

**IRAS 281958. Substantial Amendment valid for REC review**

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Tue 11/10/2020 12:54

To: Christopher Butler &lt;christopher.butler@phc.ox.ac.uk&gt;

Cc: CTRG Sponsorship Correspondence &lt;ctrg@admin.ox.ac.uk&gt;; Hannah Swayze &lt;hannah.swayze@phc.ox.ac.uk&gt;

Dear Professor Butler,

**Study title: Platform Randomised trial of INterventions against COVID-19 In older peoPLE****REC reference: 20/SC/0158****IRAS project ID: 281958****Amendment number: Substantial Amendment 10****Amendment date: 04 November 2020**

Thank you for submitting the above amendment, which was received on 10th November 2020. I can confirm that this is a valid notice of a substantial amendment and will be reviewed by the Sub Committee ASAP.

**Documents received**

The documents to be reviewed are as follows:

| <i>Document</i>                                       | <i>Version</i> | <i>Date</i>      |
|-------------------------------------------------------|----------------|------------------|
| Completed Amendment Tool [SA10 Locked Amendment Tool] | N/A            | 04 November 2020 |
| Cover Letter [REC SA10 cover letter]                  | N/A            | 09 November 2020 |
| Other [Inhaled Corticosteroid Participant Card]       | 1.0            | 07 November 2020 |
| Other [IMP_Label form_Inhaled corticosteroid]         | 1.0            | 07 November 2020 |
| Other [Privacy Notice]                                | 1.1            | 07 November 2020 |
| Other [Privacy Notice (tracked)]                      | 1.1            | 07 November 2020 |
| Other [UPH Approval]                                  | N/A            | 29 October 2020  |
| Other [Information for participants]                  | 1.1            | 09 November 2020 |
| Other [Information for participants (tracked)]        | 1.1            | 09 November 2020 |
| Other [Patient Recruitment Letter]                    | 2.2            | 09 November 2020 |
| Other [Patient Recruitment Letter (tracked)]          | 2.2            | 09 November 2020 |
| Other [Video infographic script]                      | 1.1            | 09 November 2020 |
| Other [Video infographic script (tracked)]            | 1.1            | 09 November 2020 |
| Other [Study Partner Letter]                          | 1.1            | 09 November 2020 |
| Other [Study Partner Letter (tracked)]                | 1.1            | 09 November 2020 |

|                                                                            |     |                  |
|----------------------------------------------------------------------------|-----|------------------|
| Participant consent form [Consent Form]                                    | 2.1 | 07 November 2020 |
| Participant consent form [Consent Form (tracked)]                          | 2.1 | 07 November 2020 |
| Participant information sheet (PIS) [PIS Appendices]                       | 1.3 | 07 November 2020 |
| Participant information sheet (PIS) [PIS Appendices (tracked)]             | 1.3 | 07 November 2020 |
| Participant information sheet (PIS) [PIS]                                  | 3.3 | 07 November 2020 |
| Participant information sheet (PIS) [PIS (tracked)]                        | 3.3 | 07 November 2020 |
| Participant information sheet (PIS) [Pictorial PIS]                        | 2.3 | 09 November 2020 |
| Participant information sheet (PIS) [Pictorial PIS (tracked)]              | 2.3 | 09 November 2020 |
| Study Design [Protocol]                                                    | 6.0 | 02 November 2020 |
| Study Design [Protocol (tracked)]                                          | 6.0 | 02 November 2020 |
| Summary of product characteristics (SmPC) [Pulmicort Turbohaler 400_S MPC] | N/A | 14 April 2020    |

### Notification of the Committee's decision

The Committee will issue an ethical opinion on the amendment within a maximum of 35 days from the date of receipt.

Kind regards

**Alison Doherty**

**Approvals Administrator**

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