the supervisory authority, including remedial and compensatory measures. It shall provide the supervisory authority with written confirmation that the necessary actions have been taken.

**SECTION III – LOCAL LAWS AND OBLIGATIONS IN CASE OF ACCESS
BY PUBLIC AUTHORITIES**

Clause 14

Local laws and practices affecting compliance with the Clauses

MODULE TWO: Transfer controller to processor

MODULE THREE: Transfer processor to processor

- (a) The Parties warrant that they have no reason to believe that the laws and practices in the third country of destination applicable to the processing of the personal data by the data importer, including any requirements to disclose personal data or measures authorising access by public authorities, prevent the data importer from fulfilling its obligations under these Clauses. This is based on the understanding that laws and practices that respect the essence of the fundamental rights and freedoms and do not exceed what is necessary and proportionate in a democratic society to safeguard one of the objectives listed in Article 23(1) of Regulation (EU) 2016/679, are not in contradiction with these Clauses.
- (b) The Parties declare that in providing the warranty in paragraph (a), they have taken due account in particular of the following elements:
 - (i) the specific circumstances of the transfer, including the length of the processing chain, the number of actors involved and the transmission channels used; intended onward transfers; the type of recipient; the purpose of processing; the categories and format of the transferred personal data; the economic sector in which the transfer occurs; the storage location of the data transferred;
 - (ii) the laws and practices of the third country of destination– including those requiring the disclosure of data to public authorities or authorising access by such authorities – relevant in light of the specific circumstances of the transfer, and the applicable limitations and safeguards;
 - (iii) any relevant contractual, technical or organisational safeguards put in place to supplement the safeguards under these Clauses, including measures applied during transmission and to the processing of the personal data in the country of destination.
- (c) The data importer warrants that, in carrying out the assessment under paragraph (b), it has made its best efforts to provide the data exporter with relevant information and agrees that it will continue to cooperate with the data exporter in ensuring compliance with these Clauses.
- (d) The Parties agree to document the assessment under paragraph (b) and make it available to the competent supervisory authority on request.
- (e) The data importer agrees to notify the data exporter promptly if, after having agreed to these Clauses and for the duration of the contract, it has reason to believe that it is or has become subject to laws or practices not in line with the requirements under paragraph (a), including following a change in the laws of the third country or a

measure (such as a disclosure request) indicating an application of such laws in practice that is not in line with the requirements in paragraph (a). [For Module Three: The data exporter shall forward the notification to the controller.]

- (f) Following a notification pursuant to paragraph (e), or if the data exporter otherwise has reason to believe that the data importer can no longer fulfil its obligations under these Clauses, the data exporter shall promptly identify appropriate measures (e.g. technical or organisational measures to ensure security and confidentiality) to be adopted by the data exporter and/or data importer to address the situation [for Module Three: , if appropriate in consultation with the controller]. The data exporter shall suspend the data transfer if it considers that no appropriate safeguards for such transfer can be ensured, or if instructed by [for Module Three: the controller or] the competent supervisory authority to do so. In this case, the data exporter shall be entitled to terminate the contract, insofar as it concerns the processing of personal data under these Clauses. If the contract involves more than two Parties, the data exporter may exercise this right to termination only with respect to the relevant Party, unless the Parties have agreed otherwise. Where the contract is terminated pursuant to this Clause, Clause 16(d) and (e) shall apply.

Clause 15

Obligations of the data importer in case of access by public authorities

MODULE TWO: Transfer controller to processor

MODULE THREE: Transfer processor to processor

15.1 Notification

- (a) The data importer agrees to notify the data exporter and, where possible, the data subject promptly (if necessary with the help of the data exporter) if it:
- (i) receives a legally binding request from a public authority, including judicial authorities, under the laws of the country of destination for the disclosure of personal data transferred pursuant to these Clauses; such notification shall include information about the personal data requested, the requesting authority, the legal basis for the request and the response provided; or
 - (ii) becomes aware of any direct access by public authorities to personal data transferred pursuant to these Clauses in accordance with the laws of the country of destination; such notification shall include all information available to the importer.
- [For Module Three: The data exporter shall forward the notification to the controller.]
- (b) If the data importer is prohibited from notifying the data exporter and/or the data subject under the laws of the country of destination, the data importer agrees to use its best efforts to obtain a waiver of the prohibition, with a view to communicating as much information as possible, as soon as possible. The data importer agrees to document its best efforts in order to be able to demonstrate them on request of the data exporter.
- (c) Where permissible under the laws of the country of destination, the data importer agrees to provide the data exporter, at regular intervals for the duration of the contract,

