Portsmouth Hospitals University NHS Trust

Standard Operating Procedure (SOP)

Managing External Visitors During a Pandemic

For Completion by SOP Author	
Reference Number	PHTRD/SOP/022
Version	V1.1
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For Completion by Research Dept., SOP Controller	
Name of Responsible Committee	RTM 04-06-2021
Issue Date	15/06/2021
Implementation Date	15/06/2021
Review date	08/06/2024
Electronic location	Research Office G Drive -Policies and SOPs

The definitive versions of all Portsmouth Hospitals University Trust SOPs, Templates and Forms for Research are online at https://www.porthosp.nhs.uk/research/

If you are reading this SOP in printed form then you are reading an uncontrolled document. You must therefore verify that the version number and date given below are the most recent, by cross-checking with the Trust research website before proceeding with implementation.

Portsmouth Hospitals University NHS Trust is committed to ensuring that, as far as is reasonably practicable, the way we provide services to the public and the way we treat our staff reflects their individual needs and does not discriminate against individuals or groups on any grounds. This SOP has been assessed accordingly

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1. INTRODUCTION

Portsmouth Hospitals University NHS Trust (PHU) is a research and innovation-based organisation, acting as both Host and Sponsor to high quality research activity.

All research activity at Portsmouth Hospital University NHS Trust (PHU) was suspended in March 2020 in response to COVID-19. The only exceptions were those studies which fell into priority/permitted categories (Urgent Public Health, essential treatment and follow-up studies). Studies which were actively recruiting and in follow-up had activity paused to reduce participant's unnecessary exposure to COVID-19. Studies which were in the "pipeline" to open at PHU were able to continue set-up procedures but were not permitted to open.

The purpose of this document is to help the research workforce plan and deliver efficient safe patient care while minimizing the risk of COVID-19 in the context of increasing or decreasing local prevalence.

2. PURPOSE

The SOP will outline the overarching process for:

Managing external visitors, patients and sponsor representatives alike during a pandemic to ensure visits take place as safely as possible

3. SCOPE

This SOP applies to all members of the research team from Clinical Trial Assistants (CTA), Clinical Research Associates (CRA), Nurses, Midwives, Allied Health Professionals (NMAHP's) and both the clinical and administrative team.

Planned care in the context of Research refers to all outpatient activity, interventional procedures, diagnostics and imaging and will apply to all hosted and sponsored studies.

The Trust recognises that some external sponsors, networks, funders and employers may require the use of their own SOPs for the good governance of research. In such cases it is the responsibility of the Portsmouth Hospitals University Trust user (including those individuals contracted to work on behalf of the Trust), to ensure that the external SOP is compatible with the procedure outlined below. If the external SOP contradicts the Trust's SOP then approval must be sought from a senior manager within the Research & Innovation Department at PHU.

In the event of an infection outbreak, flu pandemic or major incident, the Trust recognises that it may not be possible to adhere to all aspects of this document. In such circumstances, staff should take advice from their manager and all possible action must be taken to maintain ongoing patient and staff safety.

4. ABBREVIATIONS & DEFINITIONS

Abbreviation	Meaning
AGP	Aerosol Generating Procedure
COVID-19	Pandemic Virus
HRA	Health Regulatory Authority
MHRA	Medicine for Health Regulatory Authority
NHS	National Health Service

NIHR	National Institute for Health Research
PHU	Portsmouth Hospitals University NHS Trust
PI	Principle Investigator
PPE	Personal Protective Equipment
SOP	Standard Operating Procedure
SSD	Service Support Departments

Term	Definition
PHU Sponsored Studies	Studies which Portsmouth Hospitals University NHS Trust have ultimate responsibility for the initiation, management of and financing for. They take primary responsibility for ensuring that the design of the study meets appropriate standards and that arrangements are in place to ensure appropriate conduct and reporting.
Planned care	Planned care in the context of Research refers to all outpatient activity, interventional procedures, diagnostics and imaging and will apply to all hosted and sponsored studies.
Research Study Team	The people involved in the conduct of a research project. There may be different research teams for the project at different sites.

