Clinical Research COVID-19 Pandemic – Guidance for Home Visits

Background

As of 23rd March the NIHR Clinical Research Network paused the site set up of any new or ongoing studies at NHS and social care sites that are not nationally prioritised COVID-19 studies. In addition, given the scale of the COVID-19 challenge, the NIHR encouraged clinical and academic health and care professionals funded by NIHR who are working on topics other than COVID-19 to prioritise frontline care where requested to do so by their employing organisations. This resulted in the temporary pause of the majority of NIHR funded/supported research studies.

Rationale for re-opening non-COVID-19 studies

The number of new cases of COVID-19 are declining and we have a significant portfolio of nationally prioritised urgent public health studies which are actively recruiting participants. The time is right to work towards the restoration of a diverse and active portfolio of research funded and/or supported by the NIHR - including both non-COVID-19 research and important COVID-19 research which does not meet our urgency criteria **(NIHR statement)**

To help initiate this process, the NIHR has developed a 'Framework for restart', which is a guidance document to support local decision-making. The Framework sets out guiding principles, preconditions, study prioritisation, and local and national roles in implementing this 'Restart Framework'. SHFT staff should be familiar with the framework and employ this in their decision making when considering restarting research projects. A simplified version of the 'Study Local Restart Assessment Checklist', found in the Restart Framework document, is included in Appendix 4 of this document (Home Visit version).

Scope and purpose

Visiting research participants at their home may present an increased risk to both research staff and participants. Whilst facilities designed specifically for clinical procedures minimise the risk of cross infection, for example through the use of wipe down furniture, by allowing sufficient space for activities to take place, or by having robust cleaning schedules in place, the same considerations can often not be applied to the home environment. Study sponsors and local delivery teams must therefore give additional consideration to the risk faced by staff and participants alike, and determine whether it is appropriate to resume home research visits.

The Restart Framework states *that when assessing study viability, the sponsor should take the opportunity to consider any potential key improvements that might assist restart and completion of the study*. Where home visits are included as part of a study, the sponsor should consider amendments to facilitate alternatives to home visits, for example telephone or video consultations, or changing visits to clinic visits.

If a sponsor determines that home visits are to remain in place, there must be a clear and explicit confirmation from the sponsor and PI that this is the case and that they are satisfied that they may resume.

This plan and guidance will be followed in accordance with Good Clinical Practice guidelines, NIHR guidance, and UK Government guidance regarding the COVID-19 pandemic. At all times, the protocol and the guidance issued by the sponsor related to the COVID-19 pandemic, will take precedence over internal site guidance provided the safety of the participant is protected.

Procedure

Before the Visit

- Participants will be called by a member of the research team to review the COVID-19 questionnaire (Appendix 1) by phone within two days of the scheduled home visit. Participants will be asked to contact the R&D office if they or a close contact have symptoms of COVID-19 at any point before their appointment.
- Research staff should ascertain from the participant that the home setting is suitable for conducting home assessments, with regards to access and location. If there are any queries this must be discussed with the study investigator. Researchers should avoid back-to-back visits to reduce the risk of transmitting infectious agents between home settings.
- Study participants are to be informed that, where possible, any co-inhabitants at the home must remain outside the room where the visit procedures will take place.
- Research staff should inform the study participant they will be arriving via private vehicle (or alternative) and not using public transport.
- Research staff will advise the participant that PPE will be required to be put on and taken off in a 'protected area' of the home. This may be outside the home if appropriate or, if a suitable area is identified by the participant, an area inside the home close to the home entrance.
- The SHFT recommended procedure is for non-sharps waste generated during the visit to be double-bagged and, with the patient's permission, left for 72 hours at the participant's home before they place it in their outside bin. Research staff will discuss this with the participant during the phone call. If this is not allowable to the participant, the waste bag must be returned to the clinic base. Staff should make preparations for this eventuality, e.g., have a suitably sized plastic container in their vehicle in which the waste bag can be stored during the return journey.
- Participants will be advised that the researcher will again review the COVID-19 questionnaire with the participant prior to commencing the visit.
- The research staff member will confirm with the study participant that they are happy to continue in the study in light of the ongoing COVID-19 situation.

Arrival Before Entry to Participants Home

- When the researcher arrives at their destination (home of the participant or appropriate place of parking), they will again review the COVID-19 questionnaire (Appendix 1) with the participant (whilst maintaining social distancing), and take the participant's temperature.
- If a participant is experiencing any symptoms highlighted in Q2 of the Covid-19 questionnaire (Appendix 1) they will be asked to reschedule their visit for a later date. This should be at least 10 days after the date of the first scheduled visit. Research staff will follow the procedures outlined in this guidance document before any future visit.
- If satisfied that the participant is not experiencing any potential COVID-19 symptoms the researcher will then don the required PPE in the appropriate, identified location and will continue with the visit. The required PPE consists of:
    - Single use plastic apron
    - A fluid repellent surgical face mask (IIR)
    - Eye protection (goggles/safety glasses/visor)
    - Single use gloves
    - See Appendix 2 for the correct procedure for putting on PPE.