with as much relevant information as possible on the requests received (in particular, number of requests, type of data requested, requesting authority/ies, whether requests have been challenged and the outcome of such challenges, etc.). [For Module Three: The data exporter shall forward the information to the controller.]

- (d) The data importer agrees to preserve the information pursuant to paragraphs (a) to (c) for the duration of the contract and make it available to the competent supervisory authority on request.
- (e) Paragraphs (a) to (c) are without prejudice to the obligation of the data importer pursuant to Clause 14(e) and Clause 16 to inform the data exporter promptly where it is unable to comply with these Clauses.

15.2 Review of legality and data minimisation

- (a) The data importer agrees to review the legality of the request for disclosure, in particular whether it remains within the powers granted to the requesting public authority, and to challenge the request if, after careful assessment, it concludes that there are reasonable grounds to consider that the request is unlawful under the laws of the country of destination, applicable obligations under international law and principles of international comity. The data importer shall, under the same conditions, pursue possibilities of appeal. When challenging a request, the data importer shall seek interim measures with a view to suspending the effects of the request until the competent judicial authority has decided on its merits. It shall not disclose the personal data requested until required to do so under the applicable procedural rules. These requirements are without prejudice to the obligations of the data importer under Clause 14(e).
- (b) The data importer agrees to document its legal assessment and any challenge to the request for disclosure and, to the extent permissible under the laws of the country of destination, make the documentation available to the data exporter. It shall also make it available to the competent supervisory authority on request. [For Module Three: The data exporter shall make the assessment available to the controller.]
- (c) The data importer agrees to provide the minimum amount of information permissible when responding to a request for disclosure, based on a reasonable interpretation of the request.

SECTION IV – FINAL PROVISIONS

Clause 16

Non-compliance with the Clauses and termination

- (a) The data importer shall promptly inform the data exporter if it is unable to comply with these Clauses, for whatever reason.
- (b) In the event that the data importer is in breach of these Clauses or unable to comply with these Clauses, the data exporter shall suspend the transfer of personal data to the data importer until compliance is again ensured or the contract is terminated. This is without prejudice to Clause 14(f).
- (c) The data exporter shall be entitled to terminate the contract, insofar as it concerns the processing of personal data under these Clauses, where:

- (i) the data exporter has suspended the transfer of personal data to the data importer pursuant to paragraph (b) and compliance with these Clauses is not restored within a reasonable time and in any event within one month of suspension;
- (ii) the data importer is in substantial or persistent breach of these Clauses; or
- (iii) the data importer fails to comply with a binding decision of a competent court or supervisory authority regarding its obligations under these Clauses.

In these cases, it shall inform the competent supervisory authority [for Module Three: and the controller] of such non-compliance. Where the contract involves more than two Parties, the data exporter may exercise this right to termination only with respect to the relevant Party, unless the Parties have agreed otherwise.

- (d) [For Modules One, Two and Three: Personal data that has been transferred prior to the termination of the contract pursuant to paragraph (c) shall at the choice of the data exporter immediately be returned to the data exporter or deleted in its entirety. The same shall apply to any copies of the data.] The data importer shall certify the deletion of the data to the data exporter. Until the data is deleted or returned, the data importer shall continue to ensure compliance with these Clauses. In case of local laws applicable to the data importer that prohibit the return or deletion of the transferred personal data, the data importer warrants that it will continue to ensure compliance with these Clauses and will only process the data to the extent and for as long as required under that local law.
- (e) Either Party may revoke its agreement to be bound by these Clauses where (i) the European Commission adopts a decision pursuant to Article 45(3) of Regulation (EU) 2016/679 that covers the transfer of personal data to which these Clauses apply; or (ii) Regulation (EU) 2016/679 becomes part of the legal framework of the country to which the personal data is transferred. This is without prejudice to other obligations applying to the processing in question under Regulation (EU) 2016/679.

