Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please complete the questions in order. If you change the response to a question, please select 'Save' and review all the questions as your change may have affected subsequent questions.

Please enter a short title for this project (maximum 70 characters)
RAPid community Testing fOR COVID-19 (RAPTOR-C19)

1. Is your project research?

(●) Yes ( ) No

2. Select one category from the list below:

( ) Clinical trial of an investigational medicinal product
(●) Clinical investigation or other study of a medical device
( ) Combined trial of an investigational medicinal product and an investigational medical device
( ) Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice
( ) Basic science study involving procedures with human participants
( ) Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
( ) Study involving qualitative methods only
( ) Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)
( ) Study limited to working with data (specific project only)
( ) Research tissue bank
( ) Research database

If your work does not fit any of these categories, select the option below:

( ) Other study

2a. Is the study sponsored or funded by a device manufacturer or other commercial company?

( ) Yes (●) No

Please select one of the following:

( ) Clinical study of a non-CE marked device where commercialisation of the product is intended
( ) Clinical study of a non-CE marked device for use within the institution, where commercialisation is not intended
( ) Clinical study of one or more CE marked devices for an off-label indication
( ) Clinical study of one or more CE marked devices for a labelled indication, involving a change to standard care or randomisation between groups

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(●) Clinical study of one or more CE marked devices for a labelled indication, involving *no* change to standard care or randomisation between groups

( ) Pre-clinical device development or performance testing

2b. Please answer the following question(s):

a) Does the study involve the use of any ionising radiation? ( ) Yes (●) No

b) Will you be taking new human tissue samples (or other human biological samples)? (●) Yes ( ) No

c) Will you be using existing human tissue samples (or other human biological samples)? ( ) Yes (●) No

d) Will the study involve any other clinical procedures with participants (e.g. MRI, ultrasound, physical examination)? ( ) Yes (●) No

3. In which countries of the UK will the research sites be located?*(Tick all that apply)*

- [x] England
- [x] Scotland
- [x] Wales
- [x] Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

(●) England

( ) Scotland

( ) Wales

( ) Northern Ireland

( ) This study does not involve the NHS

4. Which applications do you require?

- [x] IRAS Form
- [ ] Confidentiality Advisory Group (CAG)
- [ ] Her Majesty's Prison and Probation Service (HMPPS)

5. Will any research sites in this study be NHS organisations?

(●) Yes ( ) No

5a. Are all the research costs and infrastructure costs (funding for the support and facilities needed to carry out research e.g. NHS Support costs) for this study provided by a NIHR Biomedical Research Centre, NIHR Collaboration for Leadership in Health Research and Care (CLAHRC), NIHR Patient Safety Translational Research Centre or Medtech and In Vitro Diagnostic Cooperative in all study sites?

Please see information button for further details.

( ) Yes (●) No

Please see information button for further details.

5b. Do you wish to make an application for the study to be considered for NIHR Clinical Research Network (CRN)

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Support and inclusion in the NIHR Clinical Research Network Portfolio?

Please see information button for further details.

(●) Yes ( ) No

The NIHR Clinical Research Network provides researchers with the practical support they need to make clinical studies happen in the NHS e.g. by providing access to the people and facilities needed to carry out research "on the ground".

If you select yes to this question, you must complete a NIHR Clinical Research Network (CRN) Portfolio Application Form (PAF) immediately after completing this project filter question and before submitting other applications. Failing to complete the PAF ahead of other applications e.g. HRA Approval, may mean that you will be unable to access NIHR CRN Support for your study.

6. Do you plan to include any participants who are children?

(●) Yes ( ) No

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

( ) Yes (●) No

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the Confidentiality Advisory Group to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

( ) Yes (●) No

9. Is the study or any part of it being undertaken as an educational project?

( ) Yes (●) No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

( ) Yes (●) No

11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?

( ) Yes (●) No

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Integrated Research Application System
Application Form for Medical Device Study

IRAS Form (project information)

Please refer to the E-Submission and Checklist tabs for instructions on submitting this application.

The Chief Investigator should complete this form. Guidance on the questions is available wherever you see this symbol displayed. We recommend reading the guidance first. The complete guidance and a glossary are available by selecting Help.

Please define any terms or acronyms that might not be familar to lay reviewers of the application.

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)
RAPid community Testing fOR COVID-19 (RAPTOR-C19)

Please complete these details after you have booked the REC application for review.

REC Name:

REC Reference Number: **Submission date:**

PART A: Core study information

1. ADMINISTRATIVE DETAILS

A1. Full title of the research:

Expanding national RAPid community Test evaluation capacity fOR COVID-19

A3-1. Chief Investigator:

	Title	Forename/Initials	Surname
	Professor	FD Richard	Hobbs
Post	Head of Department		
Qualifications	CBE, FMedSci, FRCGP, FRCP (London), FESC, FRCP (Edin), MA (Ox)		
ORCID ID	0000 0001 7976 7172		
Employer	University of Oxford		
Work Address	Nuffield Department of Primary Care Health Sciences		
	Radcliffe Primary Care Building		
	Oxford		
Post Code	OX2 6GG		
Work E-mail	richard.hobbs@phc.ox.ac.uk		
* Personal E-mail			
Work Telephone	01865 617851		
* Personal Telephone/Mobile			
Fax	01865 617851		

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** This information is optional. It will not be placed in the public domain or disclosed to any other third party without prior consent.*
A copy of a current CV (maximum 2 pages of A4) for the Chief Investigator must be submitted with the application.

A4. Who is the contact on behalf of the sponsor for all correspondence relating to applications for this project?
This contact will receive copies of all correspondence from REC and HRA/R&D reviewers that is sent to the CI.

	Title	Forename/Initials	Surname
	N/A	N/A	CTRG

Address	University of Oxford / Clinical Trials and Research Governance, Joint Research Office
	1st floor, Boundary Brook House, Churchill Drive, Headington
	Oxford
Post Code	OX3 7GB
E-mail	ctrg@admin.ox.ac.uk
Telephone	000000000
Fax	000000000

A5-1. Research reference numbers. *Please give any relevant references for your study:*

Applicant's/organisation's own reference number, e.g. R & D (if available):	N/A
Sponsor's/protocol number:	1.0
Protocol Version:	1.0
Protocol Date:	01/06/2020
Funder's reference number (enter the reference number or state not applicable):	N/A
Project website:	N/A

Registry reference number(s):
The UK Policy Framework for Health and Social Care Research sets out the principle of making information about research publicly available. Furthermore: Article 19 of the World Medical Association Declaration of Helsinki adopted in 2008 states that "every clinical trial must be registered on a publicly accessible database before recruitment of the first subject"; and the International Committee of Medical Journal Editors (ICMJE) will consider a clinical trial for publication only if it has been registered in an appropriate registry. Please see guidance for more information.

International Standard Randomised Controlled Trial Number (ISRCTN):	ISRCTN00000000
ClinicalTrials.gov Identifier (NCT number):	NCT00000000

Additional reference number(s):

Ref.Number Description	Reference Number

A5-2. Is this application linked to a previous study or another current application?

○ Yes ◉ No

Please give brief details and reference numbers.

2. OVERVIEW OF THE RESEARCH

To provide all the information required by review bodies and research information systems, we ask a number of

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specific questions. This section invites you to give an overview using language comprehensible to lay reviewers and members of the public. Please read the guidance notes for advice on this section.

A6-1. Summary of the study. *Please provide a brief summary of the research (maximum 300 words) using language easily understood by lay reviewers and members of the public. Where the research is reviewed by a REC within the UK Health Departments' Research Ethics Service, this summary will be published on the Health Research Authority (HRA) website following the ethical review. Please refer to the question specific guidance for this question.*

The NHS urgently needs quick, accurate rapid diagnostic tests to diagnose people with coronavirus or to confirm that people do not have the infection. Point-of-care Tests (POCTs) can be used in community settings where there is no easy access to a specialist laboratory. They provide quick results that allow people to get immediate advice about self-isolation and treatment, potentially blocking further spread of infection in the community. Companies are quickly developing new rapid diagnostic tests, but we do not know how well they work. Some tests give a result like a pregnancy test by using a drop of blood from a finger prick. Others use saliva, or a swab to collect a sample from the nose or throat.

Companies check tests work in their laboratories, but usually tests do not work as well when used in the field with real patients. Accurate rapid diagnostic tests are important so that people are not falsely reassured when they are infected, and are not wrongly diagnosed when they are not really infected.

Our team manages a national surveillance system with a network of community settings including GP practices from all over England that report directly to the Department of Health and Social Care about a wide range of infections. These GP practices have been testing for coronavirus since January 2020 with samples sent for laboratory tests. In this study, practices in the network will quickly compare new POCTs for coronavirus with laboratory tests so we can see how good the new tests are in a coordinated and efficient way. National COVID-19 Test centres may also support the research project.

A6-2. Summary of main issues. *Please summarise the main ethical, legal, or management issues arising from your study and say how you have addressed them.*

Not all studies raise significant issues. Some studies may have straightforward ethical or other issues that can be identified and managed routinely. Others may present significant issues requiring further consideration by a REC, HRA, or other review body (as appropriate to the issue). Studies that present a minimal risk to participants may raise complex organisational or legal issues. You should try to consider all the types of issues that the different reviewers may need to consider.

