NIHR | King's Clinical Research Facility

Reopening studies and mitigation for COVID-19 at the NIHR Kings CRF

- This document has been developed by the Clinical Research Facility (CRF) to mitigate cross infection where possible in the current COVID-19 turn-down, whilst aiming to reopen gradually studies and clinical trials at the Facility.
- The document is written to assist research teams in planning the re-start of their work.
- This document is subject to change depending on the current situation and advice from the government and King's College Hospital.

The CRF has fundamentally changed how it operates when seeing patients and subjects in the facility and this is described in the next sections. We hope that the advice set out below will go some way to reassure teams and participants attending the Facility. Appendix 1 outlines the key information.

1. Communication - What is the CRF's strategy in communicating the COVID-19 impact to their patients/ subjects in order to address concerns?

a. When recruiting subjects or inviting them in for visits for studies, we recommend that teams counsel subjects on preventive measures to reduce the risk of contracting COVID-19. This counselling should include advice on social distancing, wearing a mask, hand washing and avoiding crowded places.

b. Part of the CRF - the Clinical Trials Facility (CTF) - is situated in a fortunate position of being external to the main hospital. As a result, some of the scanning visits can be carried out without entering the hospital. This can be communicated to subjects if appropriate. Please check this option with the CRF team.

c. Since the start of the outbreak the CRF has continued to see patients needing treatment. During this time, we have adopted alternative ways to protect our patients. We advise that subjects be called the day before their visit to assess if subjects feel unwell with a temperature (>37.5°C) or any cough symptoms, rash or general malaise, loss of taste or smell. If any of these symptoms are present, they should not attend the CRF and call 111/GP for further advice.

d. Should trial patients still need to be seen in the CRF despite being symptomatic, they will be escorted directly into a dedicated area where they will be swabbed and reviewed for further interventions as necessary**.** The CRF staff will assist in doing this if required. This benefit is particularly aimed at non-clinical users of the CRF. Please speak to one of the nurses/research practitioners or reception staff to arrange the day before the visit.

e. We would ask study teams to limit the number of people / staff attending a research visit. The CRF team can help accommodate this by taking bloods

etc. Please contact the CRF team if you need additional support during your research visit.

f. Subjects/patients will be required to attend through the main hospital (Hambleden Wing) entrance, where they will be provided with a face mask and hand gel. They should then make their way to the 1st floor Cheyne Wing, CRF reception), where they will be met by the relevant research staff member. On arrival and before consenting we would suggest that the temperature be taken of the subject as a precaution before moving forward with further trial assessments. We/You can inform subjects that the CRF had limited number of COVID-19 positive patients in the facility and that the facility has been thoroughly disinfected.

g. The CRF is cleaned regularly to a high standard with equipment and resources (chairs/beds etc.) cleaned and disinfected after each use. The CRF provides Clinell wipes for the researcher to wipe down areas for the next booking.

h. Staff seeing subjects and patients, undertaking any close contact assessments should wear masks. These can be provided.

i. Information will be updated – including this document - and distributed as appropriate, as well as updates through e-mail, our website and Twitter.

2. **Participant recruitment and Retention - Does the CRF have any concerns about restarting studies, recruitment, retention?**

   a. Individual teams, Sponsors, PI's, RAGs and the respective R&I departments must decide whether it is appropriate for a study to start/restart. Subjects can decline to take part in studies should they wish to do so. In these cases, they should be followed up per protocol.

   b. Sponsors, PIs and research study teams should have a plan in place to continue to perform safety checks (whether via phone calls, use of homecare teams, remote SDVs/monitoring activities, etc.), as well as to maintain continuous study drug delivery, if applicable.