Clause 17

Governing law

MODULE TWO: Transfer controller to processor

MODULE THREE: Transfer processor to processor

OPTION 2 (for Modules Two and Three): These Clauses shall be governed by the law of the EU Member State in which the data exporter is established. Where such law does not allow for third-party beneficiary rights, they shall be governed by the law of another EU Member State that does allow for third-party beneficiary rights. The Parties agree that this shall be the law of Ireland.

Clause 18

Choice of forum and jurisdiction

MODULE TWO: Transfer controller to processor

MODULE THREE: Transfer processor to processor

- (a) Any dispute arising from these Clauses shall be resolved by the courts of an EU Member State.
- (b) The Parties agree that those shall be the courts of Ireland.
- (c) A data subject may also bring legal proceedings against the data exporter and/or data importer before the courts of the Member State in which he/she has his/her habitual residence.
- (d) The Parties agree to submit themselves to the jurisdiction of such courts.

APPENDIX

EXPLANATORY NOTE:

It must be possible to clearly distinguish the information applicable to each transfer or category of transfers and, in this regard, to determine the respective role(s) of the Parties as data exporter(s) and/or data importer(s). This does not necessarily require completing and signing separate appendices for each transfer/category of transfers and/or contractual relationship, where this transparency can be achieved through one appendix. However, where necessary to ensure sufficient clarity, separate appendices should be used.

ANNEX I

A. LIST OF PARTIES

MODULE TWO: Transfer controller to processor

MODULE THREE: Transfer processor to processor

Data exporter(s): [*Identity and contact details of the data exporter(s) and, where applicable, of its/their data protection officer and/or representative in the European Union*]

1. Name: ICON CLINICAL RESEARCH LIMITED. Role: Data Controller/Data Processor

Address: South County Business Park, Leopardstown, Dublin 18, Ireland

Contact person's name, position and contact details:

Barry Leyden (DPO), data_privacy_officer@iconplc.com

Activities relevant to the data transferred under these Clauses:

For the provision of services

Data importer(s): Supplier ("You", "Your", "Vendor" or "Supplier") as per the named legal Entity detailed within the originating agreement/SOW with ICON to include all Supplier affiliates.

Role: processor

B. DESCRIPTION OF TRANSFER

MODULE TWO: Transfer controller to processor

MODULE THREE: Transfer processor to processor

Categories of data subjects whose personal data is transferred

Data exporter may transfer Personal Data to the data importer, which may include, but is not limited to Personal Data relating to the following categories of data subjects:

- Prospective, current and former employees as well as contractors of exporter
- Business partners, suppliers and vendors (who are natural persons), including contact persons, Agents, advisors, freelancers
- Prospects, sponsor personnel
- Study team staff (e.g. investigators) (e.g. physicians, nurses, pharmacist, students, payers etc.)
- Former, current or future clinical trial participants or their relatives (including carers and parents)

Categories of personal data transferred

Personal Data which may be transferred to Exporter may include, but is not limited to Personal Data relating to the following types:

Name and title / Date of birth / sex/gender / Marital Status / Identification data (e.g. identification number, patient ID, employee ID, passport number, Tax ID, image, voice, signature or any other similar identification item) / Personal life data (e.g. family situation, private address and contact details) / Employee related data (e.g. payroll information, contract of employment information, benefits and compensation, grade, salary, trainings, mobility, career development, performance evaluation, employee records information) / Business Contact information (e.g. Company, email, phone, physical business address) / Professional life data (e.g. profession, diplomas, distinctions, publications, studies, resumes) / Customer history and interactions information, including profiling / Contract master data (contractual relationship, product and/or interest in contractual performance) and contract billing / Payments and transfers of value (for our Customers) / Connection data (e.g. logs, IP address, cookies) / Localisation data (e.g. geolocalisation), Payments and/or transfer of values.

