SOP for recruiting patients in RIDU, WGH

Version 1.5

This document should be read in conjunction with the latest version of the logistics guidance document.

1. Safety

All staff having contact with patients with confirmed COVID-19 to recruit or obtain samples for this study **must be trained and confident in use of the appropriate personal protective equipment (PPE)**.

In NHS Lothian, PPE guidance is provided in a document entitled *'Protocol for Assessing and Managing Cases of Suspected or Confirmed Cases of Severe Acute Respiratory Infections (e.g. MERS-CoV, Avian Influenza, SARS, or 2019-nCoV) in the Regional Infectious Diseases Unit (RIDU), WGH'* available on the intranet by searching *"SARI"* (to obtain the most up-to-date version).

Different units within NHS Lothian will have different ways of operationalising the PPE and staff must be familiar with these, but the equipment and donning/doffing technique will be the same.

Prior to entering the COVID cohort zone, discuss with the responsible nursing and medical staff.

2. Central document repository

We will create a shared drive on the NHS Lothian server where the most up-to-date versions of documents (PIS, consent, SOP, logistics etc.) will be available. In the meantime these will be circulated by email. In any instance of uncertainty, please email clark.russell@ed.ac.uk

3. Create study number for patient

Study number: **5-digit site code + 4-digit patient number**

Site codes:

WGH = S116H

RIE = S314H

This should be registered in REDCap on recruitment day.

4. Assemble required equipment

To stay in clean zone

- cardboard outer boxes labelled with sender (RIDU) and recipient (Combined labs reception, RIE) stickers
- partially completed sample transport form + barcode stickers for aliquots
- consent form for witness to sign, labelled with patient study number

To take into COVID cohort zone

For consenting:

- pen
- summary patient information sheet
- consent form, labelled with patient study number

For obtaining samples:

- blood tubes (EDTA[1], clotted, RNA)
- nasal SAM strip
- Oracol oral swab
- red-topped VTM + swab
- pots for urine & stool
- venepuncture equipment inc. adaptors

For packaging samples:

- 2x sealable bags
- 2 bio-bottles for research samples (1 for blood samples needing processed; 1 for other samples) - label with patient number and contents (require processing by lab yes/no) to avoid confusion when sealed

For clinical samples requested by medical team:

- any required clinical specimens
- separate sealable bag
- lab request paperwork
- separate bio-bottle

5. Label sample containers

See Figure 1.

RNA tube, throat swab, SAM strip, Oracol, stool/urine:

1. study number
2. "ISARIC RESEARCH" label
3. unique barcode label
4. biohazard sticker

EDTA and clotted blood:

1. study number
2. "ISARIC RESEARCH" label
3. patient date of birth
4. biohazard sticker

6. Complete sample transport form

- Complete fields for: study number, date, timepoint
- *Barcode stickers:*
  - stick in barcodes for samples that will be sent (inc. serum, plasma and cell pellet aliquots) - unique barcode for each specimen or aliquot
  - enclose paired barcode stickers for serum, plasma and cell pellet aliquots for lab to attach to aliquots after processing

[1] *recruitment* set requires **9mL** EDTA blood; *serial* set requires **3mL**.

7. Enter COVID cohort zone

- Carefully don PPE.
- Obtain informed or proxy consent (note that the consent boxes must be initialed by patient, not ticked) - leave the completed form in the patient room for an independent witness to look at.
- Obtain consent to post PIS to patient's home address.
- Obtain required biological samples:
  - see **this video** for correct use of SAM strip
  - note the Oracol swab should be swabbed for 1-2 minutes
- On day 1, leave a stool and urine pot, and inform patient these will be collected on day 3 visit.
- Package samples:
  - research blood tubes → one bag
  - other research samples → one bag
  - clinical samples → one bag
- Seal bags and place into bio-bottles.
- Remove outer pair of gloves and leave patient room - taking bio-bottles with you.
- When finished seeing patients, proceed to doffing room. Clean bio-bottles with chlor-prep.
- Carefully doff.
- Pick up clean bio-bottles and leave COVID cohort zone.

8. Sample packaging and transport

- Place bio-bottles into outer cardboard box with envelope containing transport form and barcode stickers for aliquots.
- Seal box with **'do not open'** sticker.
- Label boxes with large **LR924** sticker with either ***'need processed'/'don't need processed'*** (Note that research samples do not require a Priority 20 sticker - this is just for clinical samples from SARS-CoV-2 positive patients).
- The samples now need to be transported from RIDU to Combined Labs reception at RIE by taxi using the following details:

  Dial 44500

  Option 1

  Option 2

  Account: *WGH1*

  Authorised by: *David Hood*

  Cost code: *S02068*

- **Email Dr. Kate Templeton** (Kate.Templeton@nhslothian.scot.nhs.uk) notification that research samples are en route.

9. Consent, documentation and PIS

Witnessed consent

- Complete duplicate copy of consent form, filling in patient's name and adding your initials and "witnessed" to the boxes (e.g. "CR witnessed" etc). Leave the patient's signature space

blank but write their name.
- An individual independent of the study (e.g. nurse, doctor) should look at the completed consent form in patient's room at earliest opportunity, then complete the witness section of a duplicated form completed by the person who obtained consent.
- A copy of this consent document should be scanned and uploaded to Trak.

