AGREEMENT FOR A PARTICIPATING GENERAL PRACTICE IN A CLINICAL STUDY SPONSORED BY THE UNIVERSITY OF OXFORD

THIS AGREEMENT dated is made BETWEEN:

(1) **THE CHANCELLOR, MASTERS AND SCHOLARS OF THE UNIVERSITY OF OXFORD** whose administrative offices are at Wellington Square, Oxford OX1 2JD (hereinafter "University" or "Sponsor"); and

(2) **[ ]** of [ ] (hereinafter "Surgery").

The above-mentioned parties shall hereinafter individually be called "Party" and collectively be called "the Parties".

WHEREAS

A. The Chancellor, Masters, and Scholars of the University of Oxford, whose administrative offices are at Wellington Square, Oxford OX1 2JD (the "University") has agreed to act as study sponsor ("Sponsor") for the clinical study, entitled "Expanding national RAPid community Test evaluation capacity fOR COVId-19" (the "Study"), under the relevant UK Policy Framework for Health and Social Care, as amended from time to time.

B. The Surgery wishes to participate as a site in the Study and conduct the Study in accordance with the Protocol ("Protocol") for the Study at Appendix 1 of this Agreement.

C. The Chief Investigator for this Study, which for the purposes of this Agreement shall mean the person who takes overall responsibility for the design, conduct and reporting of the Study if it is at one site or if the Study involves researchers at more than one site, the person who takes primary responsibility for the design, conduct and reporting of the Study, whether or not the person is an investigator at any particular site, is Professor Richard Hobbs from The Chancellor, Masters and Scholars of the University of Oxford.

It is therefore agreed as follows:

1.1 ***RESEARCH LAWS REGULATIONS AND CODES OF GOOD PRACTICE***

1.2 The Parties agree to comply with any laws, regulations and codes of practice, as applicable, to the performance of the Study, including but not limited to the following:

- The Data Protection Act, 2018
- The General Data Protection Regulation, 2018
- The Declaration of Helsinki, 2008 titled "Ethical Principles for Medical Research Involving Human Subjects"
- The Freedom of Information Act, 2000
- The Human Rights Act, 1998
- The Human Tissue Act, 2004
- The Medical Device Regulations, 2002
- The Medicines Act, 1968
- The Medicines for Human Use (Clinical Trials) Regulations 2004, including compliance with Good Clinical Practice
- The relevant UK Policy Framework for Health and Social Care

The above references shall be deemed to include references to any statute, subordinate legislation, declaration or framework which amends, extends, consolidates or replaces the legislation and the framework referenced above.

OBLIGATIONS OF THE SURGERY

- To ensure that all practice staff involved with the study are familiar with the UK Policy Framework for Health and Social Care and the practice's data protection policy and work within the requirements of the Health & Safety Act 1974.
- To retain clinical responsibility for any patients entered into Study.
- To provide brief curricula vitae of the general practitioners and Study nurses if required by the appropriate Research Ethics Committee or Comprehensive Local Trial Network (CLRN).
- To start the Study only when ethical and R&D approval have been obtained.

- To conduct the Study in accordance with the Protocol at Appendix 1 and any Study Specific SOP, which may be defined in the Protocol.
- To complete the Study unless extenuating circumstances occur, including but not limited to notification of early termination from the Sponsor in the event that, *inter alia*, funding is withdrawn or terminated for any reason or there are insufficient funds available to continue the Study, insufficient numbers of patients are being recruited to the Study across all the study centers, interim analysis of the data from this Study or the results of another study obviates the need for completion of this Study or the Sponsor has given 30 days prior written notice of termination to the Surgery
- To arrange for space to be provided within the practice to enable the Study to be carried out.
- To ensure that all health professionals engaged in the conduct of the Study and the Surgery hold Medical Malpractice, Professional Indemnity and Public liability insurance through the duration of the Study and for a period of at least three years thereafter.
- To ensure that Study files and documents, Study records and data, medication and equipment are stored securely.
- To allow inspection of Study files and documents and Study records and data by the Study team, including but not limited to the Chief Investigator and any Study monitor as approved by the Sponsor and/or described in the Protocol , the Sponsor or an independent body for purposes of quality control, monitoring and study data audit.
- To keep patient case record forms and study documentation for twenty years from the completion of the study or, if that is not possible, to seek and obtain authorisation for alternative archiving arrangements with the Sponsor, such consent not to be unreasonably withheld.
- To ensure that Study data and any required Study activity reports are provided and submitted in accordance with the Protocol.
- To agree to undertake the Study on the understanding that the payments made to the practice are dependent upon evidence of Study activity and that the payments will be made according to Appendix 2.
- To disclose any conflicts of interest that may arise during the course of this Study, and take responsibility for ensuring that all Surgery staff involved are aware of their responsibilities to disclose conflicts of interest.
- To agree that information related to this Study and the Surgery's involvement will be held by Sponsor. This information will be managed according to the principles established in the Data Protection Act 2018 and in accordance with the General Data Protection Regulations according to Appendix 3.
- Where appropriate and required, to assign rights in data, intellectual property and, to the extent possible, know how, arising solely out of the Study to the Sponsor and at the request and expense

of the Sponsor to complete all such documents and do all such other acts and things as the Sponsor may reasonably require in order to allow the Sponsor to assume ownership of all such arising data, intellectual property rights and know how.