Sensitive data transferred (if applicable) and applied restrictions or safeguards that fully take into consideration the nature of the data and the risks involved, such as for instance strict purpose limitation, access restrictions (including access only for staff having followed specialised training), keeping a record of access to the data, restrictions for onward transfers or additional security measures.

Special categories of Personal Data (if relevant)

Sensitive Personal Data which may be deemed to come under special categories may include, but is not limited to the Personal Data detailed below:

Health data, genetic data, National identification number (e.g. social security number, Tax ID) / Bank account information / Bank account information / Bank account information / Bank account information / Bank account information / Sex life / Sexual orientation.

The frequency of the transfer (e.g. whether the data is transferred on a one-off or continuous basis).

As required for the provision of services

Nature of the processing

The personal data is processed during and for the provision of services. Processing involves collection, recording, organization, structuring, storage, adaption, retrieval, consultation, use, disclosure by transmission, dissemination, combination, restriction, erasure, destruction

Purpose(s) of the data transfer and further processing

The personal data is processed during and for the provision of services. Processing involves collection, recording, organization, structuring, storage, adaption, retrieval, consultation, use, disclosure by transmission, dissemination, combination, restriction, erasure, destruction

The period for which the personal data will be retained, or, if that is not possible, the criteria used to determine that period

As set out in the Agreement

For transfers to (sub-) processors, also specify subject matter, nature and duration of the processing

As required for the provision of services

C. COMPETENT SUPERVISORY AUTHORITY

MODULE TWO: Transfer controller to processor

MODULE THREE: Transfer processor to processor

Identify the competent supervisory authority/ies in accordance with Clause 13

Irish Data Protection Commission

ANNEX II - TECHNICAL AND ORGANISATIONAL MEASURES INCLUDING TECHNICAL AND ORGANISATIONAL MEASURES TO ENSURE THE SECURITY OF THE DATA

MODULE TWO: Transfer controller to processor

MODULE THREE: Transfer processor to processor

The technical and organisational measures must be described in specific (and not generic) terms. See also the general comment on the first page of the Appendix, in particular on the need to clearly indicate which measures apply to each transfer/set of transfers.

Description of the technical and organisational measures implemented by the data importer(s) (including any relevant certifications) to ensure an appropriate level of security, taking into account the nature, scope, context and purpose of the processing, and the risks for the rights and freedoms of natural persons.

Data importer shall implement appropriate technical and organisational measures to protect against the unauthorised or unlawful processing of personal data and against accidental loss or destruction of, or damage to, personal data, as represented by the general controls listed below. The measures taken should take into account available technology and the cost of implementing the specific measures and must ensure a level of security appropriate to the harm that might result from a breach of security and the nature of the data to be protected. This Appendix II shall not preclude the parties agreeing more specific and detailed safeguards consistent with the general controls listed in MSA or SOW.

General Controls:

- 1. Access control to premises and facilities**
Measures to prevent unauthorized physical access to premises and facilities holding personal data.
- 2. Access control to systems**
Measures to prevent unauthorized access to IT systems.
- 3. Access control to data**
Measures to prevent authorized users from accessing data beyond their authorized access rights.
- 4. Disclosure control**
Measures to prevent the unauthorized access, alteration or removal of data during transfer, and to ensure that all transfers are secure.
- 5. Input control**
Measures to ensure all data management and maintenance is logged, and an audit trail of whether data have been entered, changed or removed (deleted) and by whom must be maintained.
- 6. Job Control**
Measures to ensure that data is processed strictly in compliance with the data importer's instructions.
- 7. Availability control**
Measures to ensure that data are protected against accidental destruction or loss.
- 8. Segregation control**
Measures to allow data collected for different purposes to be processed separately.

