

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

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Author	Angelina Twumasi, Quality Assurance Manager
Approved by	Elka Giemza, CRF Manager
Authorised by	Professor Peter Goadsby, CRF Director
Related documents	<p>CRF-ADMG-FRM-12 Reopening studies and mitigation for COVID-19 at the NIHR Kings CRF</p> <p>KCH Policy for swabbing patient/staff with suspected SARS-COV-2 infection http://kingsdoc/pages/home.aspx</p> <p>KCH Infection and Prevention Control Policy</p> <p>COVID-19: infection prevention and control recommendations By PHE -20 April 2021</p> <p>Infection prevention and control for seasonal respiratory infections in health and care settings (including SARS-CoV-2) for winter 2021 to 2022 - GOV.UK (www.gov.uk)</p> <p>KCH Guidelines for behaviour in clinical areas national requirement</p> <p>Information on where to get the COVID vaccine and booster is available on the NHS website.</p>
Keywords	Covid-19, Pandemic, infection, virus, Standard Infection Prevention Control Precautions (SICPs), Aerosol Generating Procedures (AGPsare)
Supporting references	See section 6.0 , Section 7.0

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Page 1 of 11



Change History		
Date	Change details, since approval	Approved by
December 2020	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 4. Section 5.21- Addition of Yellow Clean 5. Addition of Section 6.4 6. Change to author	E. Giemza
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
November 2021	1. Section 5.21- Addition of clarification with regards to OMNISCROM variant 2. Minor administrative changes 3. Changes in author 4. Section 6.6- Reference to https://www.gov.uk/government/publications/wuhan-novel-coronavirus-infection-prevention-and-control/covid-19-guidance-for-maintaining-services-within-health-and-care-settings-infection-prevention-and-control-recommendations	E. Giemza
December 2021	1. Section 4.5, 5.1, 5.3- Reference to completing lateral flow test with a negative test result before attending the CRF/ CTF 2. Section 5.2- Reference to additional visitors accompanying patients/ volunteers 3. Section 4.6, 5.7- Reference to taking patients/ volunteers/ visitors temperatures, swabbing hub 4. Section 5.8- Reference to self-isolation advice. 5. Minor administrative changes. 6. Minor administrative changes made to the authorised v5.0.- Update error – version box above was not changed from version 4.0 to version 5.0 in error	E. Giemza
January 2022	1. Addition to related documents and supporting references Section 6.0, Section 7.2, Section 4.2- Referring to new national requirement of vaccination status for KCH & KCL staff/ vaccination/ / links 2. Section 5.27 & 5.28- Change to self-isolation requirements.	E. Giemza

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Page 2 of 11

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CRF-QA-SOP-14 v6

Review History		
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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
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January 2022	Review of V5.1 by Angelina Twumasi, CRF Quality Assurance Manager, as per the review date. Changes made as per 'Change History' and re-issued as v6.0	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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Page 3 of 11

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/ Practitioners 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 all KHP and staff to adhere to the national requirement, for the vast majority of health and social care workers to receive two doses of a COVID-19 vaccination by 31 March 2022, which our NHS Trust partners have been enacting for NHS staff, to ensure they comply with the legislation.

As part of complying with these regulations, please also note that any member of King's College staff or students who, as a result of their role, have direct in person interactions with patients in the NHS Trusts will need to have received two doses of a UK-approved Covid-19 Vaccination by 1 April 2022. This means the first vaccination must be completed by 3rd February.

This requirement would apply in a primary or secondary clinical setting where colleagues are offering front line clinical service. It also includes colleagues who are meeting patients as a result of their involvement in clinical trials, research studies or patient service-based activity, (whether in clinical, King's College London, Trust spaces or other premises). Please refer to Section 7.2 for more clarification.

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Page 4 of 11

- 4.3 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
- 4.4 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.
- 4.5 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.
- 4.6 It is the responsibility of the CRF research Nurses/ Clinical Trial Coordinator/ Practitioner to ensure that **all** visitors to the CRF have completed a lateral flow test producing a negative test result, before attendance.
- 4.7 It is the responsibility of the CRF/ CTF staff managing the front desk to the facilities to ensure all visitors have their temperature taken.

