

Safe Management of Clinical Trial visits with Covid-19 in King's Clinical Research Facility

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Author	Bidisha Chakraborty, Quality Assurance Manager
Approved by	Elka Giemza, CRF Manager
Authorised by	Professor Peter Goadsby, CRF Director
Related documents	KCH Infection and Prevention Control Policy KCH Guidelines for behaviour in clinical areas Information on where to get the COVID vaccine and booster is available on the NHS website .
Keywords	Covid-19, Pandemic, infection, virus, Infection Prevention Control, Aerosol Generating Procedures (AGP)
Supporting references	See section 7.0

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 4. Section 5.21- Addition of Yellow Clean 5. Addition of Section 6.4 	E. Giemza

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	6. Change to author	
May 2021	<ol style="list-style-type: none"> 1. Section 7.1- PPE table replaced with updated PPE table 2. Keywords- Addition of Standard Infection Prevention Control Precautions (SICPs), Aerosol Generating Procedures (AGPs) 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	<ol style="list-style-type: none"> 1. Section 5.5- Addition of text 'Bare below the elbow' 	E. Giemza
November 2021	<ol style="list-style-type: none"> 1. Section 5.21- Addition of clarification with regards to OMNICROM 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	<ol style="list-style-type: none"> 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	<ol style="list-style-type: none"> 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
September 2022	All sections were amended with updated Trust Guidelines to ensure current national regulations were followed.	E. Giemza

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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
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30 December 2021	Review of V5.0 by Angelina Twumasi, CRF Quality Assurance Manager, as per the review date. Changes made as per 'Change History' and re-issued as v5.1	E. Giemza
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
September 2022	Review of V6.0 by Bidisha Chakraborty, CRF Quality Assurance Manager, as per the review date. Changes made as per 'Change History' and re-issued as v7.0	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 order 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.

1.3 The CRF at the King's College Hospital NHS Trust ensures that its policies and guidelines on Covid-19 are up to date in alignment with the national guidelines and trust policies to practice foremost clinical care delivered to the patients.

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2.0 Purpose

2.1 The purpose of this Standard Operating Procedure (SOP) is to describe the process of safe management of clinical trial visits for patients/volunteers with covid-19 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 with covid-19 infections.

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 with Covid-19 to read, understand and adhere to the procedures described in this SOP.

4.2 From September 2022, as part of managing rise of Covid-19 infections in winter, Trust provided it's guidelines to encourage all staff to get their Covid-19 booster doses available from Trust specified sites. Information were shared on Kingsweb ([News: - Kingsweb](#)) about how and where staff can access their vaccines.

5.0 Requirements

5.1 Covid-19 Test

5.1.1 From 1 September 2022, staff will no longer be required take part in twice-weekly, asymptomatic lateral flow testing following updated guidance from NHS England. The only occasions when staff will be required to take lateral flow tests are:

- If you are displaying symptoms of COVID-19 (please visit the NHS website for a full list of symptoms). If you test positive, please continue to follow the Trust guidance around self-isolation
- If someone in your household displays symptoms of COVID-19 or tests positive for the virus
- A small number of clinical teams will be asked to continue to take twice-weekly lateral flow tests. This would be confirmed by the respective line manager in your team.

5.1.2 Patients are no longer being tested for Covid-19 prior to appointments. It is the responsibility of all CRF staff including Research Nurses/Clinical Trial Coordinator/Clinical Research Practitioner and Clinical Researchers to ensure that the participants do not have any fever/Covid-19 symptoms on the day of their appointment. Appointments are rescheduled for participants who are identified with high temperature/Covid-19 symptoms.

5.1.3 It is recommended to follow study specific guidelines for performing Covid-19 tests for participants and adhere to the instructions mandated in the protocol.

5.1.4 The national guidelines for Covid-19 testing on developing symptoms can be found here: [Living safely with respiratory infections, including COVID-19 - GOV.UK \(www.gov.uk\)](https://www.gov.uk/guidance/living-safely-with-respiratory-infections-including-covid-19)

5.2 Face Mask

(Guidelines available on Kingsweb)

5.2.1 Staff should wear a surgical face mask when:

- Entering any clinical area (excluding children's services)
- Caring for patients on a respiratory pathway. Staff should wear an FFP3 respirator when undertaking aerosol generating procedures (AGPs).

5.2.3 Patients should wear a face mask when:

- Entering any clinical areas (excluding children's services)
- They have confirmed or suspected COVID-19
- They have confirmed or suspected COVID-19 and are being transferred between wards/departments
- They are judged by their clinical team to be at higher risk from COVID-19 (e.g. if they are severely immune-suppressed).