For transfers to (sub-) processors, also describe the specific technical and organisational measures to be taken by the (sub-) processor to be able to provide assistance to the controller and, for transfers from a processor to a sub-processor, to the data exporter

Data importer (processor or sub-processor) shall implement appropriate technical and organisational measures to be able to provide assistance to the controller. This Appendix II shall not preclude the parties agreeing more specific and detailed safeguards consistent with the general controls listed in MSA or SOW.

ANNEX III – LIST OF SUB-PROCESSORS

MODULE TWO: Transfer controller to processor

MODULE THREE: Transfer processor to processor

EXPLANATORY NOTE:

This Annex must be completed for Modules Two and Three, in case of the specific authorisation of sub-processors (Clause 9(a), Option 1).

The controller has authorised the use of the following sub-processors:

As set out in the Statement of Work/Work Order

**SCHEDULE 2
(UK STANDARD CONTRACTUAL CLAUSES)**

**INTERNATIONAL DATA TRANSFER ADDENDUM TO THE EU COMMISSION
STANDARD CONTRACTUAL CLAUSES**

This Addendum has been issued by the Information Commissioner for Parties making Restricted Transfers. The Information Commissioner considers that it provides Appropriate Safeguards for Restricted Transfers when it is entered into as a legally binding contract.

Part 1: Tables

Table 1: Parties

Start date	The Effective Date as defined in this Agreement	
The Parties	Exporter (who sends the Restricted Transfer)	Importer (who receives the Restricted Transfer)
Parties' details	Please see Schedule 1 of this Agreement for the name, jurisdiction and address of each Data Exporter and Data Importer, along with the details of ICON Clinical Research Limited The appropriate point of contact for all entities listed is the ICON Global Data Protection Officer, email address: Data_privacy_officer@ICONplc.com	
Key Contact		

Table 2: Selected SCCs, Modules and Selected Clauses

Addendum EU SCCs		This Addendum is appended to the version of the Approved EU SCCs as set out in Exhibit 1 of this Agreement, detailed below, including the Appendix Information:				
Module (included in Schedule 2 to this Agreement)	Module in operation	Clause 7 (Docking Clause)	Clause 11 (Option)	Clause 9a (Prior Authorisation or General Authorisation)	Clause 9a (Time Period)	Is personal data received from the Importer combined with personal data collected

						by the Exporter?
2	Where appropriate for Transfer	Yes	No			
3	Where appropriate for Transfer	Yes	No			Yes

Table 3: Appendix Information

“Appendix Information” means the information as set out in the Appendices of Exhibit 1.

Annex 1A: List of Parties: Please see Exhibit 1 of this Agreement.
Annex 1B: Description of Transfer: Please see the information as set out in Annex I.B of Exhibit 1 to this Agreement.
Annex II: Technical and organisational measures including technical and organisational measures to ensure the security of the data: Please see the information as set out in Annex II of Exhibit 1 to this Agreement.
Annex III: List of Sub processors (Modules 2 and 3 only): Please see the information as set out in Annex III of Exhibit 1 to this Agreement.

Table 4: Ending this Addendum when Approved Addendum Changes

Ending this Addendum when the Approved Addendum changes	Which Parties may end this Addendum as set out in Section Error! Reference source not found.: <input type="checkbox"/> Importer <input type="checkbox"/> Exporter <input checked="" type="checkbox"/> neither Party
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Part 2: Mandatory Clauses

Entering into this Addendum

- Each Party agrees to be bound by the terms and conditions set out in this Addendum, in exchange for the other Party also agreeing to be bound by this Addendum.
- Although Annex IA and Clause 7 of the Approved EU SCCs require signature by the Parties, for the purpose of making Restricted Transfers, the Parties may enter into this Addendum in any way that makes it legally binding on the Parties and allows data subjects to enforce their rights as set out in this Addendum (including by executing this agreement). Entering into this Addendum will have the same effect as signing the Approved EU SCCs and any part of the Approved EU SCCs.