5. DUTIES AND RESPONSIBILITIES

Summarise the duties and responsibilities of key staff involved in conforming to the SOP

Role	Responsibilities
Investigator	▪ Ensure that the sponsor has agreed the study can restart and the clinical service has resumed
Research Study Team	▪ Ensure patient is given all the relevant COVID -19 related information to enable informed decision about proceeding care ▪ Consult with Infection Control/Engie to discuss requirements when using spaces for visits conducting aerosol generating procedures ▪ Contact patient/visitor 24 hours before they are due to attend the hospital to confirm health status ▪ Ensure surface areas and equipment used for research visit are cleaned with green Clinell universal wipes
PHU R&I Office	▪ Manage room bookings for onsite monitor visits ▪ Administer the research track and trace log

6. PROCESS

When offering planned research appointments in hospitals and diagnostic services, in the context of COVID-19, ensure reasonable adjustments are made to ensure information is accessible to all people (for example, those with a language barrier or learning disability).

Discuss the possible outcomes of the procedure or investigation with patients (and their families and carers as appropriate) before reaching a shared decision. This should include:

- The benefits of having the planned care, and the effects on their health and wellbeing of postponing or not having it.

- Ensuring that the patient understands the risks associated with COVID-19 during the planned care and has given informed consent.

- Alternative options if the planned research appointment is declined by the patient or postponed.

Explain that UK government infection prevention and control measures will be used to reduce the risk of getting COVID-19.

Research teams should think about flexible measures such as virtual appointments and telephone consultations, so that planned patient recruitment and follow-up can be delivered efficiently. Minimise participants time within the care setting through careful scheduling and encouraging patients not to arrive too early for their appointments.

6.1 Simple Patient Visits (non-interventional)

- Patients should be phoned 24 hours before scheduled appointment to reaffirm health status and run through the COVID-19 Risk Assessment. The assessment should be carried out by trained clinical staff.
- Explain to the participant their planned research appointment will be postponed if they have recently tested positive for COVID-19 (within last 14 days), have symptoms of COVID-19 or they are clinically not well enough to attend or they need to self-isolate after contact with someone with COVID-19
- Participants should attend alone if appropriate or with a career if needed to keep visitors to a minimum as per Trust policy (see reference in section 8)
- On arrival to the hospital participant is required to don Personal Protective Equipment (PPE) - face mask or face covering unless exempt (discuss with team prior to visit)
- Study team arrange to meet participant at designated waiting area and take straight to research appointment
- Encourage study participant to participate in hand hygiene on arrival to designated clinic room
- Once study visit is completed all equipment and surfaces must be cleaned with green Clinell universal wipes after use as per infection prevention guidelines (see reference in section 8). It is the responsibility of the study team to ensure this is carried out.
- All equipment to be stowed and area left clean for next participant visit

6.2 Complex patient visit requiring an Aerosol Generating Procedure (AGP)

- Prior to the patient visit engagement with the Infection prevent team is required to review clinic space & equipment in regards of facility appropriateness and necessary cleaning regime
- Procedures which are classified as aerosol generating procedures must see participants adhere to the relevant clinical service pathway (COVID swab testing and 7-14 days isolation) before procedure, please check with individual clinical departments as to requirements
- Explain to the participant that their planned research appointment will be postponed if they test positive for COVID-19, have symptoms of COVID-19 or they are clinically not well enough to attend or they need to self-isolate after contact with someone with COVID-19
- Patients should be phoned 24 hours before scheduled appointment to reaffirm health status and run through the COVID-19 Risk Assessment. The assessment should be carried out by trained clinical staff.
- Participants should attend alone if appropriate or with a career if needed to keep visitors to a minimum as per Trust Policy (see reference in section 8)
- On arrival to the hospital participants are required to wear appropriate PPE (face mask) or face covering unless currently exempt due to health conditions (please document after visit)
- Study team arrange to meet participant at designated waiting area

- Study visit should be completed as per the protocol. Equipment and surfaces must be cleaned with green Clinell universal wipes after use and relevant time given to support clean air circuits prior to reuse of the clinical space as per infection prevention guidelines. (Please note Air exchange circuits will be different in each clinical area. Contact Engie to discuss time required)

6.3 Site Initiation, Site Selection and Monitor Visits

It is important to acknowledge any changes to monitoring or administration of studies should not increase the burden on NHS sites during the current pandemic as per HRA guidance (Reference 6). Where possible site initiation, selection and monitoring visits by sponsors should be supported to be undertaken remotely with the following guidance;

