DATED

(1) Genomics England Limited

AND

(2)

(name of employer or education provider)

GeCIP Participation Agreement



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THIS AGREEMENT DATED

BETWEEN:

(1) Genomics England Limited ("Genomics England"), a company incorporated under the laws of England with company registration number 08493132 and whose principal offices are at Dawson Hall, Queen Mary University of London, Charterhouse Square, London, EC1M 6BQ; and

(2) ("Institution") of (address).

BACKGROUND:

- (A) The Prime Minister announced on 10 December 2012 that 100,000 whole genomes of patients in the NHS will be sequenced in the next five years to support their clinical care.
- (B) Genomics England, a company wholly funded and owned by the Department of Health, has been tasked to deliver the 100,000 whole genome sequences. Accordingly, Genomics England secured the services of Illumina Cambridge Limited on 1 August 2014 for sequencing of the 100,000 whole genomes of patients in the NHS.
- (C) On 1 December 2014, in his statement to the House of Commons, the Secretary of State for Health announced the establishment of the Genomics England Clinical Interpretation Partnership under which researchers, clinicians and students shall be given the opportunity to interpret and analyse specific genome sequence datasets within Genomic England's database of whole genome sequences.
- (D) Certain employees and students of the Institution may wish to participate in the Genomics England Clinical Interpretation Partnership in order to carry out research and analysis of genome sequence datasets using Genomic England's database of whole genome sequences. In some cases, the Institution may also wish that certain students be allowed to participate in the Genomics England Clinical Interpretation Partnership as part of an education and training programme for the healthcare and public health workforce. This Agreement sets out the basis upon which the Institution agrees to the participation of its employees and students in the Genomics England Clinical Interpretation Partnership.

THE PARTIES AGREE AS FOLLOWS:

1. Definitions

In this Agreement the following words shall have the meanings given to them below:

1.1 Approved Person

An Employee or a Student meeting one or more of the following criteria:-

listed in the Schedule to this Agreement; (a)



		(b)	included in any list signed by the Institution of persons approved by the Institution to participate in the GeCIP.
1.2	Business Day	•	other than a Saturday, Sunday, bank or other c holiday in England;
1.3	Commencement Date	the d	ate written at the start of this Agreement;
1.4	Commercialise	resea	se other than for non-commercial, academic rch and "Commercialisation" shall be rued accordingly;
1.5	Confidential Information	and/o public other the Co in a d "Conf the re	is any written or oral information, know-how or data which in each case: (a) is not in the c domain; (b) is disclosed by one Party to the Party pursuant to this Agreement on or after ommencement Date; and (c) where recorded ocument, is clearly and legibly marked as fidential" or which the disclosing Party notifies eceiving Party in writing is confidential at the of disclosure;
1.6	EIR	(SI 20 codes Comr	nvironmental Information Regulations 2004 004/3391) together with any guidance and/or of practice issued by the Information missioner or relevant government department ation to such regulations;
1.7	Employee	avoid contr	oyee of the Institution and includes for the ance of doubt a holder of an honorary act with the Institution and "employ" shall be rued accordingly;
1.8	FOIA	subor time t codes Comr	reedom of Information Act 2000, and any rdinate legislation made under the Act from to time, together with any guidance and/or of practice issued by the Information missioner or relevant government department ation to such legislation;
1.9	GeCIP	Partn are gi	enomics England Clinical Interpretation ership under which researchers and clinicians iven access to the GeCIP Research onment;
1.10	GeCIP Board		ody established pursuant to Rule 5 of the Paules;



