York Foundation Trust R&D Unit
SOP
Pharm/S101

Delivering clinical trials prescriptions to patient's homes under exceptional circumstances

IT IS THE RESPONSIBILITY OF ALL USERS OF THIS SOP TO ENSURE THAT THE CORRECT VERSION IS BEING USED

All staff should regularly check the R&D Unit's website and/or Q-Pulse for information relating to the implementation of new or revised versions. Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.

The definitive versions of all R&D Unit SOPs appear online. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the R&D Unit website: https://www.research.yorkhospitals.nhs.uk/sops-and-guidance-/ and/or Q-Pulse

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Version Number:	1.0
Author:	Poppy Cottrell-Howe
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Approved by:	Name/Position:	Stuart Parkes Deputy Chief Pharmacist
	Signature	
	Date:	7th April 2020
	Name/Position:	Sarah Sheath, SOP Controller
	Signature:	
	Date:	7th April 2020

This SOP will normally be reviewed at least every 3 years unless changes to the legislation require otherwise

Version History Log

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

Version	Date Implemented	Details of significant changes
1.0	8th April 2020	

Contents

1 Introduction, Background and Purpose

Due to current circumstances regarding the COVID-19 pandemic, restriction regarding patients coming in for certain treatments have been reduced or halted all together. The public is also being advised to stay indoors and avoid any unnecessary journeys outside their properties if possible. This is an ever changing situation but it has created limitation on the ability of some patients being able to get to the hospital to collect clinical trial medications.

Patients affected by the COVID-19 situation may no longer have the means to get their medication or have anyone else to do it on their behalf. In these exceptional circumstances this procedure has been put in place to allow the delivery of clinical trials medication to these patients.

The deliveries of the clinical trials medication to these patients in need of them will be conducted by any member staff from the research and development team capable of doing so.

2 Who Should Use This SOP

This SOP should be used by any member of the research and development team that is going to be involved in the delivery of clinical trial to the homes of patient who need them.

3 When this SOP Should be Used

This SOP should be used whenever a delivery of clinical trial medication is required to a patient during the COVID-19 pandemic.

4 Procedure(s)

1. A patient needing a delivery will need to be identified by the research nurse who is dealing with the patient. When clinical trials medication is required they should let the clinical trials pharmacy know that this medication will need to be delivered.
2. The prescription and dispensing procedure remains the same and should be conducted as normal.
3. Pharmacy clinical trials will also check to see if the sponsor may have made other arrangements for getting medication to patient's homes. Some sponsors are providing a deliver service themselves.
4. When the medication is ready the pharmacy clinical trials will liaise with the research and development team to organise a member of staff to take the medication to the patient.

5. Once the relevant member of staff has been selected to deliver the medications the clinical trials pharmacy staff will complete the pharmacy section on the Pharm/F92-Clinical Trials Delivery Form
    - The patient must be contacted before delivery to ensure they will be there to accept the medications. Patient consent must be given by the patient allowing the delivery of their medication by a research nurse or member of pharmacy clinical trials.
    - No information on the form must indicate the patient's care or treatment

6. The medication will be placed in a pharmacy paper bag
7. The member of staff collecting and delivering will complete the relevant section of the Pharm/F92-Clinical Trials Delivery Form
8. The member of staff delivering the medication must drive direct to the patient's address.
9. Once at the address, place the bag on the ground in front of the door, knock on the door and stand 2 meters back from the bag. Ask the patient to confirm their date of birth stated on the delivery form.
10. Complete the relevant section on the form and return it to pharmacy clinical trial when you are next on site.

If there are any problems with a planned delivery call the pharmacy clinical trials team on 01904 721684.

5 Related SOPs and Documents

Pharm/F92 Clinical Trials Delivery Form