1. Informed consent

It is imperative that all non-essential contact between the participants, researchers, and practice, or testing centre staff is prevented in order to minimise the risk of COVID-19 transmission. To achieve this, we will use a combination of digital written consent and/or researcher recorded verbal consent in this study. People can take time to consider, but many may wish to proceed at the time. Participants will be provided with a pdf record. Written information will be available in the form of posters at RAPTOR-C19 sites, and as electronic participant information accessible online, and included on the uMed platform and RAPTOR-C19 Tablet.

2. Ensuring quality of diagnostic testing

To ensure testing quality, the RAPTOR-C19 team will use manufacturer's instructions to develop training materials for the tests. RAPTOR-C19 staff will liaise with the manufacturers where clarification is required on use of the POCT. study team using material developed with the test manufacturer to ensure that biological sample collection and testing is standardised, and to minimise the occurrence of spoiled samples. If a point-of-care test machine is used and re-used it will undergo regular calibration to ensure their continued accuracy.

3. Ensuring inaccurate results are not communicated to participants

Previous studies have shown that the accuracy (sensitivity/ specificity) of the rapid point of care COVID-19 tests are not yet comparable to laboratory testing. We will not communicate the results of the point-of-care tests to the participants to ensure that inappropriate clinical management and unnecessary participant anxiety is avoided. The results of the current national standard of care, the Public Health England (PHE) laboratory tests, will be communicated to the practices to guide participant advice and management. These tests are being done as part of clinical care. Participants will agree for these results and other clinical data to be shared with the research team.

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3. PURPOSE AND DESIGN OF THE RESEARCH

A7. Select the appropriate methodology description for this research. *Please tick all that apply*:

- [ ] Case series/ case note review
- [ ] Case control
- [ ] Cohort observation
- [ ] Controlled trial without randomisation
- [x] Cross-sectional study
- [ ] Database analysis
- [ ] Epidemiology
- [ ] Feasibility/ pilot study
- [ ] Laboratory study
- [ ] Metanalysis
- [ ] Qualitative research
- [ ] Questionnaire, interview or observation study
- [ ] Randomised controlled trial
- [x] Other (please specify)

In-context diagnostic performance evaluation (observational)

A10. What is the principal research question/objective? *Please put this in language comprehensible to a lay person.*

To assess the diagnostic accuracy of multiple current and emerging point-of-care tests (POCTS) for active COVID-19 infection in the community setting.

A11. What are the secondary research questions/objectives if applicable? *Please put this in language comprehensible to a lay person.*

1. To assess the diagnostic accuracy of multiple current and emerging (POCTS) for past COVID-19 infection in the community setting.

2. To assess the diagnostic accuracy of multiple current and emerging (POCTS) for active COVID-19 infection in the community setting against a composite reference standard.

3. To assess the diagnostic accuracy of multiple current and emerging (POCTS) for past COVID-19 infection in the primary care setting against a composite reference standard.

A12. What is the scientific justification for the research? *Please put this in language comprehensible to a lay person.*

There are currently no rapid diagnostic tests that have been evaluated as fit-for-purpose in NHS primary care that aim to identify whether patients are currently, or have been, infected by the 2019 novel coronavirus (SARS-CoV-2).

The United Kingdom and wider world is in the midst of the SARS-CoV-2 / COVID-19 pandemic. Accurate diagnosis of infection, identification of past infection and monitoring the clinical progression of infection are of paramount importance to our response, and for all of these diagnostics are central. Widespread population testing has proven difficult in western countries and has been limited by test availability, diagnostic test sensitivity, human resources and long turnaround times (up to 72 hours). This has limited our ability to control the spread of infection and to develop effective clinical pathways to enable early social isolation of infected patients, early treatment for those most at risk and early return to work for those with resolved infection and potential immunity.

Point-of-care tests (POCTs) can be used in the community where there is no easy access to a specialist laboratory, in locations such as NHS general practices. POCTs provide quick results that allow people to get immediate advice about self-isolation and treatment, potentially blocking further spread of infection in the community. In-context evaluation of POCTs in the community is important as test accuracy can vary based on the prevalence of disease in the

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population tested and the operational environment in which the test is carried out. The severity of COVID-19 disease in the community is much lower than in hospital patients. Symptomatic acutely unwell hospitalised patient are likely to have higher viral loads that are easier to detect, and may be undergoing invasive procedures to collect samples from the lower respiratory tract, that have a higher yield. Testing only in severe patients introduces spectrum bias and biases results to overestimate test performance. It is important to diagnose hospital patients, but from a public health point of view the most concerning patients are ambulatory outpatients, who may spread the virus much further in the community if falsely reassured. Evaluations of COVID-19 POCTs are therefore required in each clinical setting. Community based POCTs may lead to additional public health impacts such as reducing onward household transmission of COVID-19, improving surveillance of NHS and social care staff, accurate prevalence estimates, and understanding of COVID-19 transmission dynamics in the wider population.

RAPTOR-C19 will provide the community testbed to the COVID-19 National DiagnOstic Research and Evaluation Platform (CONDOR). Its platform design will allow for both flexibility in which POCTs are evaluated and for changes in PHE choice of reference standard. All POCTs will be detailed in the Appendices to this protocol. POCTs will only be added after submission to the appropriate approval bodies. CONDOR is the collaborative national platform for COVID-19 diagnostics research and evaluation. CONDOR will evaluate the analytical performance of in vitro diagnostics (IVDs) (molecular, antigen and antibody tests) via its laboratory network, and evaluate the in-context clinical performance (diagnostic and prognostic accuracy) of IVDs (self-tests, POCTs and laboratory platforms) in the network of community and secondary care settings. These include the community, emergency departments, acute ambulatory care and acute medicine units, critical care units and hospital at home services.

A13. Please summarise your design and methodology. *It should be clear exactly what will happen to the research participant, how many times and in what order. Please complete this section in language comprehensible to the lay person. Do not simply reproduce or refer to the protocol. Further guidance is available in the guidance notes.*

RAPid Community Testing fOR COVID-19 (RAPTOR-C19) incorporates a series of prospective observational diagnostic accuracy studies of COVID-19 point-of-care diagnostic tests (also known as point-of-need or near patient tests) where performance is assessed by comparing the results of point-of-care tests with laboratory reference ('Gold') standard test used by Public Health England and composite reference standards which incorporate the results of potentially more than one test and other information about the patient. The proposed studies will be carried out in patients with suspected current or past COVID-19 attending community settings such as NHS general practices enrolled with the RCGP-RSC and national COVID-19 testing centres.

Adult patients (≥ 16 years old) with suspected current or past COVID-19 will be asked to consent to:
1. use at least one, but the intention is to assess multiple, POCTs for COVID-19
2. answer a short questionnaire about eligibility and their clinical details
3. submit an oropharyngeal/nasopharyngeal (OP/NP) swab for laboratory COVID-19 Real-Time Polymerase Chain Reaction (RT-PCR) to PHE
4. submit blood samples for PHE COVID-19 laboratory antibody testing
5. the study team accessing their NHS electronic health records (EHRs) in the future
6. further contact from the study team to track symptoms and health status after the first study visit
7. a second visit for additional serology testing

The parent or legal guardian of children (< 16 years old) with suspected current COVID-19 will be asked to consent the child to:
1. use at least one, but the intention is to assess multiple, POCTs for COVID-19
2. answer a short questionnaire about eligibility and their clinical details
3. submit an OP/NP swab for laboratory COVID-19 RT-PCR to PHE
4. the study team accessing their NHS EHRs in the future
5. further contact from the study team to track symptoms and health status after the first study visit

A14-1. In which aspects of the research process have you actively involved, or will you involve, patients, service users, and/or their carers, or members of the public?

- [x] Design of the research
- [x] Management of the research
- [ ] Undertaking the research
- [x] Analysis of results
- [x] Dissemination of findings

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☐ None of the above

Give details of involvement, or if none please justify the absence of involvement.
This work is being supported by an experienced group of patients which is being managed and chaired by Graham Prestwich, Patient and Public Involvement Lead for the Yorkshire and Humber Academic Health Science Network. A group of 24 participants met to discuss the overarching platform proposal (CONDOR) under which RAPTOR-C19 will sit. Their ongoing input will be sought as follows: two lay members will form part of the steering committee for the overarching platform under which RAPTOR-C19 will operate; the patient group will be consulted with regard to the interpretation of our findings, prioritisation of tests for evaluation, and dissemination of our findings; the patient group will contribute to the development of patient facing materials.

4. RISKS AND ETHICAL ISSUES

RESEARCH PARTICIPANTS

A15. What is the sample group or cohort to be studied in this research?

Select all that apply:

- ☐ Blood
- ☐ Cancer
- ☐ Cardiovascular
- ☐ Congenital Disorders
- ☐ Dementias and Neurodegenerative Diseases
- ☐ Diabetes
- ☐ Ear
- ☐ Eye
- ☑ Generic Health Relevance
- ☑ Infection
- ☐ Inflammatory and Immune System
- ☐ Injuries and Accidents
- ☐ Mental Health
- ☐ Metabolic and Endocrine
- ☐ Musculoskeletal
- ☐ Neurological
- ☐ Oral and Gastrointestinal
- ☐ Paediatrics
- ☐ Renal and Urogenital
- ☐ Reproductive Health and Childbirth
- ☐ Respiratory
- ☐ Skin
- ☐ Stroke

Gender:	Male and female participants
Lower age limit: 0	Years
Upper age limit: 100	Years

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A17-1. Please list the principal inclusion criteria (list the most important, max 5000 characters).

