Guidance for Management of Research Participant Visits at Royal Brompton Hospital and Harefield Hospitals

1. Background

Royal Brompton & Harefield NHS Trust Foundation (RB&HFT) is a research active organisation and many patients attending both Royal Brompton and Harefield hospitals for routine clinical care may also participate in clinical research studies during the course of their treatment at RB&HFT. Where patients are enrolled into clinical research studies, they will be seen by members of the research team during their visits to the hospital for completion of research procedures.

The majority of onsite research activity was suspended due to COVID 19, however some research studies are now being given approval to re-start where the research activity aligns with the patient's routine clinical care pathway. Approval for re-start of projects must be sought from the Research Office following consultation with the relevant clinical lead /research lead with approval from relevant clinical director, research committee chairman, and associate director of research as needed. Confirmation of support from relevant delivery teams should obtained as necessary. Arrangements for re-starting research projects should be discussed with the Sponsor, and their written agreement to re-start obtained.

Research Office COVID 19 guidance, including relevant documents relating to reactivating projects can be found here: -

https://www2.rbht.nhs.uk/services/research/covid-19/

This document provides guidance for undertaking research procedures at Royal Brompton Hospital (RB&HFT) to minimise risk of COVID 19 exposure and transmission to patients, research staff, other hospital staff, external staff, and contractors.

2. Introduction

To comply with the NHSE Pan London Principles for Infection Prevention and Control (see section 5), separate care pathways, defined as low, medium and high risk, have been developed to manage patient attendances at hospital sites for patients on these respective pathways. Whilst the Pan London guidance does not specifically reference patients participating in research studies, the principles of separated care pathways may be applied, e.g. if the research project involves an invasive surgical procedure, the patient would be managed on a low risk pathway, i.e. with COVID 19 testing prior to admission. Many research patients will be classified as medium risk for the purpose of out-patient attendance for research, i.e. will be assessed for COVID 19 symptoms prior to admission. High risk patients are those with a confirmed or suspected COVID 19 diagnosis. Some research participants may fall into the extremely vulnerable/shielding category, and special consideration will need to be made for the management of these patients within research projects. This may include the creation of specific pathways/protocols for management of these patients whilst attending RB&HFT for a research visit.

Patients may be seen in a variety of settings at Royal Brompton site, including, but not limited to, the out-patient departments and diagnostic facilities, and the Clinical Research Facility (CRF) in Fulham Road wing, the Squire Centre and pre-assessment clinics in Sydney Street wing, and the Cardiovascular Magnetic Resonance (CMR) scanners in 30 Britten Street and the Squire Centre. Research patients may be seen within the in-patient

ward areas, out-patient departments, ECG and imaging departments and pacing clinics at Harefield site.

Each clinical area within the hospitals will have specific processes in place to manage risk of exposure and infection from COVID 19 for both patients and staff, and research staff will be expected to comply with these. Any specific requirements for these areas are detailed within the relevant appendices to this document.

3. General Principles

Where feasible, onsite visits should be kept to a minimum with arrangements made for remote follow up of research participants. Any changes to the visit schedule should be discussed with, and agreed by, the Sponsor.

3.1 Patient Pre-Screening

Most patients participating in research studies will be attending RB&HFT as part of their routine clinical care, and therefore will be screened for any COVID 19 symptoms prior to arrival at the hospital by the clinical team responsible for scheduling their appointment. Patients who report symptoms will be told not to attend RB&HFT and be given appropriate advice.

If patients are required to attend RB&HFT purely for research procedures outside of their normal clinical care, then pre-screening will be performed by the research team. This pre-screening will comprise of the following steps: -

Completion of COVID 19 patient questionnaire (QN) via telephone (QN uploaded to EPR)

If patients report any COVID 19 symptoms, they will be told not to attend RB&HFT and given appropriate advice for further management of their symptoms (i.e. call NHS 111 or visit NHS 111 website). This should be documented in EPR, and any adverse events recorded and reported as per clinical trial protocol requirements.

The above steps may be modified to include a pre-admission COVID 19 test where the research patient is following a designated low risk pathway. In this scenario the patient should undergo a COVID 19 test within 72h of admission and self-isolate following their test.

3.2 Healthy Volunteers

Some research projects may include a healthy volunteer cohort. Healthy volunteers may be recruited from RB&HFT staff or recruited externally. At present any recruitment of Healthy volunteers should be minimised (where possible) to avoid any unnecessary additional footfall within Trust premises. Healthy volunteers should be assessed for COVID 19 symptoms using the COVID 19 patient questionnaire prior to attending the hospitals. If symptoms are reported by the volunteer, then they will not undergo any research procedures and will be given appropriate advice as detailed above.

