# Agreement

THIS AGREEMENT is made on the date of last signature

BETWEEN:

- (1) Genome Research Limited a company incorporated in England (under company registration number 2742969) and registered as a charity (no 1021457), operating as Wellcome Sanger Institute, whose principal place of business is at Wellcome Genome Campus, Hinxton, Cambridge, CB10 1SA, UK ("Sanger"); and
- (2) **Fundación para el Desarrollo de las Ciencias Básicas (FUNDACIBA)** whose address is Isidoro de María 1614, 6th floor, Montevideo, 11800, Uruguay ("Foundation").

## RECITALS

- (1) Sanger has been awarded funding from the Bill and Melinda Gates Foundation (the "**Funding Body**") (Investment ID INV-003570) to carry out the Project with the Department of Public Health Laboratories of the Ministry of Public Health ("**Institution**").
- (2) Sanger wishes to transfer applicable funding received from the Funding Body to Foundation, on the understanding that the Foundation will execute part of the funds to facilitate the work on the Project, as described in Schedule 1.
- (3) The Parties now wish to set out the terms under which Sanger will transfer applicable funding to Institution in accordance with the provisions of this Agreement.
- (4) Sanger will seek to enter into a separate Research Collaboration Agreement with Institution setting out the terms on which they will collaborate to undertake the Project.

# IT IS AGREED as follows:

# 1 Definitions

In this Agreement, the following terms shall have the following meanings:

"Affiliate"	in relation to a Party, any entity or person which controls, is controlled by or is under common control with that Party. For the purposes of this definition, 'control' shall mean direct or indirect beneficial ownership of 50% or more of the share capital, stock or other participating interest carrying the right to vote or to distribution of profits of that entity or person, as the case may be;	
"Award"	the funding awarded to Sanger by the Funding Body as referred to in Recital 1;	
"Commencement Date"	date of last signature;	
"Financial Contribution"	the sum due to Foundation pursuant to Clause 4.1;	
"Grant Conditions"	the conditions under which the Award was granted to Sanger by the Funding Body;	
"Parties"	Sanger and Foundation, and 'Party' shall mean either of them;	
"Project"	the programme of research entitled "GPS2: Global Pneumococcal Sequence surveillance 2.0", as described in further detail in Schedule 1;	
"Research Collaboration Agreement"	the agreement between Sanger and Institution to collaborate on the Project, as referred to in Recital 4;	
"Term"	the period from the Commencement Date to November 30, 2024, or once the Research Collaboration Agreement has been entered into, the date on which the Research Collaboration Agreement expires or is terminated, or any earlier date on	

which this Agreement is terminated under Clause 8 or Clause 14.1.

# 2 Grant Conditions Govern

2.1 Foundation agrees to be bound by the Grant Conditions. In the event of a conflict between the Grant Conditions and this Agreement or the Research Collaboration Agreement, then the Grant Conditions shall prevail.

# 3 Reports and conferences

- 3.1 During the Term, representatives of each of the Parties shall meet at times and places mutually agreed upon (or by telephone or video-conference) to discuss the progress and results, as well as ongoing plans, or changes therein, of the Project.
- 3.2 In accordance with Schedules 1 and 2, Foundation will submit a financial and summary narrative report quarterly to Sanger documenting ongoing progress at budget level regarding the expenditure, and will cooperate with any monitoring activities requested by Sanger in relation to the Project. Quarterly reports shall cover the periods as detailed in the reporting schedule provided in Schedule 2. A template for the quarterly financial report ('Expenditure Report') will be provided separately. Foundation shall also cooperate and/or shall work with Institution to cooperate with Sanger in providing any other reasonably necessary information for Sanger's annual and other reporting to the Funding Body under the terms of the Grant Conditions. Financial reports shall be prepared in USD and shall record any appropriate exchange rates that have been used in making any payments or in preparation of the reports.
- 3.3 Foundation shall also complete and submit a final report consisting of a narrative report and a financial report covering the full Project period within 30 days of completion of the Project. The final report must include a summary statement of expenses relating to the Financial Contribution, together with supporting documentation.
- 3.4 Foundation shall keep full and proper accounts and records of income and expenditure with regard to the Project. Sanger shall be entitled to receive copies of all Project information reasonably required on request (including, without limitation, receipts and vouchers for expenditure incurred) and Sanger may request at any time such evidence as may reasonably be required that Foundation and/or Institution have used the amounts paid in accordance with Clause 0 of the Agreement and for the purposes of the Project. Foundation shall maintain proper financial records relating to the Project at all times during the period of this Agreement and shall retain such records for a period of six (6) years after the expiry or earlier termination of this Agreement.