Inclusion:

Adults (≥16 years old)
• males or females
• with suspected current or past COVID-19 infection*
• having OP/NP swab for laboratory COVID-19 RT-PCR as part of clinical care/testing
• willing and able to give informed consent for participation in the study

Children (< 16 years old)
• males or females
• with suspected current COVID-19 infection*
• having OP/NP swab for laboratory COVID-19 RT-PCR as part of clinical care/testing
• parent or legal guardian is willing and able to give informed consent for participation in the study

* As the clinical features of COVID-19 are broad, especially in older or immunosuppressed individuals, restricting testing to a narrow spectrum of clinical features would lead to a limited in-context evaluation. The working definition of suspected current or past COVID-19 infection will be based on the current advice to consider COVID-19 infection in people who during the COVID-19 pandemic have:

1. Symptoms thought to be associated with COVID-19, including but not limited to: fever, cough, fatigue, dyspnoea, sputum production, shortness of breath, myalgia, chills, dizziness, headache, sore throat, hoarseness, nausea or vomiting, diarrhoea, nasal congestion.

2. Acute respiratory distress syndrome

3. Either clinical or radiological evidence of pneumonia

4. Atypical presentations, for example an acute functional decline or frailty syndrome in an older person, if they are immunocompromised.

5. lived or worked in close contact with somebody who has tested positive for COVID-19, including NHS staff.

A17-2. Please list the principal exclusion criteria (list the most important, max 5000 characters).

The participant may not enter the study if ANY of the following apply:
• adults unable to understand the study information and give consent to take part in the study
• need for immediate hospitalisation
• previously enrolled in this study in relation to the individual test being evaluated

RESEARCH PROCEDURES, RISKS AND BENEFITS

A18. Give details of all non-clinical intervention(s) or procedure(s) that will be received by participants as part of the research protocol. *These include seeking consent, interviews, non-clinical observations and use of questionnaires.*

Please complete the columns for each intervention/procedure as follows:

1. Total number of interventions/procedures to be received by each participant as part of the research protocol.
2. If this intervention/procedure would be routinely given to participants as part of their care outside the research, how many of the total would be routine?
3. Average time taken per intervention/procedure (minutes, hours or days)
4. Details of who will conduct the intervention/procedure, and where it will take place.

Intervention or procedure	1	2	3	4
Seeking consent	1	0	20	Research nurse, clinician (GP), or other appropriately trained member of the study team.
Completion of the electronic case report	1	0	10	Participant, research nurse, clinician, or other appropriately

form for each participant	trained member of the clinical team.

A19. Give details of any clinical intervention(s) or procedure(s) to be received by participants as part of the research protocol. *These include uses of medicinal products or devices, other medical treatments or assessments, mental health interventions, imaging investigations and taking samples of human biological material. Include procedures which might be received as routine clinical care outside of the research.*

Please complete the columns for each intervention/procedure as follows:

1. Total number of interventions/procedures to be received by each participant as part of the research protocol.
2. If this intervention/procedure would be routinely given to participants as part of their care outside the research, how many of the total would be routine?
3. Average time taken per intervention/procedure (minutes, hours or days).
4. Details of who will conduct the intervention/procedure, and where it will take place.

Intervention or procedure	1	2	3	4
Sampling for point-of-care testing. (the total number of samples taken e.g. nose/throat swabs and/or fingerstick blood samples / saliva samples, will not exceed 6 samples for an individual)	6	0	5	Participant, research nurse, clinician, or other appropriately trained member of the clinical team.
Clinical data collection	2	0	5	Research nurse, clinician, or other appropriately trained member of the clinical team.
Venous blood sample (adults only)	2	0	5	Research nurse, clinician, or other appropriately trained member of the clinical team.

A21. How long do you expect each participant to be in the study in total?

Children - single time point
Adults - up to 30 days to allow for second blood sampling, where possible.
Both adults and children will be followed up for fifty years in their electronic health record.

A22. What are the potential risks and burdens for research participants and how will you minimise them?

For all studies, describe any potential adverse effects, pain, discomfort, distress, intrusion, inconvenience or changes to lifestyle. Only describe risks or burdens that could occur as a result of participation in the research. Say what steps would be taken to minimise risks and burdens as far as possible.

Nose and throat swabs cause some transient discomfort to patients, but there are no clinically significant risks associated with the procedure. Fingerstick blood sampling may cause transient discomfort and localised bruising at the sampling site, however there are no clinically significant risks associated with the procedure. Venous blood sampling causes discomfort and may result in bruising and localised swelling at the sampling site. Provision of saliva samples is unlikely to cause discomfort to any participants.

To mitigate these risks, self sampling will be supported where appropriate, otherwise these procedures will be carried out by personnel who have received training in these procedures or who carry out these procedures as a routine element of their duties.

A24. What is the potential for benefit to research participants?

There is not direct benefit to research participants associated with any results yielded by the index diagnostic tests that will be evaluated. The clinical performance of the index diagnostics being tested is unknown (which is why this research is required), so the results cannot be used to guide clinical care. It is possible that patients may benefit indirectly, either because they may require testing in the future, by which time the tests being evaluated may be available or because the tests could be used to enhance the public health response to COVID-19 and may accelerate control of the pandemic.

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RECRUITMENT AND INFORMED CONSENT

In this section we ask you to describe the recruitment procedures for the study. Please give separate details for different study groups where appropriate.

A27-1. How will potential participants, records or samples be identified? Who will carry this out and what resources will be used?*For example, identification may involve a disease register, computerised search of GP records, or review of medical records. Indicate whether this will be done by the direct healthcare team or by researchers acting under arrangements with the responsible care organisation(s).*

If the clinical team suspects a diagnosis of COVID-19, then the participant may be eligible for inclusion and may be screened for potential inclusion. Potential participants may be identified opportunistically when attending the study site for clinical evaluation or testing, through telephone triage or face to face consultation. Additionally, potential participants may be identified through medical notes review (historic infection) or where they respond to RAPTOR-C19 associated publicity media.

A27-2. Will the identification of potential participants involve reviewing or screening the identifiable personal information of patients, service users or any other person?

(●) Yes ( ) No

Please give details below:
The investigating team will have no access to personal identifiable information. Those with appropriate clinical access will conduct searches of electronic health records at the sites. Note: all correspondence with the patient (digital or otherwise) will come from the site.

A27-3. Describe what measures will be taken to ensure there is no breach of any duty of confidentiality owed to patients, service users or any other person in the process of identifying potential participants.*Indicate what steps have been or will be taken to inform patients and service users of the potential use of their records for this purpose. Describe the arrangements to ensure that the wishes of patients and service users regarding access to their records are respected. Please consult the guidance notes on this topic.*

The uMed service, which is used by GP practices to process patient data, provides a gold standard that ensures that the identification of potential participants does not breach confidentiality as no information about those patients is transmitted to the RAPTOR team. Moreover, when patients are engaged they will receive an SMS (or letter/call) from their recognised GP practice, with the ability to opt-out of further correspondence. A detailed review of the uMed platform IG processes can found here: https://drive.google.com/file/d/1yOivdHJAzvgk7ERv6iUkrmsDSNw0_dCr /view

A27-4. Will researchers or individuals other than the direct care team have access to identifiable personal information of any potential participants?

( ) Yes (●) No

A28. Will any participants be recruited by publicity through posters, leaflets, adverts or websites?

(●) Yes ( ) No

If Yes, please give details of how and where publicity will be conducted, and enclose copy of all advertising material (with version numbers and dates).

Posters have been developed for participant recruitment and participant information purposes. It is the intention that copies of this poster will be displayed at participating community based study sites.

A29. How and by whom will potential participants first be approached?

Potential participants will either be approached by a staff member of a study site when they attend for a clinical appointment of for testing, by staff during telephone triage or a face to face appointment. Potential participants

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identified by electronic health records review will be contacted to assess eligibility by text message.

A30-1. Will you obtain informed consent from or on behalf of research participants?

(●) Yes ( ) No

If you will be obtaining consent from adult participants, please give details of who will take consent and how it will be done, with details of any steps to provide information (a written information sheet, videos, or interactive material). Arrangements for adults unable to consent for themselves should be described separately in Part B Section 6, and for children in Part B Section 7.

If you plan to seek informed consent from vulnerable groups, say how you will ensure that consent is voluntary and fully informed.

The RAPTOR-C19 site will ask eligible and willing patients (or their parent/carer, where applicable) to complete an e-consent process using the uMed interface.

Informed consent will be obtained in line with Good Clinical Practice (GCP) guidelines. It is imperative that all non-essential contact between the participants, researchers, and practice, or testing centre staff is prevented in order to minimise the risk of COVID-19 transmission.

To achieve this, we will use a combination of digital written consent and/or researcher recorded verbal consent in this study. Written information will be available in the form of posters at RAPTOR-C19 sites, and as electronic participant information accessible online, and included on the uMed platform and RAPTOR-C19 Tablet.

The uMed platform will guide the participant, or the participant's parents / guardians, through the consent questions, or the researcher will read out the questions from the form, recording the participant's responses electronically. The completed consent form will be exported into a .pdf document and emailed to the participant.

The participant will be allowed as much time as wished to consider the information, and the opportunity to question the researcher or other independent parties to decide whether they will participate in the study. All answers will be stored electronically and securely.

If you are not obtaining consent, please explain why not.

Please enclose a copy of the information sheet(s) and consent form(s).

A30-2. Will you record informed consent (or advice from consultees) in writing?

( ) Yes (●) No

If No, how will it be recorded?

The participant or recruiting staff member will document the consent process by completing the consent form.

A31. How long will you allow potential participants to decide whether or not to take part?

