University Hospitals Plymouth NHS Trust

Work Instruction

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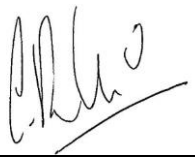
Title:	IMP Delivery to Research Participants Home During COVID-19		
Approver		Document No:	WI_IMP Delivery
Name:	Dr Chris Rollinson	Version No:	1.0
Signature:		Effective Date:	Jul-2020
		Review Date:	Dec-2020
		Date Signed:	30-Jul-2020

1. Purpose

To describe the procedure for making changes to how Investigational Medicinal Products (IMPs) are provided to a research participant during the COVID-19 pandemic. Specifically, arranging for IMP to be delivered to a research participants home *via* CitySprint courier service.

2. Scope

This WI applies to all research team members at University Hospitals Plymouth NHS Trust (UHPNT).

3. Responsibilities

In the context of the COVID-19 pandemic it may be necessary to take measures to reduce the risk of potential exposure to COVID-19 by research participants.

The Principal Investigator has overall responsibility for the conduct of the trial at UHPNT and in line with Trust guidance may deem it necessary make changes to the clinical management of their patients i.e. replace face-to-face visits with telephone consultations.

4. Documents needed for this SOP

- https://www.hra.nhs.uk/covid-19-research/covid-19-guidance-sponsors-sites-and-researchers/

5. Related documents

None.

6. Definitions

RD&I: Research Development and Innovation

IMP: Investigational Medicinal Product

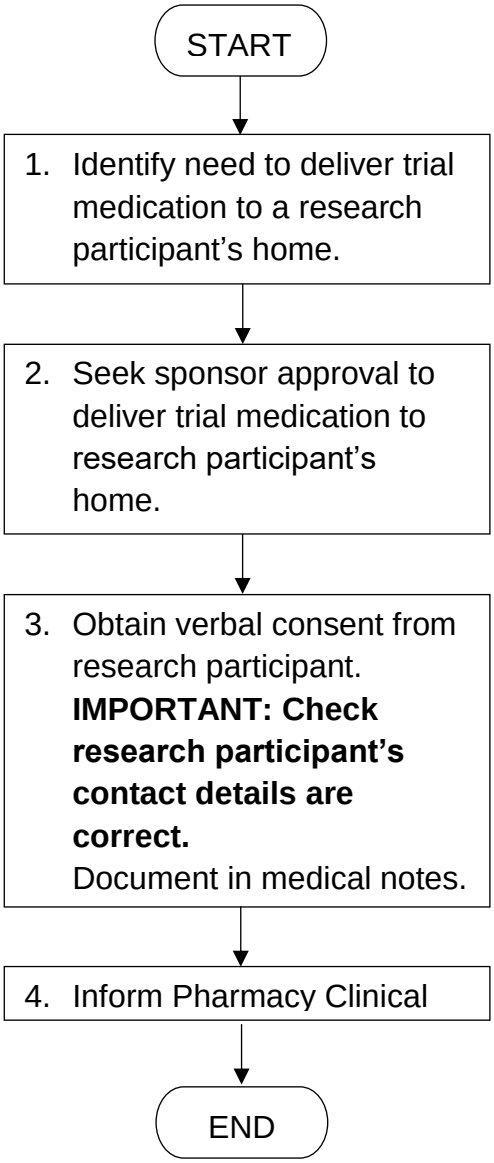
PI: Principal Investigator

Sub-I: Sub-Investigator

WI: Work Instruction

UHPNT: University Hospitals Plymouth NHS Trust

7. Process map(s)/ flow chart(s)



8. Procedure

Step	Action	Responsibility
1	Identify whether or not it is safe for the research participant to attend a hospital visit and to collect their trial medication. If participant is advised not to come in to the Trust, IMP maybe sent to their home *via* courier. **Verbal consent should be sought from the partcipant. The address for delivery must be checked and confirmed as current.** Decision based on the clinical judgement of the PI or Sub-I, Trust guidance and any COVID-19 risk assessment/ contingency plan provided by the trial Sponsor.	PI and Sub-I.
2	Seek approval from the trial Sponsor to deliver trial medication to the research participant's *via the* hospitals contracted courier service, CitySprint. *Note: the sponsor must assess the risks relating to the product and consider any shipping and storage arrangements.*	All research staff.
3	Obtain verbal consent from the research participant to provide contact details for shipping purposes each time trial medication is to be sent to them at home. **Check the participants contact details are correct,** address and telephone number each time trial medication is to be sent to them at home. Remind research participants of trial medication accountability and compliance as per protocol. For example, keeping a diary and returning empty bottles at next hospital visit. Document in medical notes conversation with research participants, if they gave verbal consent and any questions asked and answered.	Research staff delegated to assist with and/ or perform the consenting process in the trial.
4	Inform Pharmacy Clinical Trials by email of the following: • Trial medication is to be sent to research participant's home address. • Address of research participant. • Contact number for research participant. • Permission was obtained from the research participant. Booking for the delivery of trial medication to the research participants home will be made *via* CitySprint's secure booking platform.	All research staff. Pharmacy Clinical Trials staff.

9. Changes from last revision

None.