- Remote monitoring and source data verification must not result in confidential patient information being sent to/stored by the sponsor if this has not already been addressed in the participant information sheet.
- Source data verification may be done remotely by electronic means if the necessary security arrangements can be put in place, for example by using video calls but sponsors must not retain screenshots.
- The Remote Monitoring SOP 21 should be followed

Sponsors who are unable to support remote visits must comply with the following guidance;

- Contact the research department and book a visit in advance
- Only attend if they have sourced and evidenced a negative lateral flow test the day of visit
- Comply with External Visitor guidance provided, complete and return External Visitor Risk Assessment before arrival
- Comply with all PPE requests throughout the monitoring visit in accordance with Trust policy (Face Mask, hand sanitization) including the correct wearing of and disposal of PPE
- Provide contact details to the research and innovation department to support the NHS Track & Trace Programme

As the host, PHU Research Department will ensure;

- The external visitor/monitor has received the External Visitor Guideline slides
- External visitors/Monitors are contacted before their expected visit date by the hosting research team to ensure they are COVID-19 clear with no signs or symptoms. If a positive result or symptoms are reported monitoring will be cancelled and rebooked.
- Ensure the External Visitor Risk Assessment is completed and returned by the external visitor/monitor before the visit
- Provide a COVID secure room for the monitor to be based for the duration of their stay
- Record visitor contact details to support the NHS Track & Trace Programme if required
- Provide access to handwashing facilities/sanitizer and relevant PPE
- Ensure the visited study team enables RN/CTA support to facilitate access to admin support if required (photocopying, confidential waste) in order to limit exposure to the wider teams
- Escort visitor to non-clinical areas such as Research Laboratory and Clinical Trials Pharmacy as required
- Ensure the completed External Visitor Covid 19 Risk Assessment and External Visitor Covid 19 Checklist forms are kept in the study site file.

7. TRAINING REQUIREMENTS

Staff following this SOP shall confirm they have read and understood the procedures outlined above by completing their relevant training log as a record of acknowledgement.

"The Research Dept., will endeavour to notify staff of SOP developments that may be relevant to them. SOPs are available on the Research department website. Updates on SOPs will feature in Research newsletters and communications and disseminate at local research meetings. It is the responsibility of all research active staff to ensure that they read the issued updates that may be relevant to them.

When a new SOP is authorised, or when an existing SOP is revised, self directed training must be carried out by all staff to which the SOP is relevant and this training documented in their training record. A template is provided to support this process. A study specific SOP training plan will be developed for investigators on high risk PHU Sponsored studies.

Staff should take time to read and fully understand the SOP and relevant documents, ensuring that they are able to implement the SOP when required. If clarification is needed then the trainee should approach their line manager and the SOP Controller who will arrange additional training. All staff should complete their training prior to the published implementation date which will normally be between 2-6 weeks after publication.

All staff are responsible for maintaining their own SOP Training Records and copies must be made available to line managers, the SOP Controller or study monitors on request."

8. REFERENCES AND ASSOCIATED DOCUMENTATION

Associated Documents

- COVID-19 Check list, https://www.porthosp.nhs.uk/research/sops-and-templates.htm
- PHU Standard Operating Procedure for Visiting - 3.8.2020
- Infection Prevent Policy http://pht/PoliciesGuidelines/InfectionControlPolicies/AllItems.aspx
- SOP for Remote monitoring https://www.porthosp.nhs.uk/research/sops-and-templates.htm

Reference

- COVID-19 rapid guideline: arranging planned care in hospitals and diagnostic services
- COVID-19: Guidance for the remobilisation of services within health and care settings. Infection prevention and control recommendations https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/910885/COVID-19_Infection_prevention_and_control_guidance_FINAL_PDF_20082020.pdf
- NICE guideline. Published: 27 July 2020 www.nice.org.uk/guidance/ng179
- https://www.gov.uk/government/publications/wuhan-novel-coronavirus-infection-prevention-and-control/new-government-recommendations-for-england-nhs-hospital-trusts-and-private-hospital-providers : accessed 6th August 2020
- NIHR Framework for restarting NIHR Research Activities which have been paused due to Covid-19, https://www.nihr.ac.uk/documents/restart-framework/24886
- Health Regulatory Authority guidance on restarting Monitor visits: accessed 7th August 2020 (11am) https://www.hra.nhs.uk/covid-19-research/covid-19-guidance-sponsors-sites-and-researchers/#monitoring

9. VERSION HISTORY LOG

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

Version	Date Implemented	Details of Significant Changes
1.0	08/06/2021	New document
1.1	15/06/2021	Removed section regarding restarting research activities and removed reference to access to electronic health records in section 6.3

10. APPENDICES

10.1 External Visitor Covid -19 Risk Assessment

Research Department External Visitor COVID-19 Risk Assessment

Please ensure this Risk Assessment is completed and returned 24 hours prior to visitor access to the Research Department.