Potential participants will be afforded as much time as required to decide whether or not to participate in the study.

A32. Will you recruit any participants who are involved in current research or have recently been involved in any research prior to recruitment?

(●) Yes

( ) No

( ) Not Known

If Yes, please give details and justify their inclusion. If Not Known, what steps will you take to find out?

We will include patients who are at risk of current or past COVID-19 infection. Being involved in other research studies is highly unlikely to affect our ability to assess the diagnostic performance of COVID-19 POCTs.

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A33-1. What arrangements have been made for persons who might not adequately understand verbal explanations or written information given in English, or who have special communication needs?*(e.g. translation, use of interpreters)*

Where language / communication impairment (e.g. hearing impairment) are barriers to communication, the direct care team may require translation / interpretation to communicate with patients during consultation. Wherever possible, we will arrange for translation to be extended to facilitate study-related communication with potential participants where this is required.

A33-2. What arrangements will you make to comply with the principles of the Welsh Language Act in the provision of information to participants in Wales?

Where language / communication impairment (e.g. hearing impairment) are barriers to communication, the direct care team may require translation / interpretation to communicate with patients during consultation. Wherever possible, we will arrange for translation to be extended to facilitate study-related communication with potential participants where this is required.

A35. What steps would you take if a participant, who has given informed consent, loses capacity to consent during the study? *Tick one option only.*

- ○ The participant and all identifiable data or tissue collected would be withdrawn from the study. Data or tissue which is not identifiable to the research team may be retained.
- ◉ The participant would be withdrawn from the study. Identifiable data or tissue already collected with consent would be retained and used in the study. No further data or tissue would be collected or any other research procedures carried out on or in relation to the participant.
- ○ The participant would continue to be included in the study.
- ○ Not applicable – informed consent will not be sought from any participants in this research.
- ○ Not applicable – it is not practicable for the research team to monitor capacity and continued capacity will be assumed.

Further details:

We anticipate that a proportion of patients who participate in this study may deteriorate, lose capacity and potentially die during the follow-up period. It is important that such cases are represented in this research, to ensure scientific validity, so any information gathered prior to loss of capacity would be included in the analysis.

If you plan to retain and make further use of identifiable data/tissue following loss of capacity, you should inform participants about this when seeking their consent initially.

CONFIDENTIALITY

In this section, personal data means any data relating to a participant who could potentially be identified. It includes pseudonymised data capable of being linked to a participant through a unique code number.

Storage and use of personal data during the study

A36. Will you be undertaking any of the following activities at any stage (including in the identification of potential participants)?*(Tick as appropriate)*

- ☑ Access to medical records by those outside the direct healthcare team
- ☐ Access to social care records by those outside the direct social care team
- ☑ Electronic transfer by magnetic or optical media, email or computer networks
- ☑ Sharing of personal data with other organisations
- ☐ Export of personal data outside the EEA
- ☑ Use of personal addresses, postcodes, faxes, emails or telephone numbers

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- [ ] Publication of direct quotations from respondents
- [ ] Publication of data that might allow identification of individuals
- [ ] Use of audio/visual recording devices
- [x] Storage of personal data on any of the following:
  - [ ] Manual files (includes paper or film)
  - [x] NHS computers
  - [ ] Social Care Service computers
  - [ ] Home or other personal computers
  - [x] University computers
  - [ ] Private company computers
  - [ ] Laptop computers

Further details:
uMed conforms to the requirements of General Data Protection Regulation (GDPR), the NHS Data Protection & Security Toolkit, and ISO 27001. The core principle applied throughout the RAPTOR-C19 study and across the wider uMed platform is that uMed always acts as a data processor on behalf of the sites that are taking part in this study. This data processing agreement allows uMed to capture and utilise EHR data from the practice to provide services to support delivery of studies. uMed therefore cannot use or share provider data with any third party without the permission from the practice (data controller in respect of clinical data and care). Consequently, the uMed platform includes provision for an authorisation workflow to enable the practice to give permission(s) for engagement and/or sharing of data in-line with the RAPTOR study protocol. This process also ensures that an audit trail is created such that the Sponsor is able to confirm all required permissions have been given by each site. eCRF data collected by uMed will be uploaded to the secure ORCHID hub at least twice a week.

All data handling and management will follow the current RCGP-RSC Data Management Standard Operating Procedures (SOPs) which are aligned with the University of Oxford SOPs. All eCRFs will be completed electronically and uploaded using a secure web based system. Currently, the ORCHID hub will be hosted by NHSX in the Azure environment. This platform allows for a rapid implementation of both storage and computation while ensuring data integrity through network segmentation and encryption. This has the advantage of allowing the service to be flexible in reacting to the demands of the data flows and compute requirements, through bringing on additional servers to improve data processing throughput.

Each unique patient within the ORCHID hub is de-identified at source before their data is extracted from individual practices using a computer generated patient ID number. The ORCHID hub holds no identifiable data and only hashed NHS number. This pseudonymised patient level data extracted from general practice CMR systems such as EMIS (Egton Medical Information Systems, UK) and SystmOne TPP (The Phoenix Partnership, UK),will include demographic data, clinical event data coded with SNOMED CT (SNOMED International, UK), medication data coded with dm+d and free text entries. Encrypted data will be transported securely to the protected ORCHID hub, initially through providers such as the Azure environment (Microsoft Corporation, USA) hosted by NHSX. In this environment, we will create an extract, transform, and load (ETL) process that will convert the EMIS and TPP data in to the OMOP Common Data Model (CDM) and map to the Standardized Vocabularies. The implementation will be carried out using a collection of automated scripts (i.e. SQL) to enable the ETL process to be repeatable.

A37. Please describe the physical security arrangements for storage of personal data during the study?

uMed applies the latest cloud based security principles to ensure that data is held securely on our Amazon Web Service (AWS) infrastructure. In addition to conforming to the standards set by NHS Digital, the uMed platform goes beyond this to create a gold standard for information security of health data. It achieves this by ensuring patient identity information is always separated from the sensitive health data with a multi-stage encrypted communication layer that prevents the complete, identifiable patient record from being accessed by a legitimate or maleficent actor (including uMed's internal staff).

The Oxford Royal College of General Practitioners Clinical Informatics (ORCHID) Hub is compliant with Data Protection Legislation, 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, and the subsequent General Data Protection Regulation ((EU) 2016/679) ("GDPR"). It is also compliant with the NHS Digital Data Security and Privacy policy and is subject to data sharing agreements with all concerned such as NHSX. Both the University of

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Oxford and the University of Surrey (where the RSC data has historically been held) are Data Security and Privacy toolkit (DSP) compliant. Pseudonymisation of data will ensure that the work meets the common law right to privacy.

All participating general practices will be required to sign an agreement setting out the nature of their involvement in the ORCHID Hub. Data transfers between primary care CMR providers such as EMIS and TPP will be governed by data sharing agreements subject to the laws and regulations of the UK.

Patient level databases will be held in study-specific partitions on the network drives of the Medical Sciences Division IT Services at the University of Oxford which are sited behind a firewall within the University's network. It is a standalone, independent network, all in-bounded connections are block, but out-bounded connections are allowed. All staff members of the research group working within the team base work from secure workstations or secure laptops with encrypted local disks. Only relevant members of the study team at the University of Oxford will have access to the data.

A38. How will you ensure the confidentiality of personal data?*Please provide a general statement of the policy and procedures for ensuring confidentiality, e.g. anonymisation or pseudonymisation of data.*

Each unique patient within the Oxford Royal College of General Practitioners Clinical Informatics (ORCHID) hub is de-identified at source before their data is extracted from individual practices using a computer generated patient ID. The ORCHID hub holds no identifiable data and only hashed NHS numbers. Encrypted data will be transmitted securely to the protected ORCHID hub, initially through providers such as the Azure environment (Microsoft Corporation, USA) hosted by NHSX.

A40. Who will have access to participants' personal data during the study? *Where access is by individuals outside the direct care team, please justify and say whether consent will be sought.*

Access to participants personal data will be limited to the direct care team, and investigators and employees of the sponsor organisation, who are bound by University and Departmental information governance requirements.

Storage and use of data after the end of the study

A41. Where will the data generated by the study be analysed and by whom?

Data generated by the study will be analysed using IT infrastructure which is managed by the Medical Sciences Division IT services at the University of Oxford. Analysis will be carried out by members of the study team at the University of Oxford.

A42. Who will have control of and act as the custodian for the data generated by the study?

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	Oxford		
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Work Email	brian.nicholson@phc.ox.ac.uk		
Work Telephone	01865617851		
Fax			

A43. How long will personal data be stored or accessed after the study has ended?

◉ Less than 3 months

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- ◯ 3 – 6 months
- ◯ 6 – 12 months
- ◯ 12 months – 3 years
- ◯ Over 3 years

A44. For how long will you store research data generated by the study?

Years: 20
Months: 0

A45. Please give details of the long term arrangements for storage of research data after the study has ended.*Say where data will be stored, who will have access and the arrangements to ensure security.*

Data will be securely archived in accordance with the requirement of the sponsor organisation.

The University of Oxford Policy on research data (http://researchdata.ox.ac.uk/university-of-oxford-policy-on-the-management-of-research-data-and-records/), particularly clause 3.5 will guide the management and retention of study data by the research team 'Researchers will preserve and provide appropriate access to their research data supporting outputs after the end of their project for as long as it has continuing value, in accordance with legal and funder requirements and paying due regard to discipline norms and cost. Notwithstanding, the minimum retention period for research data and records is three years after publication or public release of the work of the research'.

