Work Instruction

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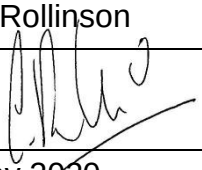
Title:	Research consent for potential COVID-19 study participants		
Approver		Document No:	WI
Name:	Chris Rollinson	Version No:	1.0
Signature:		Effective Date:	05 May 2020
Date:	5th May 2020	Review Date:	Dec 2020

1. Purpose

The purpose of this Work Instruction (WI) is to outline the process for the storage of consent forms for COVID-19 positive study participants in compliance with infection control policies, the approved protocols and Good Clinical Practice (GCP).

As required by protocol, all patients, proxies or legal guardians must provide signed written or verbal informed consent. In some COVID-19 clinical trials, informed consent may be verbal in the presence of another hospital employee and/or a patient representative, with the usual informed consent practice performed once contamination concerns are no longer an issue. This will be specified in the trial protocol.

For clinical trials whose protocols do not specify whether informed consent may be deferred, measures will need to be taken to reduce the risk of transmitting COVID-19 during this process, e.g. *via* the consent forms. This WI addresses these studies.

2. Scope

This WI applies to all core clinical staff and research team members delegated to assist with and/or perform the consenting process in any COVID-19 trials.

3. Responsibilities

All staff assisting in COVID-19 trials must ensure that they have read and understood the relevant protocols and reviewed the consent forms and other necessary documents.

The Principal Investigator has the overall responsibility for ensuring that the clinical staffs using the consent forms in their study have received the appropriate training to administer them safely and accurately.

4. Documents needed for this WI

- Public Health England (PHE) COVID_19 PPE Guidance, study protocol, risk assessment, Trust policies and research SOPs.

5. Related documents

- Trust Research SOPs:
    - T3 Consent procedures for entry into a Research study

6. Definitions

COVID-19: Coronavirus disease 2019 is an infectious disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). COVID-19 is highly infectious, spreading primarily through small droplets from the nose or mouth. COVID-19 has also been shown to survive for up to 72 hours on surfaces.

Informed Consent: A process by which a person voluntarily confirms their willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the person's decision to participate. Informed consent is usually documented by means of a written, signed and dated informed consent form.

7. Procedure

7.1 Pre-Consenting:

a. Ensure that the identified patient and/or relatives have agreed to participate.

b. Ensure that the patient meets the relevant inclusion criteria.

c. Ensure correct copies of the consent form/s and the correct patient information sheets are printed and present in the room, including a black pen.

d. Take the designated ziplock plastic wallet and plastic envelope wallet to the ward when going to consent a patient.

e. Leave the plastic envelope wallet by the inner entrance to the ward, so to minimise contact with infectious patients or surfaces. If a donning station is available, it is preferable to leave the wallet there.

f. Ensure that the ward has a scanner that is working.

7.2 During Consenting:

a. Staff must only approach the patient after donning the appropriate PPE, as per Public Health England guidelines (see **Section 8.0**). This includes a gown/apron, gloves and respirator mask.

b. Introduce self to the patient, confirm their identity and confirm that they are appropriate to give consent.

c. Ensure that Patient Information Sheet (PIS) was received by the patient and an appropriate amount of time has been given for the patient to read the PIS. Ask the patient if they have read and understood the information in the PIS. Ask them if they have any questions about the study and ensure that these are answered.

d. Add the version control number and date of the PIS used in the relevant spaces on the consent form.

e. Go through each statement on the consent form with the patient and explain as much as possible what each statement means. Ensure that the patient initials and completes the appropriate fields on the form and signs in the relevant sections in black pen.

7.3 Post-Consenting

a. Once the consent form has been completed, leave the pen at the patient's bedside. This must not be removed from the room from then onwards.

b. Remove PPE (top layer apron and gloves) as *per* PHE guidelines and wash hands.

c. Wearing a clean pair of non-sterile gloves, take the consent form outside of the patient's bed-space and scan the consent form to personal NHS email, to allow for uploading to electronic records.

d. Immediately store consent form in the ziplock plastic wallet.

e. Ensure that the wallet is sealed.

f. Using a **Yellow** Clinell wipe, clean the exterior of the wallet and put the wallet into the plastic envelope wallet which is handled by the clean nurse.

g. Remove gloves and wash hands as per local policy.

7.4 Storing Consent Forms

a. On returning to the facility, store the wallet with consent forms inside in the designated quarantine area.

b. Record the time of quarantine in the log.

c. This wallet will then remain in quarantine within this area for 72 hours, to minimise risk of transmitting COVID-19 to staff members.

d. Once 72 hours has passed, consent forms can be stored as per protocol.

8. References

8.1 World Health Organisation (WHO) 2020 COVID-19 Situation Report https://www.who.int/docs/default-source/coronaviruse/situation-reports/20200429-sitrep-100-covid-19.pdf?sfvrsn=bbfbf3d1_6

8.2 Public Health England (PHE) COVID_19 PPE Guidance https://www.gov.uk/government/publications/wuhan-novel-coronavirus-infection-prevention-and-control/covid-19-personal-protective-equipment-ppe

8.3 Public Health England (PHE) Donning and Doffing of PPE Guidance https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/879103/PHE_COVID-19_Donning_quick_guide_gown_version.pdf

9. Acknowledgement

We would like to acknowledge NIHR / Wellcome King's CRF for sharing their COVID-19 consenting process

10. Changes from last revision

Not applicable.