Name	
Date of planned visit	

		Yes	No
1	Do you or any member of your household/family have a confirmed diagnosis of COVID-19? *If yes, please follow current government guidance for possible or confirmed Covid -19 infection*		
2	Are you or any member of your household/family waiting for a COVID-19 test result? *If yes, please follow current government guidance for possible or confirmed Covid -19 infection*		
3	Have you travelled internationally in the last 14 days? *If yes, please follow current government guidance on international travel according to red, amber and green list countries.*		
4	Have you had contact with someone with a confirmed diagnosis of COVID-19, or been in isolation with a suspected case in the last 14 days? *If yes, please follow current government guidance for possible or confirmed Covid -19 infection.*		
5	Do you have any of the following symptoms? • high temperature or fever • new, continuous cough • a loss or alteration to taste or smell *If yes, please follow current government guidance for possible or confirmed Covid -19 infection*		

If the answer to any of the above questions is YES please do not continue with your planned visit. Arrange to rebook your visit to the Research Department in line with current Government guidelines

6	If applicable: please confirm that you can complete a lateral flow test before visiting site and will report the result to your Research Nurse/Clinical Trials Assistant *If no, it may not be possible for your visit to go ahead*		

10.2 External Visitor Covid 19 Checklist

Research Department External Visitor COVID-19 Checklist

Please use this checklist to ensure all actions are completed for external visitor access to the Research Department.

Name of monitor/visitor	
Date & time of planned visit	
Study name	
Primary location for visit	
Name of PHU team responsible for monitor/visitor	

		Yes	No
Before the visit:			
1	Has the monitor/visitor received the 'Information for External Visitors' email with attachment 'External Visitor Guidance'?		
2	Has the monitor/visitor completed and returned to you the 'External Visitor Covid-19 Risk Assessment? *If no, please ensure this is received before the visit goes ahead.*		
3	Have you contacted the relevant PHU support departments (pharmacy/labs) to arrange the visit.		
4	Has an appropriate room been booked for the duration of the visit?		
Day of the visit:			
5	Has the monitor/visitor provided evidence of a negative lateral flow test? *If the visitor reports a positive result or has any Covid-19 symptoms, the visitor should not come to site and the visit should be postponed.*		
6	Has the visitor completed the sign in sheet for NHS Track and Trace purposes?		
7	Confirm that the monitor/visitor will contact you if they develop COVID-19 symptoms within 48 hours after their visit.		

Checklist completed by	
Date	

10.3 External Visitor Guidance

External Visitor Guidance V1.0 08-0(

Portsmouth Hospitals University NHS Trust

CONFIRMATION OF SOP TRAINING RECORD

A copy of this record may be kept in your personal training file to confirm your training in a specific SOP. If required by a study Sponsor a record may also need to be kept in the Trial Master Files (TMF) or Investigator Site Files (ISF)

SOP Details: To be completed by the SOP Controller	
Title of SOP	Managing External Visitors during Covid-19
Reference Number	PHT/RDSOP/022
Version	1.0
Issue Date	08/06/2021
Implementation Date	08/06/2021

Personnel Details	
Name	
Job Title & Research Role	
Date of Training	
Nature of Training	Self Directed/Delivered by etc
Records of any meetings to clarify details in SOP	

Signatures
I confirm that I have read and consider myself to be sufficiently trained in the above Standard Operating Procedure with regards to my individual roles and responsibilities Signature of Trainee …… Date ……
I confirm training in the above SOP was delivered as recorded above and that the trainee may be considered sufficiently trained in their roles and responsibilities Signature of Trainer …… Date ……..

Additional Notes & Signatures
Signature of Trainer (where appropriate) I confirm training in the above SOP was delivered as recorded above and that the trainee may be considered sufficiently trained in their roles and responsibilities Signature of Trainer …… Date ……..