# 4 Financial

- 4.1 Sanger will forward to Foundation the Financial Contribution, as detailed in Schedule 2, towards the cost of the Project.
- 4.2 Payment shall be made direct to Foundation's account, as set out below:

Fundación para el Desarrollo de las Ciencias Básicas (FUNDACIBA)

Bank name: Banco de la República Oriental del Uruguay (BROU) Bank address: Av. 18 de Julio s/n SWIFT Code: BROUUYMM Beneficiary Name: Fundación para el Desarrollo de las Ciencias Básicas (FUNDACIBA) Beneficiary Address: Isidoro de María 1614 Beneficiary Acc. № 001562480-00002 Type of Account: Checking Currency: US Dollars 4.3 Foundation agrees that it will use the Financial Contribution received from Sanger solely to perform its obligations to carry out the Project in accordance with the terms of the Research Collaboration Agreement and the terms and conditions of this Agreement. Foundation may not use the Financial Contribution for any other purpose.

# 5 Publicity

- 5.1 Subject to the provisions of Clause 6 (Publications), Foundation will not use the name of Sanger, nor of any member of Sanger's Staff, in any publicity, advertising or news release without the prior written approval of Sanger, which will not be unreasonably withheld and Sanger will not use the name of Foundation, nor of any member of Foundation's Staff, in any publicity, advertising or news release without the prior written approval of Foundation, which will not be unreasonably withheld. Notwithstanding the foregoing, Foundation acknowledges that under the terms of the Grant Conditions, the Funding Body may include information about the Award, including Foundation's name, in its periodic public reports and may make such information available on its website and as part of press releases, public reports, speeches, newsletters, tax returns, and other public disclosures.
- 5.2 Foundation will obtain the written consent of Sanger before publication of (i) any promotional materials; (ii) public statements; or (iii) press releases relating to the Project.
- 5.3 Foundation may not state or otherwise imply to third parties that the Funding Body directly funds or otherwise endorses its activities.

# 6 Publications

- 6.1 Foundation acknowledges that by charity law and under Sanger's policies, and the Grant Conditions and the Global Access Commitment, the knowledge and information gained from the Project and any other results of the Project (including Foreground Information) should be publishable.
- 6.2 In any publication, the Parties shall each record the active role of the other Party in the Project with an acknowledgement and in accordance with academic custom and the contribution of the relevant researchers. Wellcome (and other sources, where applicable) will be cited as a source of funds supporting the Project. The citation format to be used shall be: "This work was supported by the Wellcome Trust grant number 206194/Z/17/Z". "This work was supported by Wellcome under grant reference 206194 and by the Bill and Melinda Gates Foundation under Investment ID OPP1189062".

# 7 Confidentiality

- 7.1 For the purposes of this Clause 7 (Confidentiality), 'Confidential Information' shall mean all nonpublic information concerning a Party ("Disclosing Party") or its Affiliates or their respective business, research activities or Background Information, and which the Disclosing Party provides, directly or indirectly to the other Party ("Receiving Party") which the Disclosing Party indicates is confidential at the time of disclosure, or which the Receiving Party should reasonably understand to be of a confidential nature; but in no event shall include information which:
  - 7.1.1 is presently public knowledge or becomes generally available to the public other than as a result of a disclosure by the Receiving Party or its directors, officers, employees, students, representatives or advisors; or
  - 7.1.2 becomes available to the Receiving Party on a non-confidential basis from a source other than the Disclosing Party or its representatives or advisors, provided that the Receiving Party has no reason to believe that there has been a breach of a confidentiality agreement with or other obligation of secrecy to the Disclosing Party; or
  - 7.1.3 the Receiving Party can establish was in its possession before receipt from the Disclosing Party or is developed independently or acquired directly or indirectly from a source independent of the Disclosing Party, its employees, students or agents; or
  - 7.1.4 has been approved for release in writing by an authorised signatory of the Disclosing Party or has been published in accordance with Clause 6 (Publications); or