Given that the project will not exclude children, research data will be retained for 20 years.

INCENTIVES AND PAYMENTS

A46. Will research participants receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in this research?

◯ Yes ◉ No

A47. Will individual researchers receive any personal payment over and above normal salary, or any other benefits or incentives, for taking part in this research?

◯ Yes ◉ No

A48. Does the Chief Investigator or any other investigator/collaborator have any direct personal involvement (e.g. financial, share holding, personal relationship etc.) in the organisations sponsoring or funding the research that may give rise to a possible conflict of interest?

◯ Yes ◉ No

NOTIFICATION OF OTHER PROFESSIONALS

A49-1. Will you inform the participants' General Practitioners (and/or any other health or care professional responsible for their care) that they are taking part in the study?

◯ Yes ◉ No

If Yes, please enclose a copy of the information sheet/letter for the GP/health professional with a version number and date.

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PUBLICATION AND DISSEMINATION

A50. Will the research be registered on a public database?

The UK Policy Framework for Health and Social Care Research sets out the principle of making information about research publicly available. Furthermore: Article 19 of the World Medical Association Declaration of Helsinki adopted in 2008 states that "every clinical trial must be registered on a publicly accessible database before recruitment of the first subject"; and the International Committee of Medical Journal Editors (ICMJE) will consider a clinical trial for publication only if it has been registered in an appropriate registry. Please see guidance for more information.

(●) Yes ( ) No

Please give details, or justify if not registering the research.
The RAPTOR-C19 team will register the study protocol with the ISCRTN Registry (https://www.isrctn.com/?gclid=CjwKCAjwqpP2BRBTEiwAfpiD--pRxJ8S48 EeSWxdIB9Zy1nm1k3LSSFMzrrwd6fR-45I3SN3_60jPxoCgG4QAvD_BwE)

Please ensure that you have entered registry reference number(s) in question A5-1.

A51. How do you intend to report and disseminate the results of the study? *Tick as appropriate:*

- [x] Peer reviewed scientific journals
- [ ] Internal report
- [ ] Conference presentation
- [x] Publication on website
- [x] Other publication
- [ ] Submission to regulatory authorities
- [ ] Access to raw data and right to publish freely by all investigators in study or by Independent Steering Committee on behalf of all investigators
- [ ] No plans to report or disseminate the results
- [x] Other (please specify)

Provision of test evaluation data to the Department of Health, Public Health England and public health authorities of the devolved nations, the NHS, and relevant government departments.

A52. If you will be using identifiable personal data, how will you ensure that anonymity will be maintained when publishing the results?

Results will be published in an aggregate form, with study outcomes expressed in diagnostic performance metrics, so it will not be possible to identify individual patients from the published data. Where required to demonstrate very relevant individual cases (e.g. important false negatives), we will only report basic, non-identifiable details.

A53. Will you inform participants of the results?

( ) Yes (●) No

Please give details of how you will inform participants or justify if not doing so.
We will not systematically contact all participants with the results of the proposed studies. However, we will publish results in open-access journals and summary reports which can be made publically available through e.g. the websites of the NIHR Community Healthcare MIC (https://www.community.healthcare.mic.nihr.ac.uk/). We will work with patient and public representatives to ensure that such reports are communicated in an appropriate manner for a lay audience.

5. Scientific and Statistical Review

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A54. How has the scientific quality of the research been assessed? *Tick as appropriate:*

- [x] Independent external review
- [ ] Review within a company
- [ ] Review within a multi−centre research group
- [x] Review within the Chief Investigator's institution or host organisation
- [x] Review within the research team
- [ ] Review by educational supervisor
- [ ] Other

Justify and describe the review process and outcome. If the review has been undertaken but not seen by the researcher, give details of the body which has undertaken the review:
The protocol has been reviewed internally, by members of the Nuffield Department of Primary Care Health Sciences (NIHR Community Healthcare MIC, Stats/Methodology Research Group, Infections and Acute Care Research Group, and the RCGP RSC team).

The overarching protocol (CONDOR) which incorporates the work proposed in RAPTOR-C19, has been reviewed and approved as an urgent public health priority study by the NIHR Urgent Public Health panel. The Urgent Public Health panel includes expert statisticians who have reviewed the methodological aspects of the project.

For all studies except non-doctoral student research, please enclose a copy of any available scientific critique reports, together with any related correspondence.

For non-doctoral student research, please enclose a copy of the assessment from your educational supervisor/ institution.

A56. How have the statistical aspects of the research been reviewed? *Tick as appropriate:*

- [x] Review by independent statistician commissioned by funder or sponsor
- [ ] Other review by independent statistician
- [ ] Review by company statistician
- [x] Review by a statistician within the Chief Investigator's institution
- [x] Review by a statistician within the research team or multi−centre group
- [ ] Review by educational supervisor
- [ ] Other review by individual with relevant statistical expertise
- [ ] No review necessary as only frequencies and associations will be assessed – details of statistical input not required

In all cases please give details below of the individual responsible for reviewing the statistical aspects. If advice has been provided in confidence, give details of the department and institution concerned.

	Title	Forename/Initials	Surname
	N/A	N/A	N/A

Department	Urgent Public Health Committee
Institution	National Institute of Health Research and UK Research and Innovation
Work Address	N/A
Post Code	N/A
Telephone	000000
Fax	000000
Mobile	000000
E-mail	ccf-nCoV@nihr.ac.uk

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Please enclose a copy of any available comments or reports from a statistician.

A57. What is the primary outcome measure for the study?

"Standard" diagnostic accuracy of point-of-care tests for active COVID-19 infection with reference to the Public Health England reference standard.

A58. What are the secondary outcome measures?*(if any)*

1. "Standard" diagnostic accuracy of point-of-care tests for past COVID-19 infection with reference to the Public Health England reference standard.

2. "Enhanced" diagnostic accuracy of POCTs for active COVID-19 infection assessed against a composite reference standard using multiple tests data, linked electronic health records data, and patient reported outcomes data.

3. "Enhanced" diagnostic accuracy of POCTs for past COVID-19 infection assessed against a composite reference standard using multiple tests data, linked electronic health records, and patient reported outcomes data.

A59. What is the sample size for the research? *How many participants/samples/data records do you plan to study in total? If there is more than one group, please give further details below.*

Total UK sample size: 2000
Total international sample size (including UK):
Total in European Economic Area:

Further details:
No single sample size is appropriate for the RAPTOR-C19 study, as sample size will be dictated by the estimated diagnostic sensitivity of the point-of-care devices to be tested and the estimated prevalence of SARS-CoV-2 infection in the patient population to be tested. Below we provide an illustration of potential sample sizes for different sensitivities and prevalence of infection. As such, the number above may be a realistic estimate for a single diagnostic, with a high level of sensitivity operating in a lower prevalence environment.

This table presents illustrative sample sizes to achieve a range of POCT sensitivities based on a standard error of 2.5%. A standard error of 2.5% will give a confidence interval of 5% on either side of the sensitivity estimate.

	Prevalence					
	40%	35%	30%	25%	20%	15%
Sensitivity 95%	190	218	254	304	380	507
90%	360	412	480	576	720	960
85%	510	583	680	816	1020	1360
80%	640	732	854	1024	1280	1707
75%	750	858	1000	1200	1500	2000
70%	840	960	1120	1344	1680	2240

The following table presents the expected standard error if the sample size was fixed at 200.

	Prevalence					
	40%	35%	30%	25%	20%	15%
Sensitivity 95%	2.4	2.6	2.8	3.1	3.4	3.9
90%	3.4	3.6	3.8	4.2	4.7	5.4
85%	3.9	4.3	4.6	5.0	5.6	6.5
80%	4.5	4.8	5.2	5.7	6.3	7.3
75%	4.8	5.2	5.6	6.1	6.8	7.9
70%	5.1	5.5	5.9	6.4	7.2	8.4

In the tested UK population there have been 3.2 tests performed for every case of COVID-19 confirmed: a prevalence

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of COVID-19 in the tested population of 31%. RAPTOR-C19 will focus on sites identified as higher prevalence surveillance sites including community “hot-hubs”.

A60. How was the sample size decided upon? *If a formal sample size calculation was used, indicate how this was done, giving sufficient information to justify and reproduce the calculation.*

We estimated the number of COVID-19 cases required by ranging the expected sensitivity of the tests from 70 to 95%. We assumed a standard error of 2.5% which would result in an expected confidence interval around sensitivity of approximately +/- 5%. We did not investigate values lower than 70% as that would be too low for a diagnostic test and unlikely to be useful. The total sample size was calculated by dividing the number of expected COVID-19 cases by the prevalence of the disease which we also varied from 15 to 40% as different estimates have been reported in the literature.

Example of how the calculation was done for reproducibility:

Number of covid19 cases required assuming a sensitivity of 90%=(0.90*0.10)/(0.025)2=144

Total sample size assuming a prevalence of 35%= 144/0.35=412

The formula used for the calculations is based on the standard error for the proportion which is given by SE = sqrt(p* (1-p))/n)

We also investigated how the standard error would be affected (and hence the likely confidence interval) if we were to decide on a fixed sample size (n=100) (if we have space it would be good to also add the table with 200). This allowed us to examine how much the precision of our estimates will be affected if our assumptions are wrong.

A61. Will participants be allocated to groups at random?

○ Yes ◉ No

A62. Please describe the methods of analysis (statistical or other appropriate methods, e.g. for qualitative research) by which the data will be evaluated to meet the study objectives.