Interpretation of this Addendum

3. Where this Addendum uses terms that are defined in the Approved EU SCCs those terms shall have the same meaning as in the Approved EU SCCs. In addition, the following terms have the following meanings:

Addendum	This International Data Transfer Addendum, incorporated in to this Agreement by this Schedule 7, which is made up of this Addendum incorporating the Addendum EU SCCs.
Addendum EU SCCs	The version(s) of the Approved EU SCCs which this Addendum is appended to, as set out in Table 2, including the Appendix Information.
Appendix Information	As set out in Table 3.
Appropriate Safeguards	The standard of protection over the personal data and of data subjects' rights, which is required by UK Data Protection Laws when you are making a Restricted Transfer relying on standard data protection clauses under Article 46(2)(d) UK GDPR.
Approved Addendum	The template Addendum issued by the ICO and laid before Parliament in accordance with s119A of the Data Protection Act 2018 on 2 February 2022, as it is revised under Section 18.
Approved EU SCCs	The Standard Contractual Clauses set out in the Annex of Commission Implementing Decision (EU) 2021/914 of 4 June 2021, and as incorporated into this Agreement under Exhibit 1.
ICO	The Information Commissioner of the United Kingdom
Restricted Transfer	A transfer which is covered by Chapter V of the UK GDPR.
UK	The United Kingdom of Great Britain and Northern Ireland.
UK Data Protection Laws	All laws relating to data protection, the processing of personal data, privacy and/or electronic communications in force from time to time in the UK, including the UK GDPR and the Data Protection Act 2018.
UK GDPR	As defined in section 3 of the Data Protection Act 2018.

4. This Addendum must always be interpreted in a manner that is consistent with UK Data Protection Laws and so that it fulfils the Parties' obligation to provide the Appropriate Safeguards.
5. If the provisions included in the Addendum EU SCCs amend the Approved SCCs in any way which is not permitted under the Approved EU SCCs or the Approved Addendum, such amendment(s) will not be incorporated in this Addendum and the equivalent provision of the Approved EU SCCs will take their place.

6. If there is any inconsistency or conflict between UK Data Protection Laws and this Addendum, UK Data Protection Laws applies.
7. If the meaning of this Addendum is unclear or there is more than one meaning, the meaning which most closely aligns with UK Data Protection Laws applies.
8. Any references to legislation (or specific provisions of legislation) means that legislation (or specific provision) as it may change over time. This includes where that legislation (or specific provision) has been consolidated, re-enacted and/or replaced after this Addendum has been entered into.

Hierarchy

9. Although Clause 5 of the Approved EU SCCs sets out that the Approved EU SCCs prevail over all related agreements between the Parties, the Parties agree that, for Restricted Transfers, the hierarchy in Section 10 will prevail.
10. Where there is any inconsistency or conflict between the Approved Addendum and the Addendum EU SCCs (as applicable), the Approved Addendum overrides the Addendum EU SCCs, except where (and in so far as) the inconsistent or conflicting terms of the Addendum EU SCCs provides greater protection for data subjects, in which case those terms will override the Approved Addendum.
11. Where this Addendum incorporates Addendum EU SCCs which have been entered into to protect transfers subject to the General Data Protection Regulation (EU) 2016/679 then the Parties acknowledge that nothing in this Addendum impacts those Addendum EU SCCs.

Incorporation of and changes to the EU SCCs

12. This Addendum incorporates the Addendum EU SCCs which are amended to the extent necessary so that:
 - (a) together they operate for data transfers made by the data exporter to the data importer, to the extent that UK Data Protection Laws apply to the data exporter's processing when making that data transfer, and they provide Appropriate Safeguards for those data transfers;
 - (b) Sections 9 to 11 override Clause 5 (Hierarchy) of the Addendum EU SCCs; and
 - (c) this Addendum (including the Addendum EU SCCs incorporated into it) is (1) governed by the laws of England and Wales and (2) any dispute arising from it is resolved using the forum and jurisdiction as specified in Clause 18 of the Relevant Schedule.
13. Unless the Parties have agreed alternative amendments which meet the requirements of Section 12, the provisions of Section 15 will apply.

