

Managing Clinical Trial visit during Covid19 Pandemic in King's Clinical Research Facility

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Author	Chifundo Stubbs, CRF Research Nurse
Approved by	Elka Giemza, CRF Manager
Authorised by	Professor Peter Goadsby, CRF Director
Related documents	CRF-ADMG-FRM-12 Reopening studies and mitigation for COVID-19 at the NIHR Kings CRF KCH Policy for swabbing patient/staff with suspected SARS-COV-2 infection http://kingsdoc/pages/home.aspx KCH Infection and Prevention Control Policy COVID-19: infection prevention and control recommendations By PHE -20 April 2021 KCH Guidelines for behaviour in clinical areas
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Supporting references	See section 6.0

Change History		
Date	Change details, since approval	Approved by
December 2020	<ol style="list-style-type: none"> 1. Minor administrative changes plus addition of document to Related documents section 2. Section 5.17- Addition of 'I am clean ' stickers 3. Section 5.20- Addition of text regarding testing symptomatic subjects 	E. Giemza

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	4. Section 5.21- Addition of Yellow Clean 5. Addition of Section 6.4 6. Change to author	
May 2021	1. Section 7.1- PPE table replaced with updated PPE table 2. Keywords- Addition of Standard Infection Prevention Control Precautions (SICPs), Aerosol Generating Procedures (AGPsare) 3. Addition to related documents section & section 6.0 4. Section 5.5- Clarification of PPE to be worn 5. Section 5.6- Clarification of PPE 6. Section 5.22- Addition of text regarding removal of PPE	E. Giemza
June 2021	1. Section 5.5- Addition of text 'Bare below the elbow'	E. Giemza

Review History		
Date	Review details	Approved by
December 2020	Review of V1.0 by Chifundo Stubbs CRF Research Nurse, as per the review date. Changes made as per 'Change History' and re-issued as v2.0	E. Giemza
May 2021	Review of V2.0 by Angelina Twumasi, CRF Quality Assurance Manager, as per the review date. Changes made as per 'Change History' and re-issued as v3.0	E. Giemza

1.0 Background

1.1 Covid-19 has placed a considerable pressure on clinical trials performed by and in the NHS particularly at the King's CRF. The NIHR, King's College Hospital and government bodies have published guidance to ensure that best practice is maintained during this time.

1.2 The King's college Hospital NHS Trust has a number of policies and guidelines to ensure preparedness for covid-19 outbreak in other to maintain safety of clinical trial patients and staff. The safety and well-being of the trial participant is the primary concern and measures have been put in place of the CRF to mitigate the spread of virus while in the facility.

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2.0 Purpose

2.1 The purpose of this Standard Operating Procedure (SOP) is to describe the process of managing clinical trial patients/volunteers during covid-19 pandemic in the CRF.

3.0 Scope

3.1 This SOP is applicable to all KHP staff who may be involved in the management of clinical trial patients/volunteers in the CRF during the covid-19 pandemic.

4.0 Responsibilities

4.1 It is the responsibility of the CRF Manager, CRF QA Manager, CRF Research Nurses, CRF Research Coordinators and CRF users who may be involved in the managing of clinical trial patients/volunteers in the CRF during the covid-19 pandemic to read, understand and adhere to the procedures described in this SOP.

4.2 It is the responsibility of CRF staff and /or user managing the patient/volunteer to check test results (between 8-24 hour turnaround time) to inform the patient, CRF manager/team and the sponsor

4.3 It is the responsibility of CRF staff to make the necessary referrals (GP if community based), and document both on the trust EPR and relevant trial document.

4.4 It is the responsibility of CRF research Nurses/Nurse delegate, or users to be trained, fit tested and have undergone a personal risk assessment before able to undertake the procedure.