3. **Accessibility to CRF/Hospital - Will subjects have to enter main hospital to access the site? Is there a designated entrance that will be separate from the COVID-19 section of hospital?**

   a. All trial subjects/ patients attending the CRF must enter the main hospital (Hambleden Wing), to access the site, where they will be given masks on arrival. They should then make their way to the 1st Floor, Cheyne Wing, CRF reception. Exception to this is where a subject/ patient are visiting only for a scanning appointment. In this case, the subject/ patient can attend via the ground floor entrance. The ground floor doorbell alerts the MRI control room but not the first floor reception. If there is no answer then a buzz to the first floor will alert reception, reception will then locate the relevant radiographers and researchers

b. If the Experimental Medicine Facility (1st Floor, Cheyne Wing) becomes too busy, visits can take place in the Clinical Trial Facility (CTF; Wellcome Foundation Building) and vice versa but control of the booking system should mitigate this. If appropriate, screening visits/one off visits can be carried out in the CTF.
c. Subjects/ patients should be reassured that all door handles, and push panels which are touched are disinfected on a regular basis.

4. **Accessibility to CRF/Hospital - Would there be any restrictions on visitors to site, for example CRAs once the site is able to initiate this study?**
    a. Yes, currently the Trust has restricted visitor numbers - CRA's would be included in this group. So far, all COVID-19 trials have been monitored remotely. Controlled access to the CRF/CTF can be managed by the teams as per section 1f.
5. **Safety - How will the site handle social distancing for volunteers during the trial (2 volunteers a day can be dosed), will these be kept separate or would this not be possible?**
    a. The CRF is a large building and each participant will be seen by themselves, in separate rooms/bed spaces. Chairs are spaced out at a suitable distance from each other with a curtain divider between spaces. If one side of the facility is getting too busy appointments / bookings will be restricted or moved to an alternative area if available.

6. **Safety - What would the site do if there is a suspected COVID-19 infection once subjects are screened? Would the other study participants be tested for COVID-19 to ensure they have not contracted the infection, and what would be the process?**
    a. If a subject becomes symptomatic during the day, we can swab the subject and send them home to be managed by their GP. We would advise subjects not to come to the CRF if they are symptomatic. If subjects are **swab positive**, it would then be the role of the contact tracing team / GP to be involved in any contact tracing. As we are keeping the subjects apart, it is unlikely that other subjects will require a test unless they are symptomatic, however we can offer it should they wish to have it.

7. **Safety - What plans do the CRF have in place if a volunteer or staff member test positive for COVID-19 during the study conduct?**
    a. As per current Public Health England (PHE) guidelines, any staff member who becomes symptomatic or tests positive for COVID-19 will be asked to self-isolate for 10 days, or if a family / household member becomes symptomatic and /or tests positive, staff member are to self-isolate for 14 days.

8. **Safety - How will the CRF manage a potential second lockdown? Is there a possibility that the CRF would be used as a COVID-19 hub again or would there be another strategy if the trial has started?**

a. The study would need to pause. Safety follow up visits would be done by telephone. However, the CRF was not previously used as a COVID-19 hub and is unlikely to be used in this way should there be a peak in infections.
b. If a patient/trial volunteer tests positive for COVID-19, they will be asked to self-isolate for at least 10 days, as per current PHE guidelines. They should be followed up remotely until resolution or asked to come back to the hospital for further interventions, as per the PI's discretion.

9. **Other safety considerations - Before recruiting / seeing your patients:**
   a. Pre-screening over telephone, ask about symptoms (e.g. high temperature > 37.5, a new continuous cough or/and anosmia-change/loss to sense of taste) – if symptomatic, they should not attend the facility.
   b. Tympanic temperature screen – patients with temperatures above 37.5°C will be asked to go home to recover after swabbing.
   c. Provide counselling about following the guidelines of safe distance, avoiding crowds hand washing etc.
   d. Obtain appropriate PPE and masks for subjects and staff to wear during the visits.

10. **Protocol and Study Documentation - Would the CRF require site-specific ICFs to be updated in the COVID-19 context?**
   a. We don't believe that ICFs will need to be updated in the COVID-19 context unless the protocol specifically changes. However, study teams are encouraged to manage this themselves as they know their patients the best. A generic advice sheet in Appendix 2 can be given to subjects.

11. **Policies and Procedures - Is there an internal green light process for the restarting of the trial as outlined by the Trust?**
   a. Yes, there is a greenlight system in place from both KCH R&I and SLaM R&D depts. Please contact them for the application forms. These need to be counter-signed by us before being submitted so the relevant groups know we have capacity.