1.11	GeCIP Domains	groups of GeCIP researchers and clinicians tasked with conducting research or analysis in relation to particular diseases, particular functions or other areas of interest;
1.12	GeCIP Domain IPRs	any and all Intellectual Property Rights that subsist in, claim and/or cover the GeCIP Domain Results;
1.13	GeCIP Domain Results	GeCIP Results that are created, developed, devised, conceived and/or reduced to practice in an Institution GeCIP Domain;
1.14	GeCIP Institution	any institution which employs individuals and or has students who are members of the GeCIP and which has entered into a GeCIP participation agreement with Genomics England;
1.15	Genomics England IP Policy	the policy named as such and made available on the Genomics England website as amended by Genomics England from time to time in accordance with the GeCIP Rules and this Agreement;
1.16	GeCIP IPRs	any and all Intellectual Property Rights that subsist in, claim and/or cover the GeCIP Results;
1.17	GeCIP Research Environment	Genomics England's IT systems that store whole genome sequences of individuals participating in the Programme and that provide access to and facilitate analysis of datasets of such whole genome sequences and associated phenotypic and clinical data;
1.18	GeCIP Results	all data, results, documentation, works, files, information, know-how, inventions, concepts, products, techniques, processes and/or discoveries that are generated in the course of carrying out activities under the GeCIP;
1.19	GeCIP Rules	the rules that govern membership of GeCIP;
1.20	GeCIP Rules Agreement	an agreement between an Approved Person and Genomics England under which the Approved Person agrees to comply with the GeCIP Rules;
1.21	Institution GeCIP Domain	any GeCIP Domain in which the Institution GeCIP Members participate;
1.22	Institution GeCIP Member	an Approved Person that is a member of the GeCIP and has entered or will enter into a



membership agreement by signing the GeCIP

Rules Agreement; 1.23 **Intellectual Property** patents, any extensions of the exclusivity granted in connection with patents, petty patents, utility models, registered designs, applications for any of the foregoing (including, but not limited to, continuations, continuations-in-part and divisional applications), the right to apply for and be granted any of the foregoing, rights in inventions, copyrights, design rights, database rights, publication rights, rights in know-how, trade secrets and confidential information and all other forms of intellectual property right having equivalent or similar effect to any of the foregoing which may exist anywhere in the world; 1.24 Party means Genomics England or the Institution and "Parties" means both Genomics England and the Institution; 1.25 Programme the programme for the 100,000 Genomes Project; 1.26 Request for Information has the meaning set out in the FOIA or the EIR, as relevant; 1.27 Student a student of the Institution; and

any entity other than the Parties.

1.28

Third Party



2. Commencement and Duration

2.1 This Agreement shall commence on the Commencement Date and, subject to earlier termination under Clause 8, shall expire at the end of any twenty four month period during which there are no Institution GeCIP Members.

3. GeCIP Membership

- 3.1 If an Employee or a Student wishes to become an Institution GeCIP Member and the Institution is content for the Employee or Student to become an Institution GeCIP Member, the Institution shall provide Genomics England (via email if preferred) with a list of those Employees and Students wishing to be Institution GeCIP Members signed by the Institution. Employees and Students that are currently Approved Persons are listed in the Schedule to this Agreement.
- 3.2 The Institution hereby consents to the participation of Approved Persons in the GeCIP.
- 3.3 The Institution acknowledges and accepts that Institution GeCIP Members will be bound by the GeCIP Rules and accordingly all GeCIP Results and GeCIP IPRs shall, subject to Clause 5.1, belong to Genomics England.
- 3.4 The Institution shall not do anything that would cause Institution GeCIP Members to breach the GeCIP Rules.
- 3.5 Save unless Genomics England and the Institution have entered a separate written agreement setting out alternative terms governing the ownership of specific GeCIP Domain Results and GeCIP Domain IPRs, to the extent, notwithstanding the GeCIP Rules, that any GeCIP Domain Results or GeCIP Domain IPRs are owned by the Institution, the Institution shall, hold such GeCIP Domain Results and GeCIP Domain IPRs on trust for the sole benefit of Genomics England and, as and when requested by Genomics England, assign to Genomics England, free of charge and without any conditions, all right, title and interest that the Institution may hold in such GeCIP Domain Results and GeCIP Domain IPRs.
- 3.6 Nothing in this Agreement shall assign or purport to assign any Intellectual Property which is (i) owned by the Institution prior to the date of this Agreement; and/or (ii) which is developed outside the GeCIP and not on the GeCIP Research Environment
- 3.7 The Institution represents and warrants that:
- 3.7.1 each Approved Person listed in the Schedule to this Agreement is an Employee or Student; and
- 3.7.2 each Approved Person listed in the Schedule to this Agreement has a designated email address issued by the Institution for use by the Approved Person.
- 3.8 The Institution undertakes that:-
- 3.8.1 each future Approved Person will be an Employee or Student; and
- 3.8.2 ensure that each future Approved Person has a designated email address issued by the Institution for use by the Approved Person.