- To agree that it shall not distribute information releases and announcements to the news media regarding the progress or research of the Study without the prior written approval of the Sponsor.
- To acknowledge that the Study is part of a multi-centre study and that an independent first publication is anticipated to be authored by the Sponsor's investigators in this multi-center Study ("First Publication") and shall agree not to publish the results of the Study independently before the publication of the First Publication.
- To agree that it shall not shall use the name, logo or registered image of the Sponsor or its employees, consultants or agents in any publicity, advertising or press release without the prior written approval of an authorised representative of the Sponsor.
- To ensure that the equipment loaned to it for the purposes of the Study (which shall include a tablet and Point of Care Testing kits) are:
  - Only used for the purpose of the Study;
  - Used in accordance with all applicable laws, regulations, and governmental guidelines; and
  - Not modified without first obtaining the Sponsor's written approval.
- To replace irreparable and lost equipment provided for the Study (at the expense of the Participating Site whilst the Participating Site has custody and control of the equipment). Risk of any loss or damage to the equipment will become the responsibility of the Participating Site on delivery to the Participating Site and will remain with the Participating Site until equipment has been returned to the Sponsor or supplier as instructed by the Sponsor.
- To return all materials and equipment related to the Study to the Sponsor or device supplier as instructed by the Sponsor promptly following the end of the Participating Site's participation in the Study.

RESPONSIBILITIES OF SPONSOR

It is the responsibility of the Study Sponsor to be satisfied that clear agreements are reached, documented and carried out, providing for proper initiation, management, monitoring and financing of the Study. It is the Sponsor's responsibility to ensure that:

- The Protocol respects the dignity, rights, safety and well-being of participating patients and the relationship with care professionals.
- An appropriate process of independent expert review has demonstrated that the Protocol is worthwhile, of high scientific quality and represents good value for money.

- The Study has appropriate ethical approval before it begins.
- Appropriate arrangements are in place for registration of a study.
- The Chief Investigator, and other key investigators and/or members of the Study team, including those staff at participating Surgeries, have the necessary expertise and experience and have access to the resources needed to conduct the proposed Study successfully.
- The arrangements and resources proposed will allow the collection of high quality, accurate data and the systems and resources proposed are those required to allow appropriate data analysis and data protection.
- Organisations and individuals involved in the Study agree the division of responsibilities between them.
- There is a clear written agreement about the arrangements for the ongoing management and monitoring of the Study.
- Arrangements will be put and kept in place for the Sponsor and other relevant organisations to be alerted if significant developments occur as the Study progresses, whether in relation to safety of individuals or to scientific direction.
- For clinical studies involving medicines this includes:
    - the licensing authority has given approval and all arrangements for the study comply with the law
    - ensuring that investigational medicinal products are made available to subjects free of charge.
    - keeping records of all adverse events reported by investigators;
    - ensuring recording and prompt reporting of suspected unexpected serious adverse reactions (SUSARS);
    - ensuring investigators are informed of SUSARs;
    - ensuring all SUSARs are entered into the European database; and
    - providing an annual list of suspected serious adverse events and a safety report.
- An agreement has been reached about compensation in the event of non-negligent harm and if any organisation, including the Sponsor itself, offers such compensation, it has made the necessary financial arrangements.
- There are arrangements for the conclusion of the Study including appropriate plans for disseminating the findings.

AS WITNESS the hands of authorised signatories for the Parties on the date first mentioned above.

SIGNED for and on behalf of THE CHANCELLOR, MASTERS AND SCHOLARS OF OXFORD	**SIGNED for and on behalf of** **[ ]**
Name:	Name:
Position:	Position:
Signature:	Signature:
Date:	Date:

APPENDIX 1

The Protocol

RAPTOR protocol V2.0.pdf

APPENDIX 2

Schedule of payments and details of payment arrangements

The Surgery shall perform the tasks below and as set out in the Protocol.

The Surgery will be paid fees to cover costs, summarized as the following:

Costs	**Invoice Study Team at the University**	**Invoice CRN**
One off set-up costs	£72.80	£102.20
Cost per patient recruited with all baseline and follow-up data entered correctly and laboratory sample request forms filled correctly.	£73.85	£66.15

All sums above are inclusive of any applicable VAT. The Surgery shall invoice the University for sums to be invoiced to the University as set out above following (i) the end of the Surgery's participation in the Study and (ii) return of all materials and equipment related to the Study to either the University or device supplier as instructed by the University. The University shall pay the Surgery within 30 days of said invoices.