12. **Policies and Procedures - Are there any overarching Kings Trust policies to consider in light of COVID-19?**
   a. Currently there is a 'no visiting policy' within the hospital. Therefore, there is a need for good justification to start inviting patients and healthy volunteers to the hospital before this policy is removed/changed. This should be reviewed by the PI, study teams and RAGs. The no visiting policy may be critical to some of the mental health studies that would require a chaperone/guardian and should be reviewed on a case by case basis.
   b. If the CRF is supporting a study in terms of staff, please contact Elka Giemza or Noah Yogo to discuss staff support to ensure there is sufficient staff to support the study. The CRF have staff who are redeployed and we are also

supporting COVID 19 trials – this will have an impact on additional support provided to re-started or new studies which are currently taking priority in the Trust.

13. **Capacity - Can the CRF still support the same number of subjects as before COVID-19 when taking in to account social distancing?**
    a. The CRF has reduced the number of venepuncture chairs which can be booked by two in the Experimental Medicines Facility, to ensure social distancing. Therefore, there may be some booking delays, and this should be taken into consideration when planning your restart.
    b. Our booking process will also be amended, along with updating technology and processes to support virtual and remote visits – information to follow soon.

14. **Capacity – Can social distancing be maintained?**
    a. The CRF aims to maintain as much social distancing as possible and where this is not possible, PPE should be used where appropriate. Please refer to section 1e.

NIHR | King's Clinical Research Facility

Appendix 1

Key Information for CRF Re-opening studies

1. Research teams to send a booking request as normal to kingscrf@kcl.ac.uk. Please note due to social distancing, there are now a reduced number of clinical facilities (chairs & beds) available to book.

2. For virtual visit bookings where a hospital number for patient needs to be generated, patient details should be sent to kingscrf@kcl.ac.uk in encrypted format or use nhs.net address.

3. Remote or virtual visits using CRF staff to carry out the visits must be still be booked

4. It is the responsibility of the research team to call patients the day before the appointment and confirm that they are well enough to attend. The researcher must inform their patients that they will be provided with a mask and gel hand wash on arrival. If they are unwell or unable to attend, please ensure you inform the CRF.

5. For patients visiting either the CTF or EMF main building, a member of the research team, whilst wearing a mask, must meet patients externally e.g. at the entrance of the CTF in order to hand over mask(s) and hand gel. The researcher should then escort the patient to their booked space.

   Visitors attending with patients must stay outside of the unit as there is a No Visiting policy currently implemented by the Trust unless they fall into the following category:
   - Patients with learning disabilities
   - Patients with specific care needs (i.e. dementia)
   - Paediatric patients

6. If a patient becomes symptomatic during study visit, it is the responsibility of the researcher to inform the CRF team on ext. 31851/2 to arrange a COVID-19 swab testing. A CRF nurse will perform the swab test in the Wellcome Foundation Building. Only one swab test can be performed at a time.

7. The following website is a helpful link to getting tested outside the hospital- https://www.gov.uk/guidance/coronavirus-covid-19-getting-tested

wellcome

KING'S HEALTH PARTNERS

NIHR | King's Clinical Research Facility

Appendix 2

General advice for subjects attending the CRF

To reduce the risk of contracting Corona Virus please maintain social distancing where possible, wear a mask on public transport wash your hands for at least 20 seconds or use hand gel if no sinks are available and avoid crowded places.

The day before your appointment your researcher will pre-screen over telephone, ask about symptoms (e.g. high temperature > 37.5, a new continuous cough or/and loss of smell or loss to sense of taste and if symptomatic, you should not attend the facility.

When you arrive at the CTF your researcher will meet you outside the clinic and escort you to the facility/booked space, they will provide masks and hand gel. On arrival and before consenting you should have your temperature measured as a precaution before moving forward with further trial assessments.

The CRF had limited number of COVID-19 positive patients in the facility and the facility has been thoroughly disinfected.

The CRF is cleaned regularly to a high standard with equipment and resources (chairs/beds etc.) cleaned and disinfected after each use.