- 7.1.5 the Receiving Party is required to disclose to the courts of any competent jurisdiction, or to any government regulatory or financial authority, provided that the Receiving Party shall:
  - a) inform the Disclosing Party as soon as is reasonably practicable; and
  - b) at the Disclosing Party's request seek to persuade the court, agency or authority to have the information treated in a confidential manner, where this is possible under the court, agency's or authority's procedures.
- 7.2 The Receiving Party undertakes that Confidential Information disclosed to it by the Disclosing Party will be used solely in connection with the Project including for publication purposes as set out at Clause 6, and that such information will be kept confidential by the Receiving Party and its representatives and advisors for the duration of the Project and, with the exception of Personal Data and confidential patient information, for three (3) years after the Term. For the avoidance of doubt, Personal Data and confidential patient information shall remain confidential indefinitely.
- 7.3 At the end of the Term (including early termination under Clause 8 or 14.1):
  - 7.3.1 the Receiving Party shall promptly return to the other Party all documents and any other physical material containing or reflecting any information included in the Confidential Information (whether provided by the Disclosing Party, its representatives or advisors or otherwise) and will not retain any copies, extracts or other reproductions in whole or in part of such documents or physical material other than one copy in its legal files; and
  - 7.3.2 the Receiving Party shall destroy all documents, memoranda, notes and other writings whatsoever prepared by the Receiving Party or its representatives or advisors incorporating the Confidential Information except as otherwise permitted under this Clause 7.3;
  - 7.3.3 the Receiving Party shall not make, and shall procure that its representatives or advisors do not make any more use of the Confidential Information.

# 8 Commencement and Termination

- 8.1 This Agreement shall be deemed to have commenced on the Commencement Date and shall terminate at the end of the Term.
- 8.2 Either Party may terminate this Agreement with immediate effect by giving written notice to the other Party if:
  - 8.2.1 the other Party is in material breach of any provision of this Agreement and (if it is capable of remedy) the breach has not been remedied within forty five (45) days after receipt of a written notice specifying the breach and requiring its remedy; or
  - 8.2.2 the other Party becomes insolvent, or if an order is made or a resolution is passed for its winding up (except voluntarily for the purpose of solvent amalgamation or reconstruction), or if an administrator, administrative receiver or receiver is appointed over the whole or any part of the other Party's assets, or if the other Party makes any arrangements with its creditors.
  - 8.2.3 Sanger and Institution are unable to enter into the Research Collaboration Agreement.
- 8.3 At the termination of this Agreement Sanger shall pay all costs incurred and falling due for payment up to the date of termination and, in the event of early termination (other than where it is for Foundation's breach or insolvency) also all expenditures and costs falling due for payment after the date of termination which arises from non-cancellable commitments reasonably and necessarily incurred by Foundation or Institution for the performance of the Project prior to the date of termination.
- 8.4 Termination of this Agreement shall not affect the rights and obligations of the Parties accrued prior to the effective date of termination of this Agreement. No termination of the Agreement,

however effected, shall release the Parties from their rights and obligations under Clauses 0, 5, 6, 7, 8.3, 9, 10, and from 14.4 to 14.15.

# 9 Warranties

Each of the Parties acknowledges that, in entering into this Agreement, it does not do so in reliance on any representation, warranty or other provision except as expressly provided in this Agreement, and any conditions, warranties or other terms implied by statute or common law are excluded from this Agreement to the fullest extent permitted by law.