Results will be presented according to the STARD guidelines for reporting diagnostic studies.

Descriptive analysis
Characteristics of recruited participants will be summarised using Tables and graphs. If applicable, these will be compared to estimates from the general population (RCGP RSC). Number of total valid tests by POCT and reference standards will also be reported (actual and percentages), stratified by children vs adults and by age groups (if feasible dependent on total counts).

Summary statistics of diagnostic accuracy
Sensitivity, specificity, positive and negative predictive values for each POCT will be calculated with exact 95% confidence intervals. Results will be stratified for adults vs children and by age groups and spectrum of disease data (if feasible dependent on total counts).

For the two co-primary outcomes:
For consecutive POCTs for active infection, the diagnostic accuracy of each POCT will be summarised independently using 2x2 tables for POCT (+/-) and the current “standard” PHE reference test (+/-) for active infection. For consecutive POCTs for past infection, the diagnostic accuracy of each POCT will be summarised independently using 2x2 tables for POCT (+/-) and the current “standard” PHE reference test (+/-) for past infection.

For the secondary outcomes:
For consecutive POCTs for active infection, the enhanced diagnostic accuracy of each POCT will be summarised independently using 2x2 tables for POCT (+/-) and the composite reference standards as defined in 10.3 (+/-). For consecutive POCTs for past infection, the enhanced diagnostic accuracy of each POCT will be summarised independently using 2x2 tables for POCT (+/-) and the composite reference standards (+/-) for past infection.

Missing data
Missing data for test results including reference tests will be reported. Potential associations between patient

characteristics (e.g. age, gender, etc.) and pattern of missing will be evaluated and reported using tables and graphs. Robustness of the estimates for accuracy will be evaluated using sensitivity analyses.

6. MANAGEMENT OF THE RESEARCH

A63. Other key investigators/collaborators. *Please include all grant co−applicants, protocol co−authors and other key members of the Chief Investigator's team, including non-doctoral student researchers.*

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	Title	Forename/Initials	Surname
	Prof	Gail	Hayward
Post	Associate Professor of Primary Care, Deputy Director NIHR Community Healthcare MIC		
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	Title	Forename/Initials	Surname
	Professor	Simon	de Lusignan
Post	Director, Oxford RCGP RSC		
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	Title	Forename/Initials	Surname
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	Title	Forename/Initials	Surname
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	Title	Forename/Initials	Surname
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	Title	Forename/Initials	Surname
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Title	Forename/Initials	Surname
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	Title	Forename/Initials	Surname
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Qualifications			
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Title	Forename/Initials	Surname
Dr	Mark	Joy

Post	RCGP RSC Statistician; Senior Researcher
Qualifications	
Employer	University of Oxford
Work Address	Nuffield Department of Primary Care Health Sciences University of Oxford
Post Code	OX2 6GG
Telephone	
Fax	
Mobile	
Work Email	mark.joy@phc.ox.ac.uk

Title	Forename/Initials	Surname
Dr	Filipa	Ferreira

Post	RCGP RSC Project Manager
Qualifications	BEng(Hons), MSc, PhD
Employer	University of Oxford
Work Address	Nuffield Department of Primary Care Health Sciences University of Oxford
Post Code	OX2 6GG
Telephone	
Fax	
Mobile	
Work Email	ilipa.ferreira@phc.ox.ac.uk

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	Title	Forename/Initials	Surname
	Dr	Mary	Logan

Post	Senior Scientific Officer / BRC Theme Manager
Qualifications	
Employer	University of Oxford
Work Address	Nuffield Department of Primary Care Health Sciences University of Oxford
Post Code	OX2 6GG
Telephone	
Fax	
Mobile	
Work Email	mary.logan@phc.ox.ac.uk

	Title	Forename/Initials	Surname
	Dr	Alexandra	Deeks

Post	RCGP RSC Practice Liaison Officer
Qualifications	
Employer	University of Oxford
Work Address	Nuffield Department of Primary Care Health Sciences University of Oxford
Post Code	OX2 6GG
Telephone	
Fax	
Mobile	
Work Email	alexandra.deeks@phc.ox.ac.uk

	Title	Forename/Initials	Surname
	Dr	James	Sheppard

Post	MRC Fellow
Qualifications	
Employer	University of Oxford
Work Address	Nuffield Department of Primary Care Health Sciences University of Oxford
Post Code	OX2 6GG
Telephone	
Fax	
Mobile	
Work Email	james.sheppard@phc.ox.ac.uk

	Title	Forename/Initials	Surname
	Prof	Maria	Zambon

Post	Director, Reference Microbiology Services; Deputy Director National Infection Service
Qualifications	FMedSci
Employer	Public Health England
Work Address	Public Health England London

DRAFT

Post Code
Telephone
Fax
Mobile
Work Email maria.zambon@phe.gov.uk

A64. Details of research sponsor(s)

A64-1. Sponsor

Lead Sponsor

Status:
- ○ NHS or HSC care organisation
- ◉ Academic
- ○ Pharmaceutical industry
- ○ Medical device industry
- ○ Local Authority
- ○ Other social care provider (including voluntary sector or private organisation)
- ○ Other

Commercial status: Non-Commercial

If Other, please specify:

Contact person

Name of organisation	University of Oxford / Clinical Trials and Research Governance
Given name	N/A
Family name	CTRG
Address	Joint Research Office, 1st floor, Boundary Brook House, Churchill Drive, Headington
Town/city	Oxford
Post code	OX3 7GB
Country	UNITED KINGDOM
Telephone	000000
Fax	000000
E-mail	ctrg@admin.ox.ac.uk

A65. Has external funding for the research been secured?

Please tick at least one check box.

- ☑ Funding secured from one or more funders
- ☑ External funding application to one or more funders in progress
- ☐ No application for external funding will be made

What type of research project is this?

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- (●) Standalone project
- ( ) Project that is part of a programme grant
- ( ) Project that is part of a Centre grant
- ( ) Project that is part of a fellowship/ personal award/ research training award
- ( ) Other

Other – please state:

Please give details of funding applications.

Organisation	University of Oxford
Address	Medical Sciences Divisional Office University of Oxford Level 3, John Radcliffe Hospital, Oxford
Post Code	OX3 9DU
Telephone	01865 289561
Fax	
Mobile	
Email	communications@medsci.ox.ac.uk

Funding Application Status: ( ) Secured (●) In progress

Date Funding decision expected:

Amount: £135,966

Duration

Years: 12

Months: 0

If applicable, please specify the programme/ funding stream:

What is the funding stream/ programme for this research project?

Oxford University Medical Sciences Division COVID-19 Research Fund (https://www.medsci.ox.ac.uk/research/internal/funding-directory/ covid-19-research-response-fund)

Organisation	Natinoal Institute of Health Research
Address	Department of Health and Social Care 39 Victoria Street Westminster, London
Post Code	SW1H 0EU
Telephone	01793 416200
Fax	
Mobile	
Email	enquiries@nihr.ac.uk

Funding Application Status: (●) Secured ( ) In progress

Amount: £262,479

Duration

Years: 12

Months: 0

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If applicable, please specify the programme/ funding stream:

What is the funding stream/ programme for this research project?

COVID-19 Rapid Response Rolling Call
https://mrc.ukri.org/funding/browse/ukri-nihr-covid-19/ukri-nih r-covid-19-rolling-call/

A66. Has responsibility for any specific research activities or procedures been delegated to a subcontractor (other than a co-sponsor listed in A64-1) ? *Please give details of subcontractors if applicable.*

○ Yes ◉ No

A67. Has this or a similar application been previously rejected by a Research Ethics Committee in the UK or another country?

○ Yes ◉ No

Please provide a copy of the unfavourable opinion letter(s). You should explain in your answer to question A6-2 how the reasons for the unfavourable opinion have been addressed in this application.

A68-1. Give details of the lead NHS R&D contact for this research:

	Title	Forename/Initials	Surname
	Dr	Vicki	Clatworthy

Organisation	NIHR Clinical Research Network: Thames Valley and South Midlands
Address	Study Support Service Facilitator, TVCN Offices Block-8 Nuffield Orthopaedic Centre Windmill Road, Headington Oxford
Post Code	OX3 7DL
Work Email	vicki.clatworthy@oxfordhealth.nhs.uk
Telephone	000000
Fax	000000
Mobile	07900 407260

Details can be obtained from the NHS R&D Forum website: http://www.rdforum.nhs.uk

A68-2. Select Local Clinical Research Network for NHS Organisation identified in A68-1:

Thames Valley and South Midlands

For more information, please refer to the question specific guidance.

A69-1. How long do you expect the study to last in the UK?

Planned start date: 04/06/2020
Planned end date: 03/06/2022
Total duration:
Years: 2 Months: 0 Days: 0

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A70. Definition of the end of trial, and justification in the case where it is not the last visit of the last subject undergoing the trial (1)

The end of study will be the last data capture for the last participant for the last test evaluated.

A71-1. Is this study?

- ○ Single centre
- ◉ Multicentre

A71-2. Where will the research take place? *(Tick as appropriate)*

- ☑ England
- ☑ Scotland
- ☑ Wales
- ☑ Northern Ireland
- ☐ Other countries in European Economic Area

Total UK sites in study Unknown

Does this trial involve countries outside the EU?

