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19 November 2021

Dear Dr Butler

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title:	**Platform Adaptive trial of NOvel antiviRals for eArly treatMent of covid-19 In the Community**
IRAS project ID:	**1004274**
Protocol number:	**PANORAMIC**
REC reference:	**21/SC/0393**
Sponsor	**University of Oxford/ Research Governance, Ethics & Assurance**

I am pleased to confirm that **HRA and Health and Care Research Wales (HCRW) Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?

HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?
HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?

The standard conditions document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

Who should I contact for further information?
Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **1004274**. Please quote this on all correspondence.

Yours sincerely,

Kathryn Murray
Approvals Specialist

Email: approvals@hra.nhs.uk

Copy to: *Dr Christopher Butler, University of Oxford*

List of Documents

The final document set assessed and approved by HRA and HCRW Approval is listed below.

Document	*Version*	*Date*
Copies of materials calling attention of potential participants to the research [Promotional Material]	1	08 November 2021
Copies of materials calling attention of potential participants to the research [Legal Representative]	1	08 November 2021
Cover Letter [REC Cover Letter]	1	08 November 2021
GP/consultant information sheets or letters [Pregnant Partner GP Letter]	1	08 November 2021
GP/consultant information sheets or letters [GP Letter-Follow up]	1	08 November 2021
GP/consultant information sheets or letters [GP Letter]	1	08 November 2021
Letter from funder [Funder Letter]	1	08 November 2021
Letter from sponsor [Sponsor Letter]	1	08 November 2021
Letters of invitation to participant [Patient Recruitment Letter]	1	08 November 2021
Miscellaneous [HAF Approval]	1	08 November 2021
Miscellaneous [CRFs]	1	08 November 2021
Organisation Information Document [OID]	1	08 November 2021
Other [PANORAMIC_PregnancyTestInstructions_V1.0_16Nov2021]	1.0	16 November 2021
Participant information and informed consent form [Pictorial PIS]	1	08 November 2021
Participant information and informed consent form [PIS – Clean and Tracked]	2.0	19 November 2021
Participant information and informed consent form [Trial Partner Letter]	1	08 November 2021
Participant information and informed consent form [End of Follow Up Letter]	1	08 November 2021
Participant information and informed consent form [Privacy Notice]	1	08 November 2021
Participant information and informed consent form [Information Booklet]	1	08 November 2021
Participant information and informed consent form [Wallet Emergency Card]	1	08 November 2021
Participant information and informed consent form [Molnupiravir Participant Card]	1	08 November 2021
Participant information and informed consent form [Consent]	1	08 November 2021
Participant information and informed consent form [Pregnant Partner ICF]	1	08 November 2021
Participant information and informed consent form [Pregnant Partner]	1	08 November 2021
Project Information - PDF [ProjectStudyInformation]		10 November 2021
Proof of Insurance [Insurance Letter]	1	08 November 2021
Protocol [Protocol – Clean and Tracked]	1.2	18 November 2021
REC Application Form [Ethics]		10 November 2021
Schedule of Events or SoECAT [SOeCAT]	1	08 November 2021
Site List [mNCA]	1	08 November 2021
Suitability of the investigator/Investigator CV [CV]	1	08 November 2021

IRAS project ID	1004274

Information to support study set up

The below provides all parties with information to support the arranging and confirming of capacity and capability with participating NHS organisations in England and Wales. This is intended to be an accurate reflection of the study at the time of issue of this letter.

Types of participating NHS organisation	Expectations related to confirmation of capacity and capability	Agreement to be used	Funding arrangements	Oversight expectations	HR Good Practice Resource Pack expectations
The study will use a Hub and Spoke model for GP practices. Hub sites will perform the same research activities as defined by the Organisation Information Document. Spoke models will refer potential participants as per standard of care referrals therefore are not classed as participating organisations for the purpose of the study.	Research activities should not commence at participating NHS organisations in England or Wales prior to their formal confirmation of capacity and capability to deliver the study in accordance with the contracting expectations detailed. Due to the nature of the activities involved, organisations will be expected to provide that confirmation to the sponsor Within **7 days** of receipt of the local information pack After HRA/HCRW Approval has been issued. If the organisation is not able to formally confirm capacity and	An Organisation Information Document has been submitted and the sponsor is intending to use a model non-commercial agreement with sites.	Study funding will be provided to sites as per the Organisation Information Document	A Principal Investigator should be appointed at study sites	No Honorary Research Contracts, Letters of Access or pre-engagement checks are expected for local staff employed by the participating NHS organisations. Where arrangements are not already in place, network staff (or similar) undertaking any of the research activities listed in the IRAS form (except for administration of questionnaires or surveys), would be expected to obtain an honorary research contract from one NHS organisation (if university employed), followed by Letters of Access for subsequent organisations. This would be on the basis of a Research Passport (if university employed) or an NHS to NHS confirmation of pre-engagement checks letter (if NHS employed). These should confirm enhanced DBS checks, including appropriate barred list checks, and occupational health clearance. For

	capability within this timeframe, they must inform the sponsor of this and provide a justification. If the sponsor is not satisfied with the justification, then the sponsor may escalate to the National Coordinating Function where the participating NHS organisation is located.				research team members only administering questionnaires or surveys, a Letter of Access based on standard DBS checks and occupational health clearance would be appropriate.

Other information to aid study set-up and delivery

This details any other information that may be helpful to sponsors and participating NHS organisations in England and Wales in study set-up.
The applicant has indicated that they intend to apply for inclusion on the NIHR CRN Portfolio.