14. No amendments to the Approved EU SCCs other than to meet the requirements of Section 12 may be made.
15. The following amendments to the Addendum EU SCCs (for the purpose of Section 12) are made:
 - (a) References to the “Clauses” means this Addendum, incorporating the Addendum EU SCCs;
 - (b) In Clause 2, delete the words:

“and, with respect to data transfers from controllers to processors and/or processors to processors, standard contractual clauses pursuant to Article 28(7) of Regulation (EU) 2016/679”;
 - (c) Clause 6 (Description of the transfer(s)) is replaced with:

“The details of the transfers(s) and in particular the categories of personal data that are transferred and the purpose(s) for which they are transferred) are those specified in Annex I.B where UK Data Protection Laws apply to the data exporter’s processing when making that transfer.”;
 - (d) Clause 8.7(i) of Module 1 is replaced with:

“it is to a country benefitting from adequacy regulations pursuant to Section 17A of the UK GDPR that covers the onward transfer”;
 - (e) Clause 8.8(i) of Modules 2 and 3 is replaced with:

“the onward transfer is to a country benefitting from adequacy regulations pursuant to Section 17A of the UK GDPR that covers the onward transfer;”
 - (f) References to “Regulation (EU) 2016/679”, “Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation)” and “that Regulation” are all replaced by “UK Data Protection Laws”. References to specific Article(s) of “Regulation (EU) 2016/679” are replaced with the equivalent Article or Section of UK Data Protection Laws;
 - (g) References to Regulation (EU) 2018/1725 are removed;
 - (h) References to the “European Union”, “Union”, “EU”, “EU Member State”, “Member State” and “EU or Member State” are all replaced with the “UK”;
 - (i) The reference to “Clause 12(c)(i)” at Clause 10(b)(i) of Module one, is replaced with “Clause 11(c)(i)”;
 - (j) Clause 13(a) and Part C of Annex I are not used;
 - (k) The “competent supervisory authority” and “supervisory authority” are both replaced with the “Information Commissioner”;
 - (l) In Clause 16(e), subsection (i) is replaced with:

“the Secretary of State makes regulations pursuant to Section 17A of the Data Protection Act 2018 that cover the transfer of personal data to which these clauses apply;”;

(m) Clause 17 is replaced with:

“These Clauses are governed by the laws of England and Wales.”;

(n) Clause 18 is replaced with:

“Any dispute arising from these Clauses shall be resolved using the forum and jurisdiction as specified in Clause 18 of the Relevant Schedule. A data subject only may also bring legal proceedings against the data exporter and/or data importer before the courts of any country in the UK. The Parties agree to submit themselves to the jurisdiction of such courts.”; and

(o) The footnotes to the Approved EU SCCs do not form part of the Addendum, except for footnotes 8, 9, 10 and 11.

Amendments to this Addendum

16. The Parties may agree to change Clauses 17 and/or 18 of the Addendum EU SCCs to refer to the laws and/or courts of Scotland or Northern Ireland.

17. If the Parties wish to change the format of the information included in Part 1: Tables of the Approved Addendum, they may do so by agreeing to the change in writing, provided that the change does not reduce the Appropriate Safeguards.

18. From time to time, the ICO may issue a revised Approved Addendum which:

(a) makes reasonable and proportionate changes to the Approved Addendum, including correcting errors in the Approved Addendum; and/or

(b) reflects changes to UK Data Protection Laws;

The revised Approved Addendum will specify the start date from which the changes to the Approved Addendum are effective and whether the Parties need to review this Addendum including the Appendix Information. This Addendum is automatically amended as set out in the revised Approved Addendum from the start date specified.

19. If the ICO issues a revised Approved Addendum under Section 18, if any Party selected in Table 4 “Ending the Addendum when the Approved Addendum changes”, will as a direct result of the changes in the Approved Addendum have a substantial, disproportionate and demonstrable increase in:

(a) its direct costs of performing its obligations under the Addendum; and/or

(b) its risk under the Addendum,

and in either case it has first taken reasonable steps to reduce those costs or risks so that it is not substantial and disproportionate, then that Party may end this Addendum at the end of a reasonable notice period, by providing written notice for that period to the other Party before the start date of the revised Approved Addendum.