# 10 Liability

- 10.1 Subject to Clause 10.3, the Parties agree that no liability whatsoever, either direct or indirect, shall rest upon either of them for the effects of any products or process that may be produced or adopted by either of them as a result of the Project, notwithstanding that the formulation of such product or process may be based upon the findings of the Project.
- 10.2 Subject to Clause 10.3, neither Party shall be liable to the other Party in contract, tort, negligence, breach of statutory duty or otherwise for any economic loss, loss of turnover, profits, business or goodwill, in each case whether direct or indirect, or for any loss, damage, costs or expenses of any nature whatsoever incurred or suffered by that other Party or its Affiliates of an indirect or consequential nature even if the Party bringing the Claim has advised the other of the possibility of those losses, or if they were within the other Party's contemplation.
- 10.3 Nothing in this Agreement limits or excludes either Party's liability for:
  - 10.3.1 death or personal injury caused by negligence of that Party;
  - 10.3.2 any fraud or for any sort of liability that, by law, cannot be limited or excluded; or
  - 10.3.3 any loss or damage caused by a deliberate breach of this Agreement or a deliberate breach of Clause 7 (Confidentiality).

# 11 Compliance with Relevant Requirements and Relevant Policies

- 11.1 Foundation shall:
  - 11.1.1 comply with all applicable laws, statutes, regulations relating to anti-bribery and anticorruption including but not limited to the Bribery Act 2010 or any equivalent legislation in the USA ("Relevant Requirements");
  - 11.1.2 have and shall maintain in place throughout the term of this Agreement its own policies and procedures to ensure compliance with the Relevant Requirements and will enforce them where appropriate;
  - 11.1.3 promptly report to Sanger any request or demand for any undue financial or other advantage of any kind received by Foundation in connection with this Agreement; and
  - 11.1.4 if requested by Sanger, certify to Sanger, in writing, signed by an officer of Foundation, compliance with this clause by Foundation. Foundation shall provide such supporting evidence of compliance as Sanger may reasonably request.
- 11.2 Breach of this Clause 11 shall be deemed a material breach of this Agreement.

## 12 Compliance with Anti- Slavery and Human Trafficking Laws and Policies

- 12.1 In performing its obligations under the agreement, Foundation shall:
  - 12.1.1 comply with all applicable anti-slavery and human trafficking laws, statutes, regulations and codes from time to time in force including but not limited to the Modern Slavery Act 2015 or any equivalent legislation in the USA;
  - 12.1.2 have and maintain throughout the term of this Agreement its own policies and procedures to ensure its compliance;
  - 12.1.3 not engage in any activity, practice or conduct that would constitute an offence under sections 1, 2 or 4, of the Modern Slavery Act 2015 if such activity, practice or conduct were carried out in the UK; and

12.1.4 include in its contracts with its suppliers anti-slavery and human trafficking provisions that are at least as onerous as those set out in this Clause 12.

### 13 Research Misconduct

Each Party shall ensure that it has (and Foundation shall confirm that Institution shall have) well defined arrangements for investigating and resolving allegations of research misconduct. Where an allegation of research misconduct arises in respect of an individual's participation in the Project and leads to a subsequent formal investigation, the relevant Party shall inform the other Party of the investigation and its outcome. Where an allegation of research misconduct arises in respect of both Parties' participation in the Project, the relevant Parties will work together to determine how the allegation will be investigated and reported.

### 14 General

## 14.1 Force majeure

Neither Party shall have any liability or be deemed to be in breach of this Agreement for any delays or failures in performance of this Agreement, which result from circumstances beyond the reasonable control of that Party, including without limitation labour disputes involving that Party. The Party affected by such circumstances shall promptly notify the other Party in writing when such circumstances cause a delay or failure in performance and when they cease to do so. However, if the delay in performance is more than six (6) months, the other Party may terminate this Agreement with immediate effect by giving written notice.

## 14.2 Amendment

This Agreement may only be amended in writing signed by duly authorised representatives of the Parties.