○ Yes ◉ No

A72. Which organisations in the UK will host the research?*Please indicate the type of organisation by ticking the box and give approximate numbers if known:*

☑ NHS organisations in England	2
☑ NHS organisations in Wales	1
☑ NHS organisations in Scotland	1
☑ HSC organisations in Northern Ireland	1
☑ GP practices in England	34
☑ GP practices in Wales	2
☑ GP practices in Scotland	2
☑ GP practices in Northern Ireland	2
☐ Joint health and social care agencies (eg community mental health teams)	
☐ Local authorities	
☐ Phase 1 trial units	
☐ Prison establishments	
☐ Probation areas	
☐ Independent (private or voluntary sector) organisations	
☐ Educational establishments	
☐ Independent research units	
☐ Other (give details)	
Total UK sites in study:	45

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A73-1. Will potential participants be identified through any organisations other than the research sites listed above?

○ Yes ◉ No

A76. Insurance/ indemnity to meet potential legal liabilities

***Note:** in this question to NHS indemnity schemes include equivalent schemes provided by Health and Social Care (HSC) in Northern Ireland*

A76-1. What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management of the research? *Please tick box(es) as applicable.*

Note: Where a NHS organisation has agreed to act as sponsor or co-sponsor, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For all other sponsors, please describe the arrangements and provide evidence.

☑ NHS indemnity scheme will apply (NHS sponsors only)

☑ Other insurance or indemnity arrangements will apply (give details below)

The University has a specialist insurance policy in place – Newline Underwriting Management Ltd, at Lloyd's of London – that would operate in the event of any participant suffering harm as a result of their involvement in the research. NHS indemnity operates in respect of the clinical treatment that is provided.

Please enclose a copy of relevant documents.

A76-2. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of the sponsor(s) or employer(s) for harm to participants arising from the design of the research? *Please tick box(es) as applicable.*

Note: Where researchers with substantive NHS employment contracts have designed the research, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For other protocol authors (e.g. company employees, university members), please describe the arrangements and provide evidence.

☐ NHS indemnity scheme will apply (protocol authors with NHS contracts only)

☑ Other insurance or indemnity arrangements will apply (give details below)

The University has a specialist insurance policy in place – Newline Underwriting Management Ltd, at Lloyd's of London – that would operate in the event of any participant suffering harm as a result of their involvement in the research.

Please enclose a copy of relevant documents.

A76-3. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research?

Note: Where the participants are NHS patients, indemnity is provided through the NHS schemes or through professional indemnity. Indicate if this applies to the whole study (there is no need to provide documentary evidence). Where non-NHS sites are to be included in the research, including private practices, please describe the arrangements which will be made at these sites and provide evidence.

☑ NHS indemnity scheme or professional indemnity will apply (participants recruited at NHS sites only)

☑ Research includes non-NHS sites (give details of insurance/ indemnity arrangements for these sites below)

The University has a specialist insurance policy in place – Newline Underwriting Management Ltd, at Lloyd's of London – that would operate in the event of any participant suffering harm as a result of their involvement in the research. NHS indemnity operates in respect of the clinical treatment that is provided.

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Please enclose a copy of relevant documents.

A78. Could the research lead to the development of a new product/process or the generation of intellectual property?

(●) Yes ( ) No ( ) Not sure

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Part B: Section 2

A. General information

Information in this sub-section will be included in applications to the Research Ethics Committee and NHS R & D offices at the research sites.

1. Is the manufacturer (or other organisation responsible for developing the device) the same organisation named as lead sponsor for this study?

○ Yes ◉ No

If No, please give details of the manufacturer or other organisation responsible for developing the device below:

Organisation	Not yet known
Address	Not yet known
Post Code	Not yet known
Country	
Telephone	Not yet known
Fax	Not yet known
Mobile	Not yet known
E-mail	

2. Details of the medical devices to be used in the study

Name of the manufacturer:	Not yet known
Manufacturer's trade name for the device:	Not yet known
Device identification name and/or number:	
Name:	Not yet known
Number:	Not yet known
Generic name of device and principal intended use(s):	In the first instance, candidate SARS-CoV-2 (COVID-19) diagnostics will be provided to the study team by the Department of Health and Social Care through a nationally coordinated triage process. At present, we do not have the details of the specific tests which will be evaluated.
Length of time since device came into use:	Not yet known

3-1. Further details of the purpose of the study

Does the study involve:

◉ Investigation of a new medical device

○ Investigation of new implantable material

○ Use of an existing product outside the terms of its CE market intended purpose

○ Use of a modified product

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○ Use of an existing product within its CE market intended purpose

3-2. Please give further details below including the following:

Description of any new device, materials, method of use or operation with a summary of the intended purpose.

The project concerns the evaluation of in-vitro diagnostics and diagnostic medical devices for SARS-CoV-2 / COVID-19. We envisage that the majority of these diagnostics will require material collected using swabs of the upper respiratory tract, sputum, or fingerprick blood as samples as previously described in this submission and in the associated protocol. This list of sample types is not exhaustive, given the rapidly changing landscape for diagnostics for this illness. The intended use of the diagnostics is likely to include:

1. The diagnosis of active SARS-CoV-2 infection through the amplification of SARS-CoV-2 genetic material.

2. The diagnosis of active SARS-CoV-2 infection through the detection of SARS-CoV-2 surface antigens.

3. The diagnosis (identification) of historic infection by SARS-CoV-2 through the identification of host antibodies developed in response to infection.

In the first instance, candidate SARS-CoV-2 (COVID-19) diagnostics will be provided to the study team by the Department of Health and Social Care through a nationally coordinated triage process to identify priority target diagnostics. At present, we do not have the details of the specific tests which will be evaluated. During the latter stages of the project, the team may identify additional target diagnostics for testing, once the immediate requirements of the public health emergency have been addressed.

Composition of any new implantable materials, including summary of biocompatibility findings from studies to date.

N/A

A summary of any modifications to CE marked devices.

Not yet known

A summary of any proposed changes to the CE market intended purpose.

Not yet known

For all products with CE mark please attach instructions for use.

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Part B: Section 5 – Use of newly obtained human tissue(or other human biological materials) for research purposes

1. What types of human tissue or other biological material will be included in the study?

Nose/throat/mouth swabs
Venous blood (and derived fractions)
Fingerstick peripheral blood
Saliva
Sputum

2. Who will collect the samples?

Participants, research nurses/practitioners or appropriately trained clinical staff.

3. Who will the samples be removed from?

- [x] Living donors
- [ ] The deceased

4. Will informed consent be obtained from living donors for use of the samples? *Please tick as appropriate*

In this research?

(●) Yes ( ) No

In future research?

( ) Yes ( ) No (●) Not applicable

6. Will any tissues or cells be used for human application or to carry out testing for human application in this research?

( ) Yes (●) No

8. Will the samples be stored: *[Tick as appropriate]*

In fully anonymised form? *(link to donor broken)*

( ) Yes (●) No

In linked anonymised form? *(linked to stored tissue but donor not identifiable to researchers)*

(●) Yes ( ) No

If Yes, say who will have access to the code and personal information about the donor.

Samples that are retained will have ID and it must be possible to link them to the consent form.

In a form in which the donor could be identifiable to researchers?

( ) Yes (●) No

9. What types of test or analysis will be carried out on the samples?

Testing for the presence of SARS-CoV-2 nucelic acid (RNA), antigens, antibodies, or other host response factors which may be associated with SARS-CoV-2 infection.

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10. Will the research involve the analysis or use of human DNA in the samples?

○ Yes ◉ No

11. Is it possible that the research could produce findings of clinical significance for donors or their relatives?

◉ Yes ○ No

12. If so, will arrangements be made to notify the individuals concerned?

○ Yes ◉ No ○ Not applicable

If No, please justify. If Yes, say what arrangements will be made and give details of the support or counselling service.

The tests we are proposing to evaluate must undergo rigorous testing prior to clinical use, as we currently have no idea how accurate they are. Therefore, release of results would be inappropriate.

13. Give details of where the samples will be stored, who will have access and the custodial arrangements.

Blood will be stored at PHE, if it is fit to be retained.

14. What will happen to the samples at the end of the research? *Please tick all that apply and give further details.*

☐ Transfer to research tissue bank

(If the bank is in England, Wales or Northern Ireland the institution will require a licence from the Human Tissue Authority to store relevant material for possible further research.)

☑ Storage by research team pending ethical approval for use in another project

(Unless the researcher's institution holds a storage licence from the Human Tissue Authority, or the tissue is stored in Scotland, or it is not relevant material, a further application for ethical review should be submitted before the end of this project.)

☐ Storage by research team as part of a new research tissue bank

(The institution will require a licence from the Human Tissue Authority if the bank will be storing relevant material in England, Wales or Northern Ireland. A separate application for ethical review of the tissue bank may also be submitted.)

☐ Storage by research team of biological material which is not "relevant material" for the purposes of the Human Tissue Act

☑ Disposal in accordance with the Human Tissue Authority's Code of Practice

☐ Other

☐ Not yet known

Please give further details of the proposed arrangements:

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PART B: Section 7 - Children

1. Please specify the potential age range of children under 16 who will be included and give reasons for carrying out the research in this age group.

Children of any age may be included in the study with their parents consent as it is important to know whether point-of-care tests for COVID-19 are effective in children as well as adults.

2. Indicate whether any children under 16 will be recruited as controls and give further details.

There are no controls in the study.

3-2. Please describe the arrangements for seeking informed consent from a person with parental responsibility and/or from children able to give consent for themselves.

The parent or legal guardian of all children will be asked to give informed consent for participation in the study by working through the electronic consent process with the assistance of study staff.

