

**Sharon Tonner**

---

**From:** berkshire.rec@hra.nhs.uk <noreply@harp.org.uk>  
**Sent:** 17 December 2020 14:41  
**To:** Christopher Butler  
**Cc:** CTRG Sponsorship Correspondence; Sharon Tonner  
**Subject:** IRAS 281958. Substantial Amendment valid for REC review

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: SA 11**

**Amendment date: 30 November 2020**

Thank you for submitting the above amendment, which was received on 14th December 2020. I can confirm that this is a valid notice of a substantial amendment and will be reviewed by the Sub Committee at its next meeting.

**Documents received**

The documents to be reviewed are as follows:

| <i>Document</i>                                              | <i>Version</i> | <i>Date</i>      |
|--------------------------------------------------------------|----------------|------------------|
| Completed Amendment Tool [Amendment Tool]                    | 1              | 30 November 2020 |
| Cover Letter [Rec SA11 Cover Letter]                         | 1              | 10 December 2020 |
| Letter from sponsor [Sponsor Confirmation]                   | 1              | 09 December 2020 |
| Letters of invitation to participant [Legal Rep Letter]      | 1              | 30 November 2020 |
| Other [IRAS_Form_12122020]                                   |                | 12 December 2020 |
| Participant consent form [Consent Form Clean]                | 2.2            | 26 November 2020 |
| Participant consent form [Consent Form Tracked]              | 2.2            | 26 November 2020 |
| Participant information sheet (PIS) [PIS Appendices Clean]   | 1.4            | 02 December 2020 |
| Participant information sheet (PIS) [PIS Appendices Tracked] | 1.4            | 02 December 2020 |
| Participant information sheet (PIS) [PIS Clean]              | 3.4            | 26 November 2020 |
| Participant information sheet (PIS) [PIS Tracked]            | 3.4            | 26 November 2020 |
| Research protocol or project proposal [Protocol Clean]       | 6.2            | 26 November 2020 |
| Research protocol or project proposal [Protocol Tracked]     | 6.2            | 26 November 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**

Bristol REC Centre | Whitefriars | BS1 2NT

**T.** 020 7104 8049

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

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

Sign up to receive our newsletter [HRA Latest.](#)