

Fwd: IRAS 281958. Substantial Amendment valid for REC review

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

Fri 7/23/2021 12:47

To: Hannah Swayze <hannah.swayze@phc.ox.ac.uk>; Emma Ogburn <emma.ogburn@phc.ox.ac.uk>

Begin forwarded message:

From: "berkshire.rec@hra.nhs.uk" <noreply@harp.org.uk>
Subject: IRAS 281958. Substantial Amendment valid for REC review
Date: 23 July 2021 at 12:31:07 BST
To: <christopher.butler@phc.ox.ac.uk>
Cc: <ctrq@admin.ox.ac.uk>, <principle@phc.ox.ac.uk>
Reply-To: <berkshire.rec@hra.nhs.uk>

Dear Professor Butler,

Study title: Platform Randomised trial of treatments in the Community for epidemic and
Pandemic influenza
REC reference: 20/SC/0158
IRAS project ID: 281958
Amendment number: Substantial Amendment 16
Amendment date: 12 July 2021

Thank you for submitting the above amendment, which was received on 23rd July 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 [SA16 Locked Amendment Tool]	n/a	20 July 2021
Copies of advertisement materials for research participants [PRINCIPLE Patient Recruitment Poster_v1.6 12.07.2021_clean]	1.5	12 July 2021
Copies of advertisement materials for research participants [PRINCIPLE Patient Recruitment	1.5	12 July 2021

Poster_v1.6 12.07.2021_tracked]		
Copies of advertisement materials for research participants [PRINCIPLE Website Advert v1.4 12.07.21_clean]	1.4	12 July 2021
Copies of advertisement materials for research participants [PRINCIPLE Website Advert v1.4 12.07.21_tracked]	1.4	12 July 2021
Copies of advertisement materials for research participants [PRINCIPLE Advert v1.2 12.07.21_clean]	1.2	12 July 2021
Copies of advertisement materials for research participants [PRINCIPLE Advert v1.2 12.07.21_tracked]	1.2	12 July 2021
Copies of advertisement materials for research participants [PRINCIPLE Radio Advert v1.1 12.07.2021_clean]	1.1	12 July 2021
Copies of advertisement materials for research participants [PRINCIPLE Radio Advert v1.1 12.07.2021_tracked]	1.1	12 July 2021
Copies of materials calling attention of potential participants to the research [PRINCIPLE Social Media v1.3 12.07.2021_clean]	1.3	12 July 2021
Copies of materials calling attention of potential participants to the research [PRINCIPLE Social Media v1.3 12.07.2021_tracked]	1.3	12 July 2021
Cover Letter [REC SA16 Cover letter]	n/a	21 July 2021
Investigator Brochure/SmPC [Favipiravir IB]	13	06 July 2021
Investigator Brochure/SmPC [Favipiravir IB (tracked)]	13	06 July 2021
Investigator Brochure/SmPC [Ivermectin IB]	3	04 May 2021
Letter from sponsor [SA16 Sponsor Approval]	n/a	20 July 2021
Letters of invitation to participant [PRINCIPLE Patient Recruitment Letter v2.5_12.07.2021_clean]	2.5	12 July 2021
Letters of invitation to participant [PRINCIPLE Patient Recruitment Letter v2.5_12.07.2021_tracked]	2.5	12 July 2021
Letters of invitation to participant [PRINCIPLE_Study Partner Letter v1.4 12.07.21_clean]	1.4	12 July 2021
Letters of invitation to	1.4	12 July 2021

participant [PRINCIPLE_Study Partner Letter v1.4 12.07.21_tracked]		
Other [PRINCIPLE Text Message Info v4.2 12.07.2021_clean]	4.2	12 July 2021
Other [PRINCIPLE Text Message Info v4.2 12.07.2021_tracked]	4.2	12 July 2021
Other [PRINCIPLE_Video Infographic Script_1.4_12.07.2021_tracked]	1.4	12 July 2021
Other [PRINCIPLE_Participant Introductory Letter v1.3 12.07.2021_clean]	1.3	12 July 2021
Other [PRINCIPLE_Participant Introductory Letter v1.3 12.07.2021_tracked]	1.3	12 July 2021
Other [PRINCIPLE_Video Infographic Script_1.4_12.07.2021_clean]	1.4	12 July 2021
Other [PRINCIPLE Text Message IMP v1.0 14.07.2021]	1.0	14 July 2021
Participant information sheet (PIS) [PIS (tracked)]	4.1	12 July 2021
Participant information sheet (PIS) [PIS (clean)]	4.1	12 July 2021
Participant information sheet (PIS) [PRINCIPLE_Pictorial PIS v2.6_12.07.2021_clean]	2.6	12 July 2021
Participant information sheet (PIS) [PRINCIPLE_Pictorial PIS v2.6_12.07.2021_tracked]	2.6	12 July 2021
Participant information sheet (PIS) [PRINCIPLE PIS_v4.1 12.07.2021_clean]	4.1	12 July 2021
Participant information sheet (PIS) [PRINCIPLE PIS_v4.1 12.07.2021_tracked]	4.1	12 July 2021
Participant information sheet (PIS) [PRINCIPLE PIS Appendices_v2.3 12.07.2021_clean]	2.3	12 July 2021
Participant information sheet (PIS) [PRINCIPLE PIS Appendices_v2.3 12.07.2021_tracked]	2.3	12 July 2021
Research protocol or project proposal [Protocol (tracked)]	9.0	12 July 2021
Research protocol or project proposal [Protocol (clean)]	9.0	12 July 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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