Invoice to study team:

Nuffield Department of Primary Care Health Sciences, University of Oxford, Radcliffe Observatory Quarter, Woodstock Road, Oxford OX2 6GG

Invoice to CRN:

Where any payments are to be made by the local CRN, these shall be invoiced directly to the CRN. If contact details for the CRN are needed, please contact the study team at the University.

Appendix 3

General Data Protection Regulation

Data Protection Legislation

DEFINITIONS

Data Protection Legislation means any law, statute, declaration, decree, directive, legislative enactment, order, ordinance, regulation, rule or other binding restriction (as amended, consolidated or re-enacted from time to time) which relates to the protection of individuals with regards to the Processing of Personal Data to which a party is subject, including the Data Protection Act 1998 and EC Directive 95/46/EC (up to and including 24 May 2018) and on and from 25 May 2018, the General Data Protection Regulation ((EU) 2016/679) ("**GDPR**");

Data Controller, **Data Processor**, **Data Subject**, and **Processing** (and variations thereof) have the meanings set out in the Data Protection Legislation.

Personal Data means any personal data (as defined in the Data Protection Legislation) Processed by any party in connection with this Agreement.

1. **DATA PROTECTION**

1.1 The Parties will comply with all applicable requirements of the Data Protection Legislation. This Clause (Data Protection) is in addition to, and does not relieve, remove or replace, a Party's obligations under the Data Protection Legislation.

1.2 The Parties acknowledge that for the purposes of the Data Protection Legislation, the Sponsor is the Data Controller and the Surgery are the Data Processor of any Personal Data which is being collected on behalf of and/or provided to the Sponsor by the Surgery and the Coordinating Centre under the Protocol. Schedule A sets out the scope, nature and purposes of processing by the Surgery, the duration of the processing and the types of Personal Data and categories of Data Subject. The Parties also acknowledge that some of such Personal Data may be information collected routinely by the Surgery as part of a Data Subject's clinical care ("Routine Clinical Data"). When processed for the purposes of clinical care or any other purpose outside the scope of the Protocol, the Parties

acknowledge that the Surgery (as relevant) is Data Controller of the Routine Clinical Data and that the Sponsor is not involved in such processing. The Sponsor consents to the Surgery's use of any Personal Data they have collected on behalf of the Sponsor under this Agreement, for the sole purpose of clinical care of the Data Subjects, provided that any such processing complies with the rest of this Appendix 3.

1.3 To the extent that the Surgery Processes any Personal Data as a Data Processor for and on behalf of the Sponsor (as the Data Controller) it shall:

(i) only Process Personal Data for and on behalf of the Sponsor for the purposes of performing its obligations under this Agreement and only in accordance with the Sponsor's written instructions from time to time, inform the Sponsor immediately if it considers any of the Sponsor's instructions infringes Data Protection Legislation;

(ii) ensure that it has in place appropriate technical and organisational measures, reviewed and approved by the Sponsor, to protect against unauthorised or unlawful processing of Personal Data and against accidental loss or destruction of, or damage to, Personal Data, appropriate to the harm that might result from the unauthorised or unlawful processing or accidental loss, destruction or damage and the nature of the data to be protected, having regard to the state of technological development and the cost of implementing any measures (those measures may include, where appropriate, pseudonymising and encrypting Personal Data, ensuring confidentiality, integrity, availability and resilience of its systems and services, ensuring that availability of and access to Personal Data can be restored in a timely manner after an incident, and regularly assessing and evaluating the effectiveness of the technical and organisational measures adopted by it);

(iii) ensure that any persons who have access to and/or Process Personal Data are obliged to keep the Personal Data confidential;

(iv) taking into account the nature of the Processing, at the Sponsor's request, assist the Sponsor to comply with the obligations imposed on the Sponsor by the Data Protection Legislation in relation to: (i) security, breach notifications, data protection impact assessments, and consultations with supervisory authorities or regulators; and (ii) responding to any requests from Data Subjects.