3.3 Infection Control Measures for Staff

Research staff attending clinical areas within Royal Brompton and Harefield sites will adhere to current guidelines regarding staff temperature checks on entering clinical areas and wearing of personal protective equipment (PPE) as appropriate to the area they are visiting. Research staff will wear surgical face masks as a minimum within clinical areas, and apron, gloves and visor in addition if undertaking any contact procedure with a patient (e.g. ECG, blood sampling) who have been assessed as medium risk or where there is risk of splashing/spraying of body fluids. If research staff are involved in any aerosol generating

procedure (AGP), or working in a high risk area such as ICU, then appropriate PPE should be worn according to current Trust guidance. PPE guidance for staff is updated regularly and can be found on the Trust intranet (see section 5) together with a list of procedures that are classified as aerosol generating . Staff will adhere to relevant RB&HFT infection control and prevention policies.

Any equipment used on the patient during the visit should be cleaned after use as per Trust policies and manufacturers guidelines.

3.4 Risk Assessment of Research Procedures

The research team will review any research assessments that are due to be performed during the patient's visit to RB&HFT to ensure that they do not pose an increased risk of COVID 19 transmission. If any AGP is deemed essential to the outcome of the research, a separate risk assessment should be undertaken and approved by relevant staff. Where such procedures are likely to be used across multiple projects, a generic risk assessment may be undertaken. These risk assessments should be approved by the relevant clinical lead and the Infection Control and Prevention (IPC) team.

Procedures that form part of the protocol safety assessments will be prioritised, and those that are required for efficacy assessment contributing to the primary endpoint(s) will be reviewed to assess whether these increase the potential for increased risk of COVID 19 exposure or transmission. Factors that may be taken into account include whether assessments can be completed within one location, whether multiple staff may be required to perform the assessments, etc. If assessments are omitted as a result of this review, this should be documented as a protocol deviation within the relevant trial documentation and the trial sponsor informed of this together with the rationale for the decision.

Where possible assessments or procedures such as informed consent, questionnaire completion, CMR safety checklists, etc. should be performed via telephone prior to the patient's visit, subject to sponsor approval, to minimise the length of time patients need to be onsite.

3.5 Patient Travel to RB&HFT sites

Where patients are attending RB&HFT as part of their routine clinical care they will be provided with guidance on travelling to site for their appointment by the relevant clinical teams.

If patients are attending RB&HFT purely for research assessments, then the research team will provide travel advice to the patient. Some research trials include a travel allowance for patients and where this is available then ideally patients should travel to their appointment by taxi or by other form of private transport. Use of public transport should be avoided if possible. Patients will be instructed to arrive at their scheduled appointment time and will be met by a member of the research team who will escort them to the relevant area for their assessments.

4. Research involving COVID positive patients

The patient population at RB&HFT will include patients who have tested positive to COVID 19 and who may be recruited into research studies on the basis of this diagnosis. These patients will be managed according to current RB&HFT infection control guidelines. Generally, these trials are designed pragmatically to minimise the number of research procedures and risk of staff exposure to COVID 19. To minimise staff exposure and use of PPE supplies, procedures such as collection of blood or other samples for research

purposes, should be combined with collection of clinical samples and the clinical team providing direct care to the patient asked to collect these samples on behalf of the research team. Managers are responsible for undertaking individual staff risk assessments for staff who may be more vulnerable to COVID 19 infection.

5. References

Current Trust guidance documents for management of COVID 19 can be found at the following intranet site listed below. This includes guidance for the levels of PPE required for patient contact, COVID 19 symptom questionnaires, AGP list, equipment cleaning, and patient pathway documents.

https://www2.rbht.nhs.uk/services/infection-control/

Research Office guidance: -

https://www2.rbht.nhs.uk/services/research/covid-19/

NHS England Pan London Guidelines

Public Health England list of AGPs

https://www.gov.uk/government/publications/wuhan-novel-coronavirus-infection-prevention-and-control/covid-19-personal-protective-equipment-ppe#section-8point1

6. Appendix 1 Squire Centre

The Squire Centre is located in the basement of Sydney Street wing and houses a cardiac catheterisation laboratory, day-case facility, echocardiography, and dedicated MRI research scanner. The Squire Centre manages patients attending for day case interventional procedures who have been classified as low risk, in addition to research patients attending for CMR scans who are classified as medium risk. In order to minimise contact between low risk and medium risk patients, the following procedures should be followed for research patients attending the Squire Centre: -

a) Staff are required to enter the Squire Centre via the designated staff entrance to have their temperature checked. If their temperature is above 37.8c they will not be allowed to enter the unit.

b) Research participants will be given a scheduled time slot for arrival and asked not to arrive early. They will be instructed to contact the research team by phone on arrival at the hospital.

