

IRAS 281958. Substantial Amendment valid for REC review

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Wed 4/28/2021 11:54

To: Christopher Butler <christopher.butler@phc.ox.ac.uk>

Cc: gram.nrspcc@nhs.scot <gram.nrspcc@nhs.scot>; CTRG Sponsorship Correspondence <ctr@admin.ox.ac.uk>; Hannah Swayze <hannah.swayze@phc.ox.ac.uk>

Dear Professor Butler,

Study title: Platform Randomised trial of treatments in the Community for epidemic and Pandemic illnesses

REC reference: 20/SC/0158

IRAS project ID: 281958

Amendment number: SA 15

Amendment date: 26 April 2021

Thank you for submitting the above amendment, which was received on 27th April 2021. I can confirm that this is a valid notice of a substantial amendment and will be reviewed by the Sub Committee as soon as possible.

Documents received

The documents to be reviewed are as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Completed Amendment Tool [SA15 Locked Amendment Tool]	n/a	27 April 2021
Cover Letter [Cover Letter]	n/a	27 April 2021
Investigator Brochure/SmPC [Investigator's Brochure]	2.0	21 April 2021
Letter from sponsor [SA15 Sponsor Approval]	n/a	27 April 2021
Other [PIS Appendices]	2.2	16 March 2021
Other [PIS Appendices (tracked)]	2.2	16 March 2021
Other [Ivermectin Participant Card]	1.0	15 March 2021
Other [IMP_Label form_ Ivermectin]	1.0	15 March 2021
Other [Wallet Emergency Card_ Ivermectin]	1.0	15 March 2021
Research protocol or project proposal [Protocol]	8.1	12 April 2021
Research protocol or project proposal [Protocol (tracked)]	8.1	12 April 2021

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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