- 3.9 The Institution shall inform Genomics England by notice in writing as soon as reasonably practical if any Approved Person ceases to be an Employee or Student or if any Approved Person is summarily dismissed.
- 3.10 The Institution may revoke a person's Approved Person status at any time by providing written notice to Genomics England. Genomics England will suspend the person's membership of GeCIP within five (5) Business days of such notice being received.

4. Funding of GeCIP Research

- 4.1 Genomics England will provide the GeCIP Domains with controlled access to relevant de-identified clinical data and whole genome sequence data generated by the Programme. It is intended that the members of each GeCIP Domain (except for the Education and Training Domain) will formulate a research plan and generate funds to cover all or part of the costs of (i) research, development or other activities to be carried out by the GeCIP and/or (ii) facilities, materials and/or services used in such research, development or other activities.
- 4.2 Genomics England may require GeCIP Domains to include elements in these applications to cover costs that are not already funded but will incurred by Genomics England in support of the activity of a GeCIP Domain.
- 4.3 Genomics England shall advise the Institution in writing of any research applications received from or on behalf of its Institution GeCIP Members or any determination made by Genomics England in relation to the scenario a research application falls within as set out in the GeCIP IP Policy.
- 4.4 From time to time Genomics England may decide that it is in the best interest of the Programme for Genomics England to apply itself for funds to perform a specific task. Genomics England reserves the right to do this and to involve any collaborators or coapplicants Genomics England may choose with the consent of the collaborators.

5. Use of GeCIP Domain Results

- 5.1 This Clause 5 is subject to the terms of any separate written agreements entered into between Genomics England and the Institution setting out alternative terms governing the ownership and use of specific GeCIP Domain Results and GeCIP Domain IPRs and to any determination made by Genomics England pursuant to the Genomics England IP Policy. Genomics England shall observe and apply the Genomics England IP Policy in administering the application of this Clause 5.
- 5.2 Genomics England grants the Institution a non-exclusive, non-assignable licence to use the GeCIP Domain Results and the GeCIP Domain IPRs for the sole purpose of undertaking non-commercial academic research. The Institution shall not sub-licence use of the GeCIP Domain Results and/or GeCIP Domain IPRs or otherwise permit any Third Party to use them for any purpose (including but not limited to conducting commercially sponsored research or for the purpose of collaborating with or carrying out research on behalf of any commercial entity) without the prior written consent of Genomics England provided that the Institution shall have the right to grant sub-



licences to academic institutions for the sole purpose of enabling the Institution to collaborate with such academic institutions to undertake non-commercial academic research. If the Institution grants any such sub-licence to an academic institution, the Institution shall promptly notify Genomics England with the name of the academic institution and a brief description of the proposed research project. The Institution shall not, without the prior written consent of Genomics England, authorise such academic institution to further sub-licence the GeCIP Domain Results and/or GeCIP Domain IPRs.

- 5.3 If the Institution wishes to Commercialise any GeCIP Domain Results and/or any GeCIP Domain IPRs, the Institution shall notify Genomics England specifying:-
- 5.3.1 the GeCIP Domain Results and the GeCIP Domain IPRs that the Institution wishes to Exploit;
- 5.3.2 the nature, aim and scope of the proposed Commercialisation;
- 5.3.3 the names of any proposed collaborators or participants in the Commercialisation; and
- 5.3.4 the source of funding for the Commercialisation.
- 5.4 Following receipt of the notification pursuant to the provisions of Clause 5.3 and subject to any Third Party rights in respect of the GeCIP Domain Results and the GeCIP Domain IPRs concerned, the Parties shall negotiate in good faith a fair and reasonable licence for the Commercialisation of the GeCIP Domain Results and the GeCIP Domain IPRs concerned. If the Institution wishes to obtain an exclusive licence and Genomics England agrees to negotiate an exclusive licence then the provisions of Clauses 5.6 and 5.7 shall apply.
- 5.5 If the Institution wishes to obtain an assignment of any of the GeCIP Domain Results and/or the GeCIP Domain IPRs and Genomics England agrees to negotiate the assignment of such GeCIP Domain Results and/or the GeCIP Domain IPRs to the Institution, the provisions of Clauses 5.6 shall apply.
- 5.6 If the Institution wishes to obtain an exclusive licence or assignment of any GeCIP Domain Results and/or GeCIP Domain IPRs and Genomics England agrees to negotiate such exclusive licence or assignment, then before granting any such exclusive licence or making such assignment:
- 5.6.1 Genomics England shall notify each of the other GeCIP Institution's whose GeCIP members participate in the relevant Institution GeCIP Domain;
- 5.6.2 each GeCIP Institution notified pursuant to Clause 5.6.1 may make an alternative proposal to Genomics England for the Commercialisation of the relevant GeCIP Domain Results and GeCIP Domain IPRs (such as exclusive licensing to such other GeCIP institution instead, non-exclusive licensing and/or publication of the relevant GeCIP Results) within twenty (20) Business Days of receiving notice from Genomics England;
- 5.6.3 if Genomics England receives notice of any alternative proposals pursuant to and in accordance with Clause 5.6.2, Genomics England shall give reasonable consideration to each such alternative proposal provided that Genomics England shall be entitled to make the final decision as to which proposal (if any) is accepted.