4. If you intend to provide children under 16 with information about the research and seek their consent or agreement, please outline how this process will vary according to their age and level of understanding.

We have developed distinct patient information resources for <6 year olds, 6-9 year olds, and 10-15 year olds. These have been checked by children and parents of children.

Copies of written information sheet(s) for parents and children, consent/assent form(s) and any other explanatory material should be enclosed with the application.

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PART C: Overview of research sites

Please enter details of the host organisations (Local Authority, NHS or other) in the UK that will be responsible for the research sites. *For further information please refer to guidance.*

Investigator identifier	Research site		Investigator Name
IN3	(●) NHS/HSC Site ( ) Non-NHS/HSC Site		Forename Middle name Family name Email
	Organisation name	NIHR CRN: North East and North Cumbria	Qualification (MD...)
	Address	Regent Point Regent Farm Road Gosforth Newcastle upon Tyne	Country
	Post Code	NE3 3HD	
	Country	ENGLAND	
IN4	(●) NHS/HSC Site ( ) Non-NHS/HSC Site		Forename Middle name Family name Email
	Organisation name	NIHR CRN: North West Coast	Qualification (MD...)
	Address	Royal Liverpool and Broadgreen University Hospitals NHS Trust Prescot Street Liverpool	Country
	Post Code	L7 8XP	
	Country	ENGLAND	
IN5	(●) NHS/HSC Site ( ) Non-NHS/HSC Site		Forename Middle name Family name Email
	Organisation name	NIHR CRN: Yorkshire and Humber	Qualification (MD...)
	Address	8 Beech Hill Road SHEFFIELD	Country
	Post Code	S10 2SB	

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Country	ENGLAND

IN6

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

Organisation name	NIHR CRN: Greater Manchester
Address	2nd Floor Citylabs Nelson Street Manchester
Post Code	M13 9NQ
Country	ENGLAND

Forename
Middle name
Family name
Email
Qualification (MD...)
Country

IN7

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

Organisation name	NIHR CRN: East Midlands
Address	Knighton Street Outpatients 1st Floor Leicester Royal Infirmary
Post Code	LE1 5WW
Country	ENGLAND

Forename
Middle name
Family name
Email
Qualification (MD...)
Country

IN8

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

Organisation name	NIHR CRN: West Midlands
Address	James House Newport Road Albrighton Wolverhampton
Post Code	WV7 3FA
Country	ENGLAND

Forename
Middle name
Family name
Email
Qualification (MD...)
Country

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IN9

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

Organisation name	NIHR CRN: West of England
Address	Whitefriars Lewins Mead Bristol
Post Code	BS1 2NT
Country	ENGLAND

Forename
Middle name
Family name
Email
Qualification (MD...)
Country

IN10

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

Organisation name	NIHR CRN: Thames Valley and South Midlands
Address	John Radcliffe Hospital Headley Way Headington Oxford
Post Code	OX3 9DU
Country	ENGLAND

Forename
Middle name
Family name
Email
Qualification (MD...)
Country

IN11

- (●) NHS/HSC Site
- ( ) Non-NHS/HSC Site

Organisation name	NIHR CRN: Eastern
Address	Floor 4 Rouen Road Norwich Norfolk
Post Code	NR1 1QQ
Country	ENGLAND

Forename
Middle name
Family name
Email
Qualification (MD...)
Country

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IN12

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

Organisation name	NIHR CRN: Kent, Surrey and Sussex
Address	Bevendean House Room BE205 University of Brighton Falmer Sussex
Post Code	BN1 9PH
Country	ENGLAND

Forename
Middle name
Family name
Email
Qualification (MD...)
Country

IN13

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

Organisation name	NIHR CRN: Wessex
Address	Unit 7, Berrywood Business Village Tollbar Way Hedge End Southampton
Post Code	SO30 2UN
Country	ENGLAND

Forename
Middle name
Family name
Email
Qualification (MD...)
Country

IN14

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

Organisation name	NIHR CRN: South West Peninsula
Address	F7 Bowmoor House Royal Devon and Exeter Hospital (Wonford) Exeter
Post Code	EX2 5DW
Country	ENGLAND

Forename
Middle name
Family name
Email
Qualification (MD...)
Country

IN15

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

Forename
Middle name

DRAFT

Family name
Email
Qualification (MD...)
Country

Organisation name	NIHR CRN: North Thames
Address	3rd floor 170 Tottenham Court Road London
Post Code	W1T 7HA
Country	ENGLAND

IN16

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

Forename
Middle name
Family name
Email
Qualification (MD...)
Country

Organisation name	NIHR CRN: South London
Address	16th Floor BRC Faculty Guy's Tower Guy's Hospital Great Maze Pond London
Post Code	SE1 9RT
Country	ENGLAND

IN17

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

Forename
Middle name
Family name
Email
Qualification (MD...)
Country

Organisation name	NIHR CRN: North West London
Address	Imperial College Healthcare NHS Trust 3rd Floor Administrative Block South Hammersmith Hospital Du Cane Road London
Post Code	W12 0HT
Country	ENGLAND

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PART D: Declarations

D1. Declaration by Chief Investigator

1. The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.

2. I undertake to fulfil the responsibilities of the chief investigator for this study as set out in the UK Policy Framework for Health and Social Care Research.

3. I undertake to abide by the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research.

4. If the research is approved I undertake to adhere to the study protocol, the terms of the full application as approved and any conditions set out by review bodies in giving approval.

5. I undertake to notify review bodies of substantial amendments to the protocol or the terms of the approved application, and to seek a favourable opinion from the main REC before implementing the amendment.

6. I undertake to submit annual progress reports setting out the progress of the research, as required by review bodies.

7. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of patient or other personal data, including the need to register when necessary with the appropriate Data Protection Officer. I understand that I am not permitted to disclose identifiable data to third parties unless the disclosure has the consent of the data subject or, in the case of patient data in England and Wales, the disclosure is covered by the terms of an approval under Section 251 of the NHS Act 2006.

8. I understand that research records/data may be subject to inspection by review bodies for audit purposes if required.

9. I understand that any personal data in this application will be held by review bodies and their operational managers and that this will be managed according to the principles established in the Data Protection Act 2018.

10. I understand that the information contained in this application, any supporting documentation and all correspondence with review bodies or their operational managers relating to the application:

    - Will be held by the REC (where applicable) until at least 3 years after the end of the study; and by NHS R&D offices (where the research requires NHS management permission) in accordance with the NHS Code of Practice on Records Management.
    - May be disclosed to the operational managers of review bodies, or the appointing authority for the REC (where applicable), in order to check that the application has been processed correctly or to investigate any complaint.
    - May be seen by auditors appointed to undertake accreditation of RECs (where applicable).
    - Will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made under the Acts except where statutory exemptions apply.
    - May be sent by email to REC members.

11. I understand that information relating to this research, including the contact details on this application, may be held on national research information systems, and that this will be managed according to the principles established in the Data Protection Act 2018.

12. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the Health Research Authority (HRA) together with the contact point for enquiries named below. Publication will take place no earlier than 3 months after the issue of the ethics committee's final opinion or the withdrawal of the application.

Contact point for publication*(Not applicable for R&D Forms)*

HRA would like to include a contact point with the published summary of the study for those wishing to seek further

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information. We would be grateful if you would indicate one of the contact points below.

- (●) Chief Investigator
- ( ) Sponsor
- ( ) Study co-ordinator
- ( ) Student
- ( ) Other – please give details
- ( ) None

Access to application for training purposes *(Not applicable for R&D Forms)*

Optional – please tick as appropriate:

☐ I would be content for members of other RECs to have access to the information in the application in confidence for training purposes. All personal identifiers and references to sponsors, funders and research units would be removed.

This section was signed electronically by Professor Richard Hobbs on 02/06/2020 12:46.

Job Title/Post:	HoD
Organisation:	University of Oxford
Email:	Richard.hobbs@phc.ox.ac.uk

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D2. Declaration by the sponsor's representative

If there is more than one sponsor, this declaration should be signed on behalf of the co−sponsors by a representative of the lead sponsor named at A64-1.

I confirm that:

1. This research proposal has been discussed with the Chief Investigator and agreement in principle to sponsor the research is in place.

2. An appropriate process of scientific critique has demonstrated that this research proposal is worthwhile and of high scientific quality.

3. Any necessary indemnity or insurance arrangements, as described in question A76, will be in place before this research starts. Insurance or indemnity policies will be renewed for the duration of the study where necessary.

4. Arrangements will be in place before the study starts for the research team to access resources and support to deliver the research as proposed.

5. Arrangements to allocate responsibilities for the management, monitoring and reporting of the research will be in place before the research starts.

6. The responsibilities of sponsors set out in the UK Policy Framework for Health and Social Care Research will be fulfilled in relation to this research.

   Please note: *The declarations below do not form part of the application for approval above. They will not be considered by the Research Ethics Committee.*

7. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named in this application. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

8. Specifically, for submissions to the Research Ethics Committees (RECs) I declare that any and all clinical trials approved by the HRA since 30th September 2013 (as defined on IRAS categories as clinical trials of medicines, devices, combination of medicines and devices or other clinical trials) have been registered on a publically accessible register in compliance with the HRA registration requirements for the UK, or that any deferral granted by the HRA still applies.

This section was signed electronically by Clinical Trial and Research Governance CTRG Sponsorship on 02/06/2020 12:50.

Job Title/Post: Nigel Wellman

Organisation: University of Oxford

Email:

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