

**South Central - Berkshire Research Ethics Committee**

Bristol REC Centre  
Whitefriars  
Level 3, Block B  
Lewins Mead  
Bristol  
BS1 2NT

04 November 2020

Christopher Butler  
University of Oxford  
Radcliffe Observatory Quarter, Woodstock Road  
Oxford  
OX2 6GG

Dear Professor Butler

**Study title:** Platform Randomised trial of INterventions against COVID-19 In older peoPLE  
**REC reference:** 20/SC/0158  
**Protocol number:** PRINCIPLE  
**EudraCT number:** 2020-001209-22  
**Amendment number:** Substantial Amendment 9  
**Amendment date:** 02 November 2020  
**IRAS project ID:** 281958

Thank you for submitting the above amendment, which was received on 2<sup>nd</sup> November 2020.

<i>Research site</i>	<i>Principal Investigator / Local Collaborator</i>
South Central Ambulance Service NHS Foundation Trust	Charles Deakin
North East Ambulance Service NHS Foundation Trust	Paul Aitken-Fell
West Hertfordshire Hospitals NHS Trust	Andrew Barlow
South Tees Hospitals NHS Foundation Trust	Ramamurthy Sathyamurthy

The amendment relates solely to the addition of new site(s) and/or investigator(s) within the National Health Service (NHS) or Health and Social Care (HSC) in Northern Ireland. Site-specific assessment (SSA) for any site within the National Health Service (NHS) or Health and Social Care (HSC) in Northern Ireland will form part of the nation specific local processes for that site. Guidance on how to work with sites is provided in the IRAS help section at <https://www.myresearchproject.org.uk/help/hlpnhshscr.aspx>

On behalf of the Committee, I am pleased to confirm the extension of the favourable opinion to the new site(s) and/or investigator(s), subject to management permission being given by the relevant host organisation prior to the study starting at the site.

**Statement of compliance**

This Committee is recognised by the United Kingdom Ethics Committee Authority under the Medicines for Human Use (Clinical Trials) Regulations 2004, and is authorised to carry out the ethical review of clinical trials of investigational medicinal products.

The Committee is fully compliant with the Regulations as they relate to ethics committees and the conditions and principles of good clinical practice.

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

<b>IRAS Project ID: 281958</b>	<b>Please quote this number on all correspondence</b>
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Yours sincerely



**Alison Doherty**  
**Approvals Administrator**

Email: berkshire.rec@hra.nhs.uk

Copy to: *N/A N/A CTRG*

## Nargis Begum

**From:** Hannah Swayze  
**Sent:** 05 November 2020 10:05  
**To:** Nargis Begum; Julie Allen  
**Subject:** Fw: IRAS Project ID 281958. HRA and HCRW Approval for the Amendment  
**Attachments:** IRAS 281958 SL23b\_Confirmation\_of\_opinion.pdf

**From:** "berkshire.rec@hra.nhs.uk" <noreply@harp.org.uk>  
**Subject:** IRAS Project ID 281958. HRA and HCRW Approval for the Amendment  
**Date:** 4 November 2020 at 15:57:09 GMT  
**To:** <christopher.butler@phc.ox.ac.uk>, <ctr@admin.ox.ac.uk>  
**Cc:** <hannah.swayze@phc.ox.ac.uk>  
**Reply-To:** <berkshire.rec@hra.nhs.uk>

Dear Professor Butler,

<b>IRAS Project ID:</b>	281958
<b>Short Study Title:</b>	PRINCIPLE [COVID-19] [UPH]
<b>Amendment No./Sponsor Ref:</b>	Substantial Amendment 9
<b>Amendment Date:</b>	02 November 2020
<b>Amendment Type:</b>	Substantial CTIMP - New Site / PI Only

I am pleased to confirm **HRA and HCRW Approval** for the above referenced amendment.

You should implement this amendment at NHS organisations in England and Wales, in line with the guidance in the amendment tool.

### User Feedback

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<http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/>.

Please contact [amendments@hra.nhs.uk](mailto:amendments@hra.nhs.uk) for any queries relating to the assessment of this amendment.

Kind regards

**Alison Doherty**

**Approvals Administrator**

**Health Research Authority**

Ground Floor | Skipton House | 80 London Road | London | SE1 6LH

**E.** [amendments@hra.nhs.uk](mailto:amendments@hra.nhs.uk)

**W.** [www.hra.nhs.uk](http://www.hra.nhs.uk)

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