- 5.7 Genomics England shall notify the Institution of any proposal received from another GeCIP Institution for the grant of an exclusive licence or assignment of any GeCIP Domain Results and/or GeCIP Domain IPRs. The Institution may make an alternative proposal to Genomics England for the Commercialisation of the relevant GeCIP Domain Results and GeCIP Domain IPRs (such as exclusive licensing to the Institution instead, non-exclusive licensing and/or publication of the relevant GeCIP Results). Any such alternative proposal shall be notified by the Institution to Genomics England in writing within 20 Business Days of receipt by the Institution of the relevant notification from Genomics England. Genomics England shall give reasonable consideration to any such alternative proposal notified to it by the Institution in accordance with this Clause 5.7 provided that Genomics England shall be entitled to make the final decision as to which proposal (if any) is accepted
- 5.8 During the period the Parties are negotiating the licence referred to in Clause 5.4, Genomics England shall not grant a licence to any Third Party in respect of the GeCIP Domain Results and the GeCIP Domain IPRs concerned that would conflict with the licence being negotiated with the Institution provided that Genomics England shall be free to:-
- 5.8.1 grant any licence to any Third Party in respect of the GeCIP Domain Results concerned if no licence agreement in respect of the GeCIP Domain Results concerned has been executed by the Parties within 6 months of the date of the notification submitted by the Institution pursuant to Clause 5.3; and
- 5.8.2 grant a licence to any Third Party for the sole purpose of undertaking non-commercial academic research.
- 5.9 If Genomics England receives any revenue derived from Commercialisation of any GeCIP Results created and developed in whole or in part by Institution GeCIP Members, then after recouping from such revenue Genomics England's costs in relation to facilitating such Commercialisation (which may include without limitation patent and licensing costs but which, for clarity, would not include Genomics England's entire cost of setting up the GeCIP) Genomics England shall share that revenue on a fair and reasonable basis with the Institution and any medical funding charities that have funded the work (either directly or indirectly via the Institution).

6. Confidentiality

- 6.1 The GeCIP Domain IPRs and the GeCIP Domain Results shall be deemed to be the Confidential Information of Genomics England and Genomics England shall be deemed to be the disclosing Party with respect to the GeCIP Domain IPRs and the GeCIP Domain Results.
- 6.2 Each Party receiving Confidential Information undertakes to the disclosing Party that it shall keep, and shall procure that its respective directors and employees to whom Confidential Information is disclosed pursuant to Clause 6.2 shall keep, secret and confidential the Confidential Information and shall not disclose the same or any part of the same to any person whatsoever other than to its directors, employees, students,



