



Health Research
Authority

South Central - Oxford A Research Ethics Committee

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**Please note: This is an
acknowledgement letter from
the REC only and does not
allow you to start your study
at NHS sites in England until
you receive HRA Approval**

20 May 2021

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

Dear Prof Bath

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

Thank you for your letter of 20 May 2021. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 18 May 2021

Documents received

The documents received were as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
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
Investigator's brochure / IMP Dossier [Ciclesonide IMPD]		
IRAS Checklist XML [Checklist_19052021]		19 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 0.7/ Final 1.0	10 May 2021
Other [IMP Appendix B (niclosamide)]	Draft 0.7/ Final 1.0	10 May 2021
Other [Legal Representative E-mails]	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 [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
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 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

Approved documents

The final list of approved documentation for the study is therefore as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
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 Checklist XML [Checklist_19052021]		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
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 [Legal Representative E-mails]	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 [PLR emails tracked changed (for review only)]	Draft 0.9/ Final 1.0	18 May 2021
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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
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Research protocol or project proposal [Trial Protocol]	Draft 1.0/ Final 1.0	13 May 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

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

IRAS Project ID: 294832	Please quote this number on all correspondence
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Yours sincerely

A handwritten signature in black ink, appearing to read 'Alex Thorpe', is centered below the text 'Yours sincerely'.

Alex Thorpe
Approvals Manager

E-mail: oxforda.rec@hra.nhs.uk

Copy to: Ms Angela Shone, Sponsor's Representative