Documentation

- Recruitment of the patient to the study should be documented on **Trak**.
- Patient study number, samples obtained and date should be recorded in the **sample spreadsheet** (ISARIC4C S drive)

Patient information sheet

- A copy of the full PIS should be posted to the patient's home address.

For patients lacking capacity where *proxy consent* has been obtained

- Plan a review date to assess for regained capacity (see *Regained Capacity* PIS and consent form).
- Note that obtaining proxy consent by telephone is acceptable.

10. Serial biological sampling and clinical data collection

Ensure patient contact details are recorded to arrange appointment for convalescent samples 3 months after recruitment.

Biological samples

- **Day 1:** recruitment set
- **Day 3:** serial set
- **Day 9:** serial set
- **3-months:** convalescent set

Case report form

- **Day 1:** core form
- **Alternate subsequent days:** daily form
- **Death/discharge:** outcome form

11. Contact details for questions

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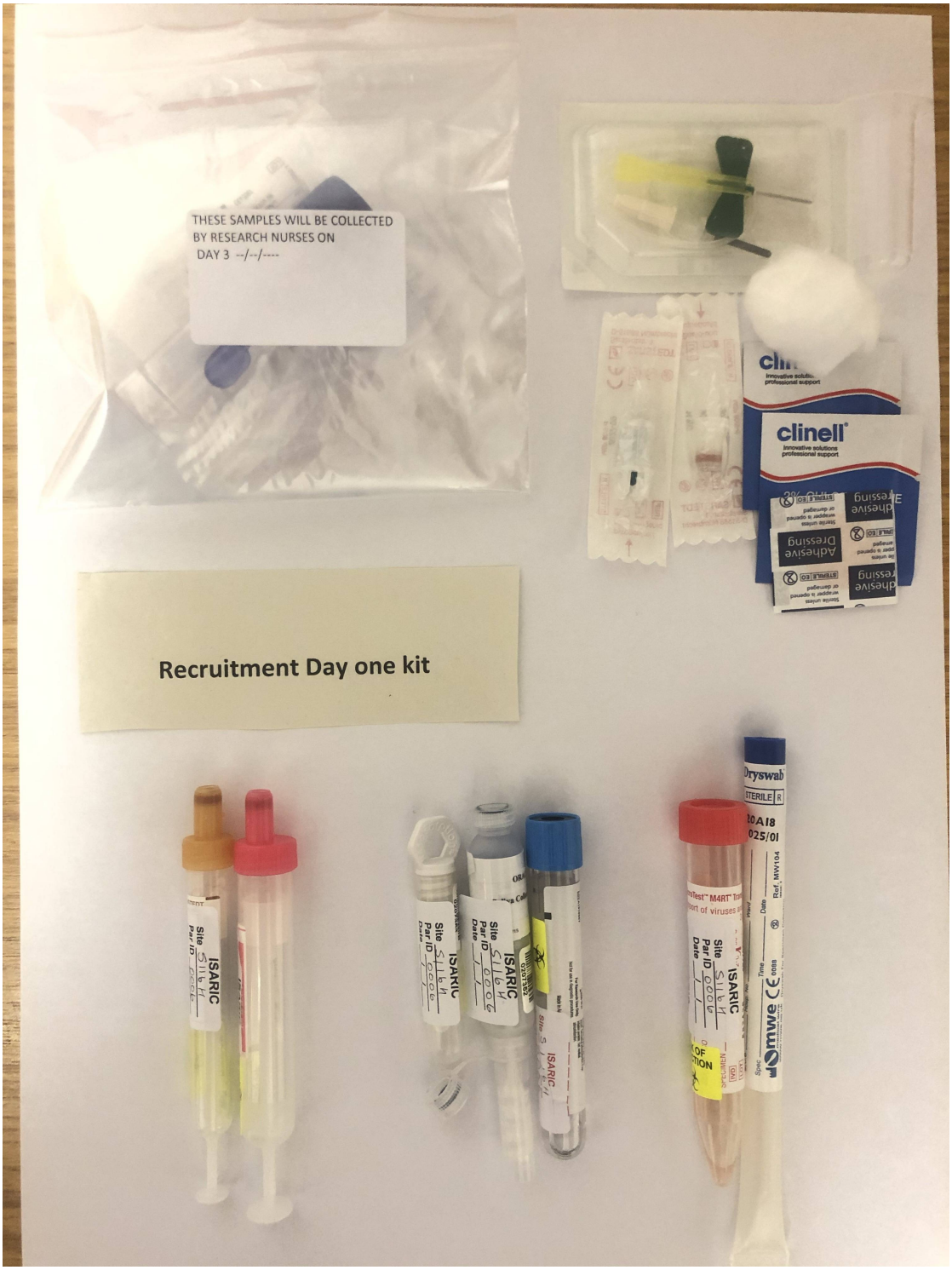

Figure 1: Sampling equipment