- subcontractors or agents directly or indirectly and necessarily concerned in the performance of the Programme.
- 6.3 The provisions of Clause 6.1 shall not apply to Confidential Information which:
- 6.3.1 the receiving Party can prove to have been in its lawful possession (other than under an obligation of confidence to another Party or to a Third Party) at the date of receipt without any obligations of confidentiality or restrictions on use prior to first receiving it from the disclosing Party;
- 6.3.2 is or subsequently enters the public domain through no improper conduct on the part of the receiving Party; or
- 6.3.3 the receiving Party can prove that it has independently developed; or
- 6.3.4 the receiving Party is legally obliged to disclose pursuant to an order of a court of competent jurisdiction or governmental authority provided that the receiving Party shall use its reasonable endeavours to limit such disclosure and to provide the disclosing Party with an opportunity to make representations to the relevant court or governmental authority; or
- 6.3.5 is shared with other members of GeCIP with whom the Institution GeCIP Members are in collaboration with.
- 6.4 The provisions of this Clause 6 shall remain in force:
- 6.4.1 without limit in time in respect of Confidential Information which comprises Participant Personal Data or which relates to national security; and
- 6.4.2 for all other Confidential Information for a period of three (3) years after the expiry or earlier termination of this Agreement unless otherwise agreed in writing by the Parties.
- 6.5 The Institution shall not, without the prior written consent of Genomics England, make any presentations or written publications that refer to data, information and/or results that arise or result from activities with respect to GeCIP that are carried out by the GeCIP members, including any information forming part of the GeCIP Domain IPRs and/or GeCIP Domain Results except where such data, information and/or results have previously been published with the consent of Genomics England.

7. Freedom of Information

- 7.1 Each Party acknowledges that the other Party is subject to the requirements of the FOIA and the EIRs. Each Party shall:
- 7.1.1 provide all necessary assistance and cooperation as reasonably requested by the other Party to enable that Party to comply with its obligations under the FOIA and EIRs; and
- 7.1.2 transfer to the other Party all Requests for Information relating to this Agreement that it receives as soon as practicable and in any event within 2 Working Days of receipt.



- 7.2 Each Party acknowledges and agrees that each Party shall be responsible for determining in its absolute discretion whether any information is exempt from disclosure in accordance with the FOIA and EIRs.
- 7.3 Where the Party responding to a Request for Information determines that it will disclose information in response to that Request for Information it will notify the other Party in writing, giving at least 4 Working Days' notice of its intended disclosure.

8. Amendment of the GeCIP Rules, the GeCIP IP Policy and this Agreement

- 8.1 The Institution acknowledges that the GeCIP Rules and the Genomics England IP Policy may be amended by the GeCIP Board from time to time.
- 8.2 Before making any material change to the GeCIP Rules and/or the Genomics England IP Policy, Genomics England shall notify the Institution of the changes it proposes to make and allow a reasonable period for the Institution to comment on the proposed amendments before implementing such change.
- 8.3 If Genomics England wishes to update the form of this Agreement, it shall notify the Institution in writing and unless the institution objects within 20 Working Days the Institution shall be deemed to be subject to the terms of the new agreement.

9. Limit of Liability

9.1 Under no circumstances shall any Party be liable to another Party, whether in contract, tort (including negligence or breach of statutory duty) or otherwise howsoever arising for any loss of profit, business, reputation, contracts or anticipated savings or any indirect, special or consequential losses which arise, directly or indirectly, from any default on the part of the other Party.

10. Termination and Consequences of Termination

- 10.1 Each Party shall have the right to terminate this Agreement upon written notice to the other Party, if the other Party materially breaches any provision of this Agreement and fails to remedy such breach within a reasonable period after being notified by the innocent Party of such breach.
- 10.2 Clauses 3.3, 3.4, 3.5 and Clauses 6 to 14 (inclusive) shall survive expiry or termination of this Agreement.

11. General

11.1 No Party shall without the prior written consent of the other Party assign the benefit and/or burden of this Agreement, such consent not to be unreasonably withheld or delayed.