Visit Procedures

- Home visits should be conducted by a single member of staff where safe to do so (please adhere to Southern Health NHS Foundation Trust lone working procedure SH NCP 24; Research and Development Lone Working Safe Practices NCP-R&D_012; Research and Development Safe Working Practices NCP-R&D_013).
- Research staff should ensure they only take the minimal equipment required for the visit with them into the home setting. Additional bags or clothing not required for the visit should not be taken onto the premises.
- Research staff should maintain physical distancing of 2 metres at all times (unless the member of staff is wearing appropriate PPE to provide clinical assessments) and advise other patients/visitors to comply.
- Research staff will limit direct physical contact with participants when conducting assessments to the extent possible.
- Research staff will limit their contact with objects that have come in direct physical contact with study participants (e.g., the participant and the researcher will use different pens to sign the consent form).
- Each piece of equipment used for assessment will be wiped down with Clinell wipes (leave in contact for 60 seconds) following contact with the participant to the extent possible by the person conducting the visit.
- If a researcher or participant coughs or sneezes they will be encouraged to do so into a tissue and then disinfect their hands after discarding the tissue (participants will be reminded of this prior to beginning the assessment).

Post Visit Procedures

- Following the completion of all required assessments the participant will be advised to wash their hands.
- Research staff will remove their PPE either in an appropriate location within the home, or immediately outside the home (see Appendix 3 – Removing Protective Clothing).
- The researcher will exit the home setting and proceed directly back to their car.
- Upon returning to the site the researcher should cleanse hands with sanitiser, don fresh gloves and apron, and remove from research box the equipment used for the study assessment.
- Each piece of equipment used for assessment will be wiped down with Clinell wipes (leave in contact for 60 seconds) following contact with the participant.
- The researcher should again perform adequate hand hygiene procedures.

Appendix 1: COVID-19 Questionnaire

1. *Have you or a close personal contact tested positive for COVID-19?*

   If yes, obtain more information about who tested positive, when the test was performed, etc.

2. *Do you have any of the following symptoms: fever (temp over 37.8 C or forehead very hot when touched with back of hand), cough, shortness of breath, extreme fatigue, body aches, loss of taste or smell, nausea, vomiting or diarrhoea?*

   If yes, obtain more information.

3. *Do any of your close contacts including members of your household have any of the following symptoms: fever (temp over 37.8 C), cough, shortness of breath, extreme fatigue, body aches, loss of taste or smell, nausea, vomiting or diarrhoea?*

   If yes, obtain more information.

4. *Do you think you may have been in contact with someone who has coronavirus?*

   If yes, but the individual does not have symptoms and has not been told to self-isolate, they should continue to follow social distancing advice.

5. *Have you recently returned from travelling abroad?*

   If yes, ascertain whether this was from a country that require travelers to self-isolate for 14-days upon reentry to the UK. Travel to some countries (known as the Covid-19 travel corridor) may not require self-isolation upon return

6. *Do you have any known allergies? Include example of latex.*

   If yes, obtain more information.

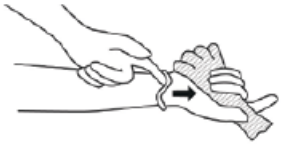
Appendix 2: Putting on PPE

***** Staff should first review the SHFT Infection Prevention and Control team guidance on Recommended PPE, available on the SHFT Intranet

Appendix 3: Removing PPE

Surgical masks are single session use, gloves and apron should be changed between patients.

1. Remove gloves, grasp the outside of the cuff of the glove and peel off, holding the glove in the gloved hand, insert the finger underneath and peel off second glove.



2. Perform hand hygiene using alcohol hand gel or rub, or soap and water.

3. Snap or unfasten apron ties the neck and allow to fall forward.

Snap waste ties and fold apron in on itself, not handling the outside as it is contaminated, and put into clinical waste.

4. Once outside the patient room. Remove eye protection.

5. Perform hand hygiene using alcohol hand gel or rub, or soap and water.

6. Remove surgical mask.

7. Now wash your hands with soap and water.

Appendix 4: Study Local Restart Assessment Checklist (Home visits)

Study title:	
Date of assessment:	
Completed by:	

Factor	Requirement	Assessment
Viability	Sponsor and study PI have assessed and agreed to restart (There must be a clear and explicit confirmation to resume home visits)	
	Regulatory approvals in place (have any submitted amendments been approved)	
	No impact on support for UPH COVID-19 studies	
	All necessary research funding is confirmed	
Safety	Risk of exposure to COVID-19 for patients and staff has been mitigated	
	Review of study participant group risk (are participants those considered 'clinically extremely vulnerable' who are 'shielded'?)	
	Physical access complies with government restrictions on social distancing	

	Assessment of COVID-19 testing and PPE requirements completed	
	Study arrangements comply with local organisation / site policies in respect of COVID-19	
	Site compliance with regulatory requirements has been confirmed by the organisation's R&D Director or equivalent	
	Strategy for notifying participants or staff who may have come in contact with a person with COVID-19 symptoms	
	Clear guidance on safety issues and precautions has been provided to participants and staff	
	Participants are asked and reassured about any concerns regarding COVID-19 - participants need to feel safe and confident	
Capacity and site readiness	Local clinical lead (Principal Investigator) confirmed and in place	
	Research staff in place	
	Health and care site / service 'open for business' to the full extent required for the study (eg, where required, have routine clinical care clinics resumed for relevant service)	
	Research management and support in place (at all required management institutions, e.g., site R&D office, support CROs, academic institutions)	

	All necessary supporting departments (e.g. pharmacy, pathology) have resource and capacity.	
	All necessary supplies have been procured and are in place (including IMPs and PPE)	
	Physical access arrangements for researcher have been assessed and are satisfactory	