#### 14.3 Assignment

Neither Party shall assign, mortgage, charge or otherwise transfer or sub-contract any rights or obligations under this Agreement without the prior written consent of the other Party, such consent not to be unreasonably withheld or delayed.

# 14.4 <u>Waiver</u>

No failure or delay on the part of either Party to exercise any right or remedy under this Agreement shall be construed or operate as a waiver thereof, nor shall any single or partial exercise of any right or remedy preclude the further exercise of such right or remedy.

### 14.5 Invalid clauses

If any provision or part of this Agreement is held to be invalid, amendments to this Agreement may be made by the addition or deletion of wording as appropriate to remove the invalid part or provision but otherwise retain the provision and the other provisions of this Agreement to the maximum extent permissible under applicable law.

#### 14.6 No agency

Neither Party shall act or describe itself as the agent of the other, nor shall it make or represent that it has authority to make any commitments on the other's behalf.

#### 14.7 Interpretation

In this Agreement:

- 14.7.1 The headings are used for convenience only and shall not affect its interpretation.
- 14.7.2 References to persons shall include incorporated and unincorporated persons; references to the singular include the plural and vice versa; and references to the masculine include the feminine.
- 14.7.3 References to Clauses and Schedules shall mean clauses of, and schedules to, this Agreement respectively.

# 14.8 **Notices**

- 14.8.1 Any notice to be given under this Agreement shall be in writing and shall be delivered by hand (including by courier) or sent by first class mail or air mail to the address of the relevant Party set out at the head of this Agreement or such other address as that Party may from time to time notify to the other Party in accordance with this Clause 14.8.
  - a) Notices to Foundation shall be marked for the attention of Inés Nieto (Project Manager), and sent by email to nieto@fundaciba.uy with a copy to fundaciba@fundaciba.uy.
  - b) Notices to Sanger shall be marked for the attention of the General Counsel and sent to the address set out at the head of this Agreement with a copy to Sanger's Principal Investigator, and to <u>legalnotices@sanger.ac.uk</u>.
- 14.8.2 Notices sent as above shall be deemed to have been received on the business day after delivery in the case of delivery by hand or 3 working days after the day of posting (in the case of inland first class mail), or 7 working days after the date of posting (in the case of air mail).

## 14.9 Law and jurisdiction

The validity, construction and performance of this Agreement shall be governed by English law

and shall be subject to the exclusive jurisdiction of the English courts to which the Parties hereby

submit, except that a Party may seek an interim injunction in any court of competent jurisdiction.

# 14.10 Dispute Resolution

If any dispute arises out of this Agreement, the Parties will first attempt to resolve the matter informally through designated senior representatives of each Party to the dispute, who are not otherwise involved with the Project. If the Parties are not able to resolve the dispute informally within a reasonable time not exceeding one (1) month from the date the informal process is requested by notice in writing, they will attempt to settle it by mediation in accordance with the Centre for Effective Dispute Resolution (CEDR) Model Mediation Procedure.

## 14.11 Further action

Each Party agrees to execute, acknowledge and deliver such further instruments, and do all further similar acts, as may be necessary or appropriate to carry out the purposes and intent of this Agreement.

## 14.12 Entire agreement

This Agreement, including its Schedules, sets out the entire agreement between the Parties relating to its subject matter and supersedes all prior oral or written agreements, arrangements or understandings between them relating to such subject matter. The Parties acknowledge that they are not relying on any representation, agreement, term or condition which is not set out in this Agreement.

## 14.13 Third parties

This agreement does not create any right enforceable by any person not a party to it. In particular, Institution shall not be entitled to enforce this Agreement.

# 14.14 Insurance

Each Party will maintain insurance coverage sufficient to cover the activities, risks, and potential omissions of the Project in accordance with generally accepted industry standards and as required by law.

## 14.15 Compliance with laws

Each Party will comply with all applicable laws, statutes, regulations, rules and codes from time to time in force and that relate to its activities under this Agreement.