- 11.2 No variation, modification, amendment, extension or release from any provision of this Agreement shall be effective unless it is in writing and signed by the Parties.
- 11.3 This Agreement represents the entire understanding, and constitutes the whole agreement, in relation to its subject matter and supersedes any previous agreement between the Parties with respect thereto.
- 11.4 This Agreement may be executed in any one or more counterpart agreements each of which, when executed, shall be deemed to form part of and together constitute this Agreement.
- 11.5 No provision of this Agreement shall be deemed to constitute a partnership between the Parties and none of the Parties shall have any authority to bind another Party in any way, except as provided in this Agreement.
- 11.6 No provision of this Agreement shall operate to:-
- 11.6.1 exclude any provision implied into this Agreement by English law and which may not be excluded by English law; or
- 11.6.2 limit or exclude any liability, right or remedy to a greater extent than is permissible under English law including in relation to (1) death or personal injury caused by the negligence of a party to this Agreement or (2) fraud, fraudulent misrepresentation or deceit.
- 11.7 If any provision of this Agreement is declared by any judicial or other competent authority to be void, voidable, illegal or otherwise unenforceable then the remaining provisions of this Agreement shall continue in full force and effect. The judicial or other competent authority making such determination shall have the power to limit, construe or reduce the duration, scope, activity and/or area of such provision, and/or delete specific words or phrases as necessary to render, such provision enforceable.
- 11.8 Failure or delay by either Party to exercise any right or remedy under this Agreement shall not be deemed to be a waiver of that right or remedy, or prevent it from exercising that or any other right or remedy on that occasion or on any other occasion.
- 11.9 Except as otherwise stated in this Agreement and subject to the prior written consent of the other Party, such consent not to be unreasonably withheld or delayed, each of the Parties shall have the right to subcontract all or any of its obligations under this Agreement to any Third Party, provided that the Party subcontracting its obligations shall:
- 11.9.1 remain fully responsible to the other Party for the proper performance of those obligations; and
- 11.9.2 be liable to the other Party for any negligent act or omission made by the Third Party or its staff in relation thereto.
- 11.10No term of this Agreement is enforceable under the Contracts (Rights of Third Parties) Act 1999 by a Third Party.



12. Notices

- 12.1 All notices shall be in writing and shall (unless express permission is granted by this Agreement for notice to be transmitted by e-mail) be sent by hand, facsimile, or post and shall be deemed to be properly served: (i) if sent by hand on a Business Day, when delivered at the relevant address and if delivered at any other time, on the next Business Day; and (ii) if sent by post, five (5) Business Days after posting.
- 12.2 Notices shall be sent to the addresses set out above or the email addresses set out below marked for the person set out below's attention:
- 12.2.1 Genomics England: chiefscientist@genomicsengland.co.uk; and

12.2.2 Institution:

[Insert position and email address of authorised signatory].

13. Dispute Resolution

- 13.1 Any dispute which may arise concerning the construction, meaning or effect of this Agreement or concerning the rights and liabilities of the Parties hereunder or any other matter arising out of or in connection with this Agreement shall first be submitted for resolution to the persons named in Clause 12.2, who may call on others to advise them as they see fit.
- 13.2 If the persons named in Clause 12.2 fail to resolve the dispute within twenty (20) Business Days the Parties agree to submit the dispute for resolution of the Chief Executive Officer or equivalent of each Party who may call upon other individuals to advise them as they see fit.
- 13.3 If the Chief Executive Officers fail to resolve the dispute within twenty (20) Business Days, the parties shall attempt to settle it by mediation in accordance with the CEDR Model Mediation Procedure. Unless otherwise agreed between the Parties, the mediator will be nominated by CEDR. To initiate the mediation, either Party can submit a notice in writing ('ADR notice') to the other Party requesting mediation. The requesting Party shall send a copy of the request to CEDR. The mediation will commence no later than 14 days after the date of the ADR notice. Each Party shall bear its own costs in relation to any mediation. If the Parties reach agreement on the resolution of the dispute, the agreement shall be reduced to writing and shall be binding on the Parties once it is signed by their duly authorised representatives.
- 13.4 Failing agreement, either Party may invite the mediator to provide a non-binding but informative opinion in writing. Such an opinion shall be provided on a without prejudice basis and shall not be used in evidence in any proceedings relating to the Agreement without the prior written consent of both Parties.
- 13.5 If the Parties fail to reach agreement in the negotiations conducted under the guidance of the mediator in accordance with Clause 13.3, within 60 business days of the mediator being appointed (or such longer period as may be agreed by the Parties), then either Party may refer the dispute to the courts.



14. Law and Jurisdiction

14.1 This Agreement shall be governed by and construed in accordance with the laws of England. Subject to Clause 13.1, the Parties submit irrevocably to the exclusive jurisdiction of the English courts in respect of any disputes arising out of or in connection with this Agreement or its subject matter or formation (including non-contractual disputes or claims).

The Parties hereby execute this Agreement by their duly authorised representatives:



SCHEDULE

APPROVED PERSONS

If there is insufficient space here to enter all verified GeCIP researchers, please include the full list in an email to Genomics England Service Desk



For Genomics England Limited

Authorised Signatory:
Print name:
For (name of employer or education provider)
Authorised Signatory:
Drint name: