Professor Philip Bath
University of Nottingham
D floor, South Block, Queen's Medical Centre
Nottingham
NG7 2UH

Email: approvals@hra.nhs.uk

07 June 2021

Dear Prof Bath

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

Study title:	**COVID-19: Prophylactic therapy in care homes trial-CH**
IRAS project ID:	**294832**
EudraCT number:	**2021-000185-15**
Protocol number:	**21001**
REC reference:	**21/SC/0166**
Sponsor	**University of Nottingham**

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 **294832**. Please quote this on all correspondence.

Yours sincerely,

Alex Thorpe

Approvals Manager

Email: approvals@hra.nhs.uk

Copy to: *Ms Angela Shone, Sponsor's Representative*

List of Documents

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

Document	*Version*	*Date*
Contract/Study Agreement template [Care home contract template]		27 April 2021
Contract/Study Agreement template [GP contract template]		27 April 2021
Contract/Study Agreement template [PI contract template]		27 April 2021
Copies of materials calling attention of potential participants to the research [Participant poster]	Draft 0.2/Final 1.0	01 April 2021
Copies of materials calling attention of potential participants to the research [Participant video]	1.0	27 April 2021
Covering letter on headed paper [HRA REC Cover Letter]		28 April 2021
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Sponsor Clinical Trials Insurance]		20 July 2020
GP/consultant information sheets or letters [GP eligibility check letter]	Draft 0.1/Final 1.0	21 April 2021
GP/consultant information sheets or letters [GP IMP letter]	Draft 0.1/Final 1.0	21 April 2021
GP/consultant information sheets or letters [GP standard care letter]	Draft 0.1/Final 1.0	21 April 2021
Investigator's brochure / IMP Dossier [Ciclesonide IMPD stability data]	April 2021	01 April 2021
Investigator's brochure / IMP Dossier [Ciclesonide IMPD]		
Investigator's brochure / IMP Dossier [Niclosamide IMPD 2.1P]	5.0	15 April 2021
Investigator's brochure / IMP Dossier [Niclosamide IB]	2.0	23 September 2020
IRAS Application Form [IRAS_Form_29042021]		29 April 2021
IRAS Application Form XML file [IRAS_Form_29042021]		29 April 2021
IRAS Checklist XML [Checklist_26052021]		26 May 2021
IRAS Checklist XML [Checklist_19052021]		19 May 2021
MHRA Notice of No Objection Letter (Medical Devices) and relevant correspondence [MHRA CTA]	1	18 May 2021
Organisation Information Document [OID - care homes]	N/A	21 April 2021
Organisation Information Document [OID - GPs]	N/A	21 April 2021
Organisation Information Document [OID - PIs and research nurses]	N/A	21 April 2021
Other [Legal Representative E-mails]	Draft 0.9/Final 1.0	18 May 2021
Other [IMP Appendix A (ciclesonide)]	Draft 0.7/ Final 1.0	10 May 2021
Other [IMP Appendix B (niclosamide)]	Draft 0.7/ Final 1.0	10 May 2021
Other [LR IS tracked changes (for review only)]	Draft 0.7/ Final 1.0	18 May 2021
Other [PLR emails tracked changed (for review only)]	Draft 0.9/ Final 1.0	18 May 2021
Other [LR IS tracked changes (for review only)]	Draft 0.7/ Final 1.0	18 May 2021
Other [Participant ICF tracked changes (for review only)]	Draft 0.7/ Final 1.0	18 May 2021
Other [Participant IS tracked changes (for review only)]	Draft 0.12/ Final 1.0	18 May 2021
Other [Protocol Appendix A tracked changes (for review only)]	Draft 0.7/ Final 1.0	10 May 2021

Other [Protocol Appendix B tracked changes (for review only)]	Draft 0.6/ Final 1.0	10 May 2021
Other [Protocol tracked changed (for review only)]	Draft 1.0/ Final 1.0	13 May 2021
Other [Letter responding to conditions]		19 May 2021
Other [IMP Appendix A (ciclesonide)]	Draft 0.6/Final 1.0	27 April 2021
Other [IMP Appendix B (niclosamide)]	Draft 0.5/Final 1.0	27 April 2021
Other [Sponsor professional indemnity letter]	N/A	20 July 2020
Other [Legal Representative Consent Letter 1]	Draft 0.5/Final 1.0	23 April 2021
Other [Legal Representative Participation Update Letter 2]	Draft 0.1/Final 1.0	22 April 2021
Other [Legal Representative Consent Letter 3]	Draft 0.4/Final 1.0	23 April 2021
Other [Legal Representative Eligibility & Randomisaion Confirmation Letter 4]	Draft 0.1/Final 1.0	23 April 2021
Other [Ciclesonide dosing instructions]	Draft 0.2/Final 1.0	27 April 2021
Other [Niclosamide dosing instructions]	Draft 0.2/Final 1.0	27 April 2021
Other [Consent and eligibility overview]	Draft 0.2/Final 1.0	23 April 2021
Other [Flowchart from point of outbreak (PEP)]	Draft 0.3/Final 1.0	21 April 2021
Other [Safety reporting flowchart]	Draft 0.2/Final 1.0	16 April 2021
Participant consent form [Participant Informed Consent Form]	Draft 0.7/Final 1.0	18 May 2021
Participant consent form [Legal Represent Consent Form]	Draft 0.7/Final 1.0	18 May 2021
Participant information sheet (PIS) [Participant Information Sheet]	Draft 0.12/Final version 1.0	18 May 2021
Participant information sheet (PIS) [Legal Representative Information Sheet]	Draft 0.7/Final 1.0	18 May 2021
Research protocol or project proposal [Trial Protocol]	Draft 1.0/ Final 1.0	13 May 2021
Schedule of Events or SoECAT [SoECAT]	4.0	27 April 2021
Summary CV for Chief Investigator (CI) [Chief Investigator CV]		
Summary of product characteristics (SmPC) [SmPC ciclesonide]		29 June 2020
Validated questionnaire [QoL (EQ5D5L)]	1.0	07 April 2021
Validated questionnaire [QoL (EQ5D5L) proxy]	1.0	07 April 2021

IRAS project ID	294832

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
For the purpose of this study, the applicant has explained that sites are determined by investigator and not location. Each Principal Investigator will be responsible for coordinating and overseeing the study at the GP surgeries and care homes within that region.	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.	An Organisation Information Document has been submitted and the sponsor is intending to use a separate site agreement. The agreement has been modified and the sponsor has explained that a list of modifications has been provided to sites. These changes are provided by the sponsor and the HRA and HCRW	Please note that the SoECAT submitted for this study has been authorised by an AcoRD Expert. No funding will be provided to NHS organisations acting as recruiting sites. Funding will be provided to GP surgeries and care homes as per the agreement.	A Principal Investigator should be appointed at study sites of this type.	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

		take no position on the acceptability of these changes. Participating NHS organisations should now determine its acceptability and liaise with the sponsor to confirm the content of the agreement.			checks letter (if NHS employed). These should confirm enhanced DBS checks, including appropriate barred list checks, and occupational health clearance. For 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 do intend to apply for inclusion on the NIHR CRN Portfolio.