c) A member of the research team wearing appropriate PPE (surgical mask) will meet the participant at the Sydney Street hospital entrance. where they will check their temperature. If the temperature is above 37.8c, the participant will be asked to return home and contact NHS 111 or 111.nhs.uk for further advice. If the participant's temperature is <37.8c the research team will confirm whether the patient has any COVID 19 symptoms (re-confirm COVID symptom QN). If the participant answers yes to any of the questions, they will be asked to return home and contact NHS 111 or 111.nhs.uk for further advice. Patient temperature checks and QN completion should be documented on EPR.

d) If there are no issues with the COVID 19 QN, the participant will be provided with hand sanitiser and a face mask (if not already wearing a face covering) and escorted to the Squire Centre. The patient and staff member will enter the Squire Centre via the entrance to the patient hold area outside the CMR scanner door.

e) Staff will wear appropriate PPE (surgical mask, visor, apron, gloves) prior to any procedure requiring patient contact or where there is a risk of splashing/spraying of body fluids. The Trust hand hygiene policy will be adhered to, i.e. hand washing/use of hand sanitiser before putting on gloves.

f) The participant will be escorted to the patient changing room by research staff (wearing appropriate PPE). Once the participant has changed into a gown, they will be escorted to the scanner by research staff.

g) The participant should have completed the MRI safety checklist prior to their appointment – this will be verified by the CMR technologist, prior to commencing the scan.

h) Once the scan is complete, the participant will be escorted back to the changing room. The changing room will be cleaned after each patient visit by the research staff, to include any equipment, locker space, and frequently touched surfaces such as door handles. Sufficient time will be scheduled between patient visits to allow cleaning to be completed.

i) The scanner will be cleaned by the CMR technologist between each scan, and sufficient time will be scheduled between scans to allow cleaning to take place.

7. Appendix 2 Clinical Research Facility

The CRF is a comprehensive research facility located on the first floor of Royal Brompton Hospital, Fulham Road wing and accommodates a purpose built out-patients day-care unit. The majority of patients attending the CRF are designated as medium risk and therefore screening of patients follows that pathway. Pre-screening will be undertaken by a member of the research team 24hrs prior to a visit. A COVID 19 patient questionnaire (QN) will be completed via telephone and the completed QN uploaded to EPR. If patients report any COVID 19 symptoms, they will be told not to attend RB&HFT and given appropriate advice for further management of their symptoms (i.e. call NHS 111 or visit NHS 111 website). This should be documented in EPR, and any adverse events recorded and reported as per clinical trial protocol requirements.

The procedures to be followed for research patients attending the CRF are as follows: -

a) Research patients will be given a scheduled time slot for arrival and asked not to arrive early. They will be instructed to contact the research team by phone on arrival at the hospital.

b) A member of the research team wearing appropriate PPE (surgical mask), will meet the patient at the hospital entrance where they will be provided with a face mask, if they are not already wearing one, and asked to sanitise their hands, and then have their temperature checked. If the temperature is above 37.8c, the patient will be asked to return home and contact NHS 111 or 111.nhs.uk for further advice. If the patient's temperature is <37.8c the COVID 19 patient questionnaire may then be completed. If the patient answers yes to any of the questions, they will be asked to return home and contact NHS 111 or 11.nhs.uk for further advice. Patient temperature checks and QN completion should be documented on the Electronic Patient Record system (EPR).

c) If there are no issues with the temperature checks or COVID 19 questionnaire(s), the patient will be escorted to the CRF to register at reception.

d) The patient will be escorted to the CRF bed-spaces/Clinical rooms by research staff wearing appropriate PPE (surgical mask). Staff will wear appropriate PPE (surgical mask, visor, apron, gloves) prior to any procedure requiring patient contact. The Trust hand hygiene policy will be adhered to, i.e. hand washing/use of hand sanitiser before putting on gloves

e) Patients, attending the CRF must be considerate of other patients and maintain required social distancing at all times. Visitors will only be allowed to accompany patients to the CRF in exceptional circumstances, e.g. if they are a carer.

f) Lung function (LF) procedures such as spirometry, or other AGPs, may be performed within the CRF subject to appropriate risk assessment and approval by the CRF Director. Specific areas within the CRF will be identified for performance of AGPs. Any risk assessment must include the protocol for decontaminating the area at the end of the procedure.

g) Upon completion of the research visit a member of the research team wearing appropriate PPE (surgical mask), will escort the patient to the hospital exit.

h) Cleaning of the room/bed space, equipment and frequently touched areas such as door handles will be undertaken by research staff at the end of each patient visit to ensure infection control procedures are adhered to. AGP protocol cleaning will be

carried out as necessary. Sufficient time will be scheduled between subject visits to allow this cleaning to take place.