AGREED by the Parties through their authorised signatories:

For and on behalf of	For and on behalf of	
Genome Research Limited DocuSigned by: Nadia Muliti	Fundación para el Desarrollo de las Ciencias Básicas Docu <sup>Signed by:</sup> David Gomálus	
Signed Nadia Meliti	Signed	
Print name	David González Print name	
General Counsel	Administration Counsel President	
Title	Title	
25 August 2023	01 de septiembre de 2023	
Date	Date	

# **SCHEDULE 1**

# Project Title: GPS2: Global Pneumococcal Sequence surveillance 2.0

Sanger Prelim number: S2693

Description of the Project:

# BACKGROUND

PCV targets the capsule around pneumococcal cells and has been very effective in reducing disease. However, the vaccine is only able to target some strains and the population overall is able to evolve to evade the vaccine. This creates an arms race between the vaccine and the pathogen, in which surveillance plays an important role to maintain the diseases at low level or further reduce them. The Global Pneumococcal Sequencing (GPS) project has been successful in creating the international network of partners necessary to perform a global genomic survey and generated valuable information for decision making in pneumococcal disease control. It also highlighted the further needs for a follow-up project (GPS2) that aims to understand the pneumococcal population dynamics in response to the vaccine with extending temporal and geographical coverage of data to inform future vaccine design. The aims will be achieved by building a federalized system for local generation and analysis of genomic data that will be sustainable into the future.

# GOALS:

The overarching aim of this project is to provide evidence for:

- pneumococcal evolution in response to PCV
- current and future effectiveness of current vaccines
- design of future vaccine

# **EXPERIMENTAL PLAN:**

Partners with links to local hospitals and laboratories will collect pneumococcal isolates that represents the region(s). Pneumococcal isolates will be prepared in cryovials by partner and send to Sanger for DNA extraction and whole-genome sequencing. From the sequence data we will be able to capture variations across the entire genome so as to understand the pneumococcal evolution that results in vaccine evasion. To assess the effectiveness of current and future vaccine, we will infer the capsule type (vaccine target) and strain type from sequence data so as to monitor the dynamics in response to the vaccine and identify any emerging strains that are not targeted by the current vaccine. This information together will be invaluable for future vaccine design. Along this process, Sanger will support capacity for local data generation, provide training in data analysis and interpretation, build infrastructure for data sharing and integration, develop web-based bioinformatics tools to achieve the goals of the project. To translate the research output into policy, Sanger will work with project partners to actively engage with policy makers and the wider community to explain the value of GPS resources and importance of the findings for decision-making in pneumococcal disease prevention.

Funder (if applicable): Bill and Melinda Gates Foundation

Sanger activities:

Administration of funds and reporting to funder. Project management, data analysis and interpretation, bioinformatics training.

FOUNDATION activities:

Execute the funds established according to current regulations, complying with the schedule and budget established between Sanger and the Department of Public Health Laboratories. Maintain the correct control and file of the legal receipts resulting from the execution of the funds.

# **SCHEDULE 2**

### Payments

The Parties acknowledge and agree that the amount to be contributed by Sanger, via Foundation, for the performance of the services set out in Schedule 1, sample preparation cost of \$12 per sample for a total of \$5,292 ("Grant Funds"), plus the additional cost of administrative handling that is \$500. Total \$5,792.

The Financial Contribution shall be paid according to the following payment schedule. For each payment Foundation shall invoice Sanger on the specified date or milestone and such invoice will be paid in accordance with Clause 5.1. The budget and payment schedule are in addition subject to further revision as may be agreed by the Parties and Institution in writing in advance.

Date/milestone	Payment to be made (USD)
Signature Date of this Agreement	5792

# Budget

Ítem	Description	Amount (US \$)
Materials	Tubes, Petri dishes, disposable	1702
	loops	
Reagents	Culture medium, transport	3330
	medium, sheep blood,	
	biochemical tests, antisera	
Administrative costs		500
Contingencies		260
TOTAL		5792

# Reporting

An annual expense report will be made on December 1 of each project year until the Initial Payment has been spent.