5.0 Procedure

5.1 Call patients a day before the visit to confirm that patient/volunteer is well enough to attend.

5.2 Collect covid-19 test swab from central command a day before patient/volunteer's visit.

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- 5.3 Register patient/volunteer on the EPR system and request for covid-19 RNA on EPR and print labels.
- 5.4 Provide patient/volunteer with facemask and gel hand wash on arrival.
- 5.5 Wear full PPE before undertaking test. (Sleeves should be worn above the elbows, staff must be bare below the elbow. Disposable gloves (to be put on after washing your hands), apron, face mask, goggles or visor) Please refer to section 6.0 and Section 7.0
- 5.6 Wash your hands thoroughly for at least 20 seconds with soap and warm running water to ensure your hands are clean. Put on a pair of disposable gloves
- 5.7 Remove swab stick from the packet and hold it in your hand. Ask patient to open their mouth wide so you can see the back of throat.
- 5.8 Holding the stick in your hand, gently rub the swab over both tonsils and back of throat for 10 seconds, (using a torch may help you do this). Remove the swab from the back of their throat.
- 5.9 Using the same end of the same swab, gently rub into their nostrils about 1 inch (2.5cm) or until you feel some resistance. Patient/volunteer can do the swab themselves if they wish to do so.
- 5.10 Rotate the swab for 10-15 seconds and slowly remove it.
- 5.11 Place the swab into a virus transport medium tube provided and snap off the other end of swab so it fits inside of the tube.
- 5.12 Label the sample with an EPR label printed
- 5.13 Double bag the labelled sample and send sample to the virology department on the second floor for analysis.
- 5.14 Inform the patient of the test result which could be obtained from EPR.
- 5.15 Patient to follow the PHE guideline on Track and Trace and wait for further instructions from sponsor when to restart the study if result is positive.
- 5.16 Patients/ volunteer who test negative will be called with an appointment for study visit.
- 5.17 Disinfect (with Clinell wipes) of all supplies and surfaces used immediately after discharge procedure and ensure proper labelling of cleaned surfaces with 'I am clean' stickers.
- 5.18 Non-clinical staff who use the facility must wear Facemask at all times as per trust policy and should wear PPE when accompanying patient to the facility.
- 5.19 Facial mask to be provided at the CRF reception for non-clinical staff who do not have one.

- 5.20 In the event that a patient/ volunteer presents as symptomatic or has come into close contact with someone who is symptomatic or confirmed COVID positive, escort the participant to the Testing Hub opposite the Wellcome Foundation Building to perform the procedure.
- 5.21 Ensure that you order a 'yellow clean' through Medirest, after testing this patient/ volunteer.
- 5.22 Ensure that disposable gloves and aprons are removed before leaving clinical or laboratory areas and entering non-clinical/ laboratory areas.

6.0 Related documents & References

- 6.1 KCH policy for swabbing patient/staff with suspected SARS-COV-2 infection
<http://kingsdocs/pages/home.aspx>.
- 6.2 <https://www.gov.uk/government/publications/wuhan-novel-coronavirus-infection-prevention-and-control>
- 6.3 CRF-ADMG-FRM-12 Reopening studies and mitigation for COVID-19 at the NIHR Kings CRF v2.0
- 6.4 KCH Infection and Prevention Control Policy
- 6.5 COVID-19: infection prevention and control recommendations by PHE 20 April 2021
- 6.6 KCH Guidelines for behaviour in clinical areas

7.0 List of Appendices

7.1 Table 1: PPE recommendations by risk pathway- Public Health England

Low-risk pathway (PPE required for SICPs)^[A]				
SICPs/PPE (all settings/all patients/individuals)	Disposable gloves	Disposable apron/gown	Face masks	Eye/face protection (visor)
If contact with blood and/or body fluids is anticipated	Single use	Single-use apron (gown required if risk of spraying/splashing)	FRSM Type IIR for direct patient care and surgical mask Type II for extended use ^[A]	Risk assess and use if required for care procedure/task where anticipated blood/body fluids spraying/splashes
Medium-risk pathway (PPE required by type of transmission/exposure)				
PPE required by type of transmission/exposure	Disposable gloves	Disposable apron/gown	Face masks	Eye/face protection (visor)
Droplet/contact PPE for direct patient care <2 metres	Single use	Single-use apron (gown required if risk of	FRSM Type IIR ^[B]	Single-use or reusable ^[D]

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		spraying/splashing)		
Airborne PPE (when undertaking or if AGPs are likely)	Single use	Single use apron or gown	FFP3 ^[C] or respirator/hood for AGPs	Single use or reusable
When undertaking AGPs on patients/individuals with no COVID-19 symptoms and no test result	Single use	Single-use gown	FFP3 or hood for AGPs	Single use or reusable
<p>Standard Infection Prevention Control Precautions (SICPs)</p> <p>Aerosol Generating Procedure (AGPsare)</p> <p>[A] Sessional/extended use of face masks apply across the UK for healthcare workers in any health or other care settings</p> <p>[B] FRSM can be worn sessionally if providing care for COVID-19 cohorted patients/individuals</p> <p>[C] FFP3 can be worn sessionally (includes eye/face protection) in high risk areas where AGPsare undertaken for COVID-19 cohorted patients/individuals</p> <p>[D] Risk assess and use if required for care procedure/task where anticipated blood/body fluids spraying/splashes below single use/reusable</p>				

8.0 Approval and sign off

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Name: Chifundo Stubbs

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