5.0 Procedure

- 5.1 Call patients/ volunteers 2 days before the visit to confirm that patient/volunteer is well enough to attend. Advise them that they need to complete a lateral flow test, with a negative test result, before attending.
- 5.2 Patients/ volunteers are not permitted to bring another person to their visit unless the patient/ volunteer lacks capacity to travel in on their own due to a disability. This must be discussed with Research staff before attending their visit.
- 5.3 This additional visitor must complete a lateral flow test, with a negative test result, before attending.
- 5.4 Collect covid-19 test swab from central command a day before patient/volunteer's visit. (If required as per protocol)
- 5.5 Register patient/volunteer on the EPR system and request for covid-19 RNA on EPR and print labels.
- 5.6 Provide patient/volunteer with facemask and gel hand wash on arrival.
- 5.7 Take the patient/ volunteer's temperature, if the temperature shows 37.8 degrees, the patient/ volunteer/ additional visitor should immediately be taken to the swabbing hub to perform a PCR test.
- 5.8 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

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Page 5 of 11

- 5.9 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
- 5.10 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.
- 5.11 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.
- 5.12 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.
- 5.13 Rotate the swab for 10-15 seconds and slowly remove it.
- 5.14 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.
- 5.15 Label the sample with an EPR label printed
- 5.16 Double bag the labelled sample and send sample to the virology department on the second floor for analysis.
- 5.17 Inform the patient of the test result which could be obtained from EPR.
- 5.18 The affected person should be advised to leave the hospital and self-isolate according to Government guidelines
- 5.19 Advise the patient/ volunteer/ visitor 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.
- 5.20 Patients/ volunteer who test negative will be called with an appointment for study visit.
- 5.21 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.
- 5.22 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.
- 5.23 Facial mask to be provided at the CRF reception for non-clinical staff who do not have one.
- 5.24 In the event that a patient/ volunteer/ visitor 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.

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Page 6 of 11

- 5.25 Ensure that you order a 'yellow clean' through Medirest, after all testing , patient/ volunteer within the swabbing hub
- 5.26 Ensure that disposable gloves and aprons are removed before leaving clinical or laboratory areas and entering non-clinical/ laboratory areas.
- 5.27 In the event of contact with symptomatic people, you must self-isolate for at least 5 days, ensure that you return a negative lateral flow test at any time on day 5 of your self-isolation period, and at the start of your day 6.
- 5.28 If you have a positive lateral flow test, you will be required to self-isolate immediately and won't be required to take a confirmatory PCR test unless symptomatic. If you have COVID-19 symptoms, you need to isolate and book a PCR test regardless of any lateral flow test results.

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
- 6.4 KCH Infection and Prevention Control Policy
- 6.5 COVID-19: infection prevention and control recommendations by PHE 20 April 2021
- 6.6 [Infection prevention and control for seasonal respiratory infections in health and care settings \(including SARS-CoV-2\) for winter 2021 to 2022 - GOV.UK \(www.gov.uk\)](#)
- 6.7 KCH Guidelines for behaviour in clinical areas
- 6.8 Link to [national requirement](#)
- 6.9 Link to Information on where to get the COVID vaccine and booster is available on the [NHS website](#)

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 spraying/splashing)	FRSM Type IIR ^[B]	Single-use or reusable ^[D]

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Page 8 of 11

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 (AGPs) are</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 AGPs are 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>				

7.2 There is now a national requirement for the vast majority of health and social care workers to receive two doses of a COVID-19 vaccination by 31 March 2022, which our NHS Trust partners have been enacting for NHS staff, to ensure they comply with the legislation. As part of complying with these regulations, please also note that any member of King's College staff or students who, as a result of their role, have direct in person interactions with patients in the NHS Trusts will need to have received **two doses of a UK-approved Covid-19 Vaccination by 1 April 2022. This means the first vaccination must be completed by 3rd February.**

This requirement would apply in a primary or secondary clinical setting where colleagues are offering front line clinical service. It also includes colleagues who are meeting patients as a result of their involvement in clinical trials, research

studies or patient service-based activity, (whether in clinical, King's College London, Trust spaces or other premises).

Please discuss this with your line manager or HR people partner if you have any concerns or questions. At this time, the requirement would apply to the following staff categories:

- Clinical Academic and Clinical Research staff - who ordinarily have honorary contracts/KHP passports and provide front line clinical service.
- Academic, Research or Professional Services staff - who are engaged in research studies, who have direct face to-face interactions with patients.
- Clinical Trials staff involved in managing and administering clinical trials, who have direct face-to-face interactions with patients.
- Academic, Research or Professional Services staff who provide patient facing services, who have direct face-to face interactions with patients.

However, please note that this is an evolving situation, and more staff categories.

8.0 Approval and sign off

Author:

Name: Angelina Twumasi

Position: Quality Assurance Manager

Signature:

Date:

Approved by:

Name: Elka Giemza

Position: CRF Manager

Signature:

Date:

Authorised by:

Name: Professor Peter Goadsby

Position: CRF Director

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Date:

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Page 11 of 11

Effective Date: 24 January 2022

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CRF-QA-SOP-14 v6