5.2.4 Visitors should wear a face mask when:

- Entering any clinical areas (excluding children's services)
- They themselves are at higher risk from COVID-19 (e.g. if they are immune-suppressed)

Face masks are not mandatory in any other areas of the hospital. However, all staff are encouraged to wear a face mask. Personal preference to wear masks in non-clinical areas is fully supported by the Trust. The same applies to patients and visitors.

5.3 Self-Isolation

There is no need to self-isolate in the event of contact with symptomatic people as per updated national guidelines (please see section 7.0 for supporting documents). The following measures are recommended to help reduce the spread of Covid-19 and other respiratory infections:

- 5.3.1 Get vaccinated
- 5.3.2 Let fresh air in if meeting others indoors
- 5.3.3 Practise good hygiene (Wash your hands, cover you coughs and sneezes, clean your surroundings frequently)
- 5.3.4 Wear a face covering or a face mask

6.0 Guidance for use of Personal Protective Equipment (PPE)

The current Trust guidelines on requirements of PPE mandates the following:

6.1 Non-respiratory pathway (no respiratory symptoms and negative COVID test)

- Fluid resistant surgical masks (type IIR) must be worn by all staff in clinical areas, including out-patients.
- Gloves and aprons are not required for routine care for patients on the non-respiratory pathway, unless contact with blood or body fluids, as per standard precautions
- For AGPs on the non-respiratory pathway, type IIR surgical masks and eye protection must be worn (if TB is suspected wear FFP3 mask).

6.2 Respiratory pathway (confirmed or suspected respiratory infection)

- Droplet PPE for routine care (surgical mask type IIR*, visor/goggles, gloves and apron). Gowns may be worn if there is a high risk of body fluid splash.

(*Individuals may elect to wear FFP3 masks for routine care based on their assessment of risks after considering factors such as ventilation in the clinical area, proximity/length of anticipated patient contact and their personal factors such as vaccination status and co-morbidities)

- Aerosol PPE for aerosol-generating procedures (AGPs) - gown, gloves, FFP3 mask/Powered Air Purifying Respirators (PAPRs), visor

There is no need to wear surgical masks in public and non-clinical areas e.g. admin offices, training rooms and corridors.

6.3 Patient use of PPE

Surgical facemasks should be worn by patients with symptomatic or suspected respiratory infection where possible, and always on transfer. The aim of this is to minimise the dispersal of respiratory secretions and reduce environmental contamination. A surgical facemask should not be worn by patients if there is potential for their clinical care to be compromised (such as when receiving oxygen therapy).

6.4 Visitor use of PPE

Surgical face masks must be made available to visitors at the entrance to the hospital, to wear if they choose. Visitors should also wear face masks when visiting patients on the respiratory pathway and on high risk wards (e.g. haematology, liver, respiratory and renal wards).

7.0 Related documents & References

7.1 KCH policy for swabbing patient/staff with suspected SARS-COV-2 infection
<http://kingsdocs/pages/home.aspx>.

7.2 KCH Infection and Prevention Control Policy

7.3 [Infection prevention and control for seasonal respiratory infections in health and care settings \(including SARS-CoV-2\) for winter 2021 to 2022 - GOV.UK](https://www.gov.uk/government/publications/infection-prevention-and-control-for-seasonal-respiratory-infections-in-health-and-care-settings-including-sars-cov-2-for-winter-2021-to-2022)
(www.gov.uk)

7.4 KCH Guidelines for behaviour in clinical areas

7.5 Link to [national requirement](#)

7.6 Link to Information on where to get the COVID vaccine and booster is available on the [NHS website](#)

7.7 [Living safely with respiratory infections, including COVID-19 - GOV.UK](https://www.gov.uk/government/publications/living-safely-with-respiratory-infections-including-covid-19)
(www.gov.uk)

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- 7.8 [COVID-19 supplement to the infection prevention and control resource for adult social care - GOV.UK \(www.gov.uk\)](https://www.gov.uk/government/publications/covid-19-supplement-to-the-infection-prevention-and-control-resource-for-adult-social-care)
- 7.9 [COVID-19 Green Book chapter 14a \(publishing.service.gov.uk\)](https://publishing.service.gov.uk/government/publications/covid-19-green-book-chapter-14a)
- 7.10 [UKHSA IPC for seasonal respiratory infections guideline | PHE/DH/DWP guideline | Guidelines](https://www.gov.uk/government/publications/ukhsa-ipc-for-seasonal-respiratory-infections-guideline)

8.0 Approval and sign off

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