(v) notify the Sponsor promptly following its receipt of any request from a Data Subject to exercise their rights under the Data Protection Legislation or any correspondence from a supervisory authority or regulator and shall:

(A) not disclose any Personal Data without first consulting with and obtaining the Sponsor's prior written consent; and

(B) provide the Sponsor with all reasonable co-operation and assistance required by the Sponsor in relation to any such request or correspondence;

(vi) notify the Sponsor without undue delay and in any event within twenty-four (24) hours) upon becoming aware of any actual or suspected Personal Data breach, and:

(A) conduct or support the Sponsor in conducting such investigations and analysis that the Sponsor reasonably requires in respect of such breach;

(B) implement any measures necessary to restore the security of compromised Personal Data; and

(C) assist the Sponsor to make any notifications to supervisory authorities or regulators and affected Data Subjects;

(vii) keep a record of any Processing of the Personal Data it carries out on behalf of the Sponsor and hold the Personal Data in such a manner that it is capable of being distinguished from other data or information processed by Surgery;

(viii) promptly comply with any request from the Sponsor to amend, transfer or delete any Personal Data;

(ix) at the written direction of the Sponsor, delete or return Personal Data and copies thereof to the Sponsor on termination of the Agreement unless required by Applicable Data Processing Law to store the Personal Data;

(x) at the Sponsor’s reasonable request: (i) make available to the Sponsor evidence to demonstrate the Surgery’s compliance with the requirements of this Clause; and (ii) allow for and contribute to audits, including inspections, conducted by or

on behalf of the Sponsor, on reasonable notice and subject to appropriate confidentiality obligations;

(xi) not engage a third party processor of Personal Data under this Agreement (a sub-processor) unless the Sponsor in its absolute discretion gives a specific or general written authorisation; and where such consent is given, the Surgery:

(A) shall inform the Sponsor of any intended changes to a general written authorisation to add or replace processors, thereby giving the Sponsor the opportunity to object to such changes;

(B) impose data protection obligations that are substantially the same to those set out in this Agreement;

(C) acknowledges that the Surgery remains fully liable to the Sponsor for the performance of any sub-contracted Processing obligations,

(xii) not transfer any Personal Data outside of the European Economic Area ("EEA") or to an international organisation[1] except:

(A) with the prior written consent of the Sponsor and in accordance with any written instructions and terms the Sponsor may impose on such transfer to ensure that transfers of Personal Data outside of the EEA have adequate protections in place as set out in the Data Protection Legislation; or

(B) if required by Applicable Data Processing Law, in which case the Coordinating Centre shall inform the Sponsor of that legal requirement before transferring, unless the law prohibits such information on important grounds of public interest.

1.4 Surgery shall indemnify on demand and keep indemnified the Sponsor from and against:

[1] Defined as an organisation and its subordinate bodies governed by public international law, or any other body which is set up by, or on the basis of, an agreement between two or more countries (GDPR Article 4(26))

(i) any monetary penalties or fines levied by supervisory authorities or regulators on the Sponsor; and

(ii) any losses, liabilities, damages, costs, and expenses howsoever arising (including but not limited to any direct, indirect or consequential losses, loss of profit, loss of reputation and all interest, penalties and legal costs (calculated on a full indemnity basis) and all other reasonable professional costs and expenses) suffered or incurred by, awarded against, or agreed to be paid by, the Sponsor pursuant to a claim, action or challenge made by a third party against the Sponsor (including by a Data Subject),

in each case to the extent arising as a result of a breach by the Surgery (or its permitted sub-contractors) of this Agreement and/ or their respective obligations under the Data Protection Legislation.

1.5 Nothing in this Agreement will exclude, limit or restrict the Surgery's liability under the indemnity set out in Clause 1.4.

1.6 Notwithstanding anything in the Agreement to the contrary, this Clause (Data Protection) shall continue in full force and effect for so long as the Surgery processes any Personal Data.

Schedule A – Data Protection Particulars

The subject matter and duration of the Processing	The data will include pseudonymised clinical and test result data for patients with suspected current or past COVID-19 who are registered at an RCGP RSC practice and who have consented to participate in the RAPTOR-C19 study. The data will be collected to ascertain the diagnostic accuracy of rapid diagnostic tests (also known as Point of Care Tests or POCTS) for COVID-19. Data will be captured on an electronic Case Report Form (eCRF) completed by participants and personnel supporting the RAPTOR study, including but not limited to, a CRN Nurse, a Practice Nurse, a GP, a Practice Liaison Officer

	etc. eCRF data will be collected by uMed, which will act as a Data Processor on behalf of the practices, which are the Data Controllers. eCRF data will be uploaded to the secure ORCHID hub at least twice a week using the secure NHS number hashing algorithm. Oxford administers this hub as a data processor on behalf of the practices. After baseline data collection at the first study visit, participants will be asked to submit a daily symptom diary remotely, and adults will be invited back 28 days after the initial appointment. Processing time will therefore usually be 1 to 5 weeks for each participant.
The nature and purpose of the Processing	Processing of pseudonymised data to provide an accurate record of participant clinical record and tests results for analysis in accordance with the RAPTOR protocol. Part of the research data collected under the NIHR 'Urgent Public Health Research' category
The type of Personal Data being Processed	Pseudonymised sensitive personal and medical data collected by the uMed eCRF.
The categories of Data Subjects	Research participants in the RAPTOR Study: members of the general public and professionals. Includes data collected on people under 18 with the relevant and consent and ethics permissions.