

Re-Packaging of IMP at participating GP Practices, NHS Trust and Health Boards

Version 2 31st May 2020

Please note that this task can **ONLY** be carried out by a doctor, a pharmacist, or an individual working under a pharmacist's supervision.

Items needed:

Documents will be supplied in the post or can be printed from the electronic set-up folder

	Description	Document Name
1	Envelope (ideally C5)	N/A
2	1x blister pack of 15 tablets hydroxychloroquine	N/A
3	Trial drug label	<i>PRINCIPLE_IMP_Label form_v1.0 23.03.20</i>
4	Patient instructions on how to use the study medication	<i>IMP Participant Information_V1.0_27.03.2020</i>
5	Participant Booklet: i) If providing a swab OR ii) If NOT providing a swab	<i>PRINCIPLE Information for Participants (SWAB)_V1.0_18.05.2020</i> <i>OR</i> <i>PRINCIPLE Information for Participants_V1.3_18.05.2020</i>

Instructions

Your practice will be able to prepare the envelopes with the documents we send you, or we will provide envelopes that are already prepared.

1. Please have an envelope ready and affix the trial drug label to the front of the envelope (document named *PRINCIPLE_IMP_Label form_v1.0 23.03.20*).
2. Please fill in the patient's trial ID number on the drug label.
3. If not already pre-prepared in the envelope, please insert:
 - i) Patient instructions on how to use the study medication - *IMP Participant Information_V1.0_27.03.2020*
 - ii) Participant Information Booklet (either *PRINCIPLE Information for Participants (SWAB)_V1.0_18.05.2020* (if sending a swab with the medication)

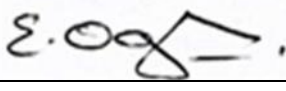
OR

PRINCIPLE Information for Participants_V1.3_18.05.2020 (if not sending a swab with the medication)

iii) Participant Trial ID Card- **PRINCIPLE_Participant_Contact_Card_V1.0_27.03.2020**

4. Please remove **one** of the blister packs (containing 15 tablets) from the supply provided to you by Public Health England (PHE) or any other trial authorised provider and put it in the envelope.
5. Seal the envelope and provide it to the trial participant or their representative.
6. Complete on your drug accountability log the participant's trial ID number, serial number (of the box the blister pack came in), name and signature of the person dispensing the medication.

If you require further assistance please contact us [at principle@phc.ox.ac.uk](mailto:at.principle@phc.ox.ac.uk).

	NAME	TITLE	SIGNATURE	DATE
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Approved by:	Emma Ogburn	CTU Director of Operations		31.05..2020