20. The Parties do not need the consent of any third party to make changes to this Addendum, but any changes must be made in accordance with its terms.

SCHEDULE 3

SWISS TRANSFERS

1. Application

- (a) In respect of any Swiss Transfers to a Transferee in a country which does not provide an adequate level of data protection (within the meaning of Swiss Data Protection Law), the Parties agree that the terms and conditions set out in this Schedule to this Agreement shall apply as amending the terms of Schedules above detailing the relevant EEA standard contractual clauses related to module 1, 2, 3 and 4, as appropriate (the “**Relevant schedule**”).
- (b) In respect of any Swiss Transfers to a Transferee in a country which does not provide an adequate level of data protection (within the meaning of Swiss Data Protection Law and the GDPR) which require compliance with Swiss Data Protection Law and with Chapter V of the GDPR, the Parties agree that the terms set out in this Schedule to this Agreement shall apply in addition to, and not in substitution for, the terms of the relevant schedule above detailing the appropriate modules.
- (c) In respect of any Swiss Transfers to a Transferee in a country which does not provide an adequate level of data protection (within the meaning of Swiss Data Protection Law), which do not require compliance with Chapter V of the GDPR, the Parties agree that the terms and conditions set out in this Schedule to this Agreement shall apply as amending, and in substitution for, the terms of the relevant schedule above detailing the appropriate modules.
- (d) The Parties agree that, for Swiss Transfers as described in Clause 1(c) of this Schedule, in the event of any conflict between the remaining terms of the Relevant schedule and the terms of this Schedule, the terms of this Schedule shall prevail to the extent necessary to resolve the conflict.

2. Competent supervisory authority

- (a) In respect of Swiss Transfers as described in Clause 1(b) of this Schedule, the Competent Supervisory Authority as may be listed in Annex I.C, and as may be provided under Clause 13, of the Relevant module shall be the Federal Data Protection and Information Commissioner (“**FDPIC**”) to act
 - (i) insofar as the Swiss/EEA Transfer is governed by Swiss Data Protection Law, and
 - (ii) in parallel to the Data Protection Commission (Ireland), acting as Supervisory Authority insofar as the Swiss/EEA Transfer is governed by the GDPR.

The criteria as may be provided under Clause 13(a) of the Relevant Schedule for the selection of the Competent Supervisory Authority continue to apply.

- (b) In respect of Swiss Transfers as described in Clause 1(c) of this Schedule, the Competent Supervisory Authority as may be listed in Annex I.C, and as may be provided under Clause 13, of the Relevant Schedule shall be FDPIC.

3. **Governing law**

- (a) The governing law as specified in Clause 17 of the Relevant Schedule continues to apply.
- (b) In respect of Swiss Transfers as described in Clause 1(c) of this Schedule, in any eventuality where the third party beneficiary rights of Data Subjects cease to be enforceable under the governing law as specified in Clause 17 of the Relevant Schedule, the clauses of the Relevant Schedule, as amended by this Schedule, shall be governed by the laws of Switzerland.

4. **Choice of forum and jurisdiction**

The choice of forum and jurisdiction for proceedings of any disputes between the parties as specified in Clause 18 of the Relevant Schedule continues to apply.

5. **Interpretation of “member state”**

The term “member state” as included in any provision of the Relevant Schedule shall include Switzerland and shall not be interpreted in such a way as to exclude Data Subjects in Switzerland from the possibility of seeking legal remedy in respect of a breach of their rights in their place of habitual residence, as may be provided under Clause 18(c) of the Relevant Schedule.

6. **Reference to the “GDPR”**

Any reference to the GDPR shall be interpreted as a reference to the equivalent provisions under Swiss Data Protection Law insofar as the Swiss Transfer is subject to Swiss Data Protection Law.