Standard Operating Procedure

RESEARCH ACTIVITY INVOLVING PATIENTS WITH CONFIRMED OR SUSPECTED COVID-19

SETTING Trustwide

AUDIENCE All research delivery staff undertaking research activity involving patients with confirmed or suspected COVID-19

ISSUE Research delivery staff undertaking research activities involving patients with confirmed or suspected COVID-19 may be at risk of contracting and/or spreading the virus. This SOP seeks to ensure delivery staff follow the correct procedures to protect themselves and others.

QUERIES Research Matron via email: Research@uhbw.nhs.uk

Document History

SOP number	SOP 023	**SOP Version**	1.0
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Review date	Version number	Version date	Effective date	Author/ Reviewer	Authorised by
06/APR/2020	1.0	06/APR/2020	06/APR/2020	Nicola Manning	Tom Llewellyn

Version Number	Reason for change
1.0	Original

1. Introduction

In January 2020 the World Health Organization (WHO) declared the outbreak of a new coronavirus disease, COVID-19, to be a Public Health Emergency of International Concern.

In March 2020, WHO made the assessment that COVID-19 was to be characterised as a pandemic.

The UK Chief Medical Officer has asked all NHS trusts, health and care providers and universities to prioritise support for the Urgent Public Health COVID-19 studies that have been nationally prioritised. In response to this, University Hospitals Bristol & Weston NHS Foundation Trust (UHBW) has created a COVID-19 research team to deliver these studies safely and effectively.

This SOP describes the processes that research delivery teams will follow when entering clinical areas and interacting with patients where COVID-19 is confirmed or suspected.
The following scenarios are included:

- Consenting patients for urgent public health studies
- Medical notes review relating to participation in urgent public health studies
- Any other research procedure relating to urgent public health studies that is performed in restricted clinical areas

2. Purpose

The purpose of this SOP is to describe the process that research delivery teams will follow when entering clinical areas and interacting with patients where COVID-19 is confirmed or suspected.

3. Scope

In Scope: All research delivery staff working on research studies involving patients with confirmed or suspected COVID-19

Out scope: Research that does not involve patients with confirmed or suspected COVID-19. In these cases the most up to date infection control guidance for all patient contact must be followed.

4. Responsibilities

The Chief Investigator (CI), Principal Investigators (PIs) and Sponsor are responsible for ensuring the research protocol clearly documents the process for patient facing research activities and that staff receive training on these processes.

UHBW is responsible for ensuring the correct PPE and training in its use is available to research delivery staff.

Research delivery staff are responsible for attending training and following infection control procedures as per UHBW policies and procedures

5. Abbreviations and Definitions

Abbreviations	
CI	Chief Investigator
FFP3	Filtering Face Piece level 3
PI	Principal Investigator
PPE	Personal Protective Equipment
WHO	World Health Organisation

6. Procedure

6.1 Prior to attending the clinical area

- Research delivery staff to undertake PPE training and fit testing for FFP3 respirators
- Research delivery staff will identify potentially eligible study patients and their location using the COVID-19 tracker, daily positive swab result emails or via referral from medical/nursing staff
- Research delivery staff will contact the relevant clinical area to confirm patients location, condition and to advise the nursing staff that they plan to attend the ward to review the patient in relation to a research study
- Research delivery staff will confirm with the staff in the clinical area what current infection control restrictions are in place and the necessary procedures to follow e.g. the need to change into scrubs

6.2 Attending clinical area for notes review only

- On arrival to the clinical area research delivery staff will undertake correct infection control precautions (handwashing or alcohol gel)
- Where possible research delivery staff must remain in the clean area of the ward and arrange for medical notes to be available to them for review
- Research delivery staff will obtain the minimum information required from the medical notes minimising the amount of time required to spend in the clinical area
- If research delivery staff are unable to remain within the clean area, then infection control procedures relevant to that area must be followed including use of scrubs and PPE
- On leaving the clinical area research delivery staff will undertake correct infection control precautions (handwashing or alcohol gel)

6.3 Attending clinical area for activities that involve patient contact

- On arrival to the clinical area research delivery staff will undertake correct infection control precautions including handwashing and changing into scrubs if this is relevant to the area
- For areas classified as a high risk, research staff need to wear a gown, an FFP3 mask and eye protection at all times. Gloves and a plastic apron are also required which should be changed between each patient interaction.
- For areas not classified as high risk the use of PPE will be as per current infection control guidance
- On leaving the clinical area research delivery staff will undertake correct infection control precautions (changing out of scrubs, handwashing/alcohol gel)

6.4 Obtaining informed consent from patients with suspected or confirmed COVID-19

- Consent will be obtained in line with the research study protocol
- 2 team members will be required for consent procedures.
- One team member will enter the patient's room (in full PPE) with the patient information sheet and consent form and will receive informed consent.
- When the patient has signed the consent form, the team member inside the room will hold the signed consent form up to the window where the second team member (outside the room) will take a photograph of the consent form with a trust iPod/iPad
- This photograph will then be emailed to the research delivery staff who will print and file the copy of consent
- The original consent form and pen will remain with the patient.
- The trust IPod/IPad will be cleaned with Clinell universal wipes prior to leaving the clinical area

7. Dissemination and training in the SOP

This SOP will be disseminated to applicable research staff (including R&I) and will be available in the R&I website.

All staff whose activities are subject to this SOP should ensure that they read and understand the content of the SOP. The personal training log of the individual (and the Investigator Site File/Trial Master File if required) should be completed to document that the content of this SOP has been read and understood as described in *SOP 007 Research Training*.