ISARIC/WHO Clinical Characterisation Protocol UK (CCP-UK)
CASE REPORT FORM GUIDANCE

v10.6 10/05/2022

DESIGN OF THE CCP-UK CASE REPORT FORM (CRF)

This CRF is divided into a "**ADMISSION**" form (4 pages), a "**DAILY**" form (1 pages) for daily clinical and laboratory and data, an "**OUTCOME**" form (4 pages) and a **"WITHDRAWAL"** form (1 page).

HOW TO USE THIS CRF

The CRF is designed to complement the **Tier** of activity that a site has capacity and capability to work to. This is likely to vary over the course of an outbreak. The decision on which **Tier** to use is up to the Local Principal Investigator and does not need discussion with the Chief Investigator. No delegation log is required by sponsor or protocol but may be by local R&D policy. The REDCAP data upload is considered this primary record and will be archived by the study team.

IMPORTANT CHANGES effective from 12th May 2022

Tier Zero sites	With consent, please enrol all cases of admissions (and those discharged) with confirmed or suspected **exposure of Public Health Interest as defined by a public health agency or the CCP-UK study team** • Please complete the **ADMISSION CRF** and **DAILY CRF** for the first day of hospital admission (day 1), and then the **DAILY CRF** again for each following day, then the **OUTCOME CRF** at day 28, discharge, or death (whichever occurs first) • Current activation criteria: **Elevated liver transaminases in child <16yrs, and not due to other diagnoses such as hepatitis viruses A-E, autoimmune hepatitis, trauma, or poisoning. Elevated transaminases defined as ALT >500 iU/L and/or AST >500 iU/L.** These criteria may be refined as knowledge is gained.
Tier 1 & 2 sites	With consent, enrol all cases as per T0, AND where there is site capacity, sample for Tier 1 or Tier 2 **according to the protocol schedule**

CASE REPORT FORMS

GENERAL GUIDANCE

- The CRF is designed to collect data obtained through examination, interview and review of hospital notes. Data may be collected retrospectively if the patient is enrolled after the admission date or deceased after admission.
- Participant Identification Numbers consist of a 5-digit CPMS / ODS site code and a 4 or 5-digit participant number. You should obtain a site code by contacting your local R&D office or CCP@liverpool.ac.uk
- Participant numbers should be assigned sequentially for each site beginning with 0001. In the case of a single site recruiting participants on different wards, or where it is otherwise difficult to assign sequential numbers, it is acceptable to assign numbers in blocks. E.g. Ward X will assign numbers from 0001 onwards and Ward Y will assign numbers from 5001 onwards. Enter the Participant Identification Number at the top of every page.
- **Please generate a new subject ID for each re-admission**
- CRF data should be entered to the central database at https://ncov.medsci.ox.ac.uk
- REDCap registration access is obtained by contacting mailto:lyndsey.castle@ndm.ox.ac.ukCCP.REDCap@liverpool.ac.uk
- Please contact us at CCP.REDCap@liverpool.ac.uk for help with database problems.

RULES DEFINING DAYS

1. Day of Admission = Day of Admission regardless, e.g. even if admitted 2 months ago for a broken leg.

CASE REPORT FORMS

FRONT PAGE 3 of 3

- Ideally complete every line of every section, except for where the instructions say to skip a section based on certain responses. This may not be possible in surge conditions.
- Selections with square boxes (☐) are single selection answers (choose one answer only). Selections with circles (**o**) are multiple selection answers (choose as many answers as are applicable).
- Some fields are considered **URGENT AND ESSENTIAL**. These are marked **BOLD AND UNDERLINED**
  IN ALL CIRCUMSTANCES PLEASE PRIORITISE THESE DATA POINTS FOR URGENT UPLOAD.
- Mark 'N/K' for any results of laboratory values that are not known or not available.
- Avoid recording data outside of the dedicated areas. Sections are available for recording additional information.
- We recommend writing clearly in black ink, using BLOCK-CAPITAL LETTERS.
- Place an (X) when you choose the corresponding answer. To make corrections, strike through (-------) the data you wish to delete and write the correct data above it. Please initial and date all corrections.
- In the case of a participant transferring between study sites, such as to a Nightingale Hospital, or other surge facility, it is preferred to maintain the same Participant Identification Number across the sites. When this is not possible a new Participant Identification Number should be assigned, the transferred participant will be linked by their identifiable data.
- Please keep all of the sheets for a single participant together e.g. with a staple or participant-unique folder.
- These four **FRONT PAGES** do not need to be retained.
- **NEVER SEND CRFs to anyone by unsecure email or post.**
- See the training guide on how to send consent to **CCP@liverpool.ac.uk** using [SECURE] encryption
- The Dalhousie University Clinical Frailty Score is provided below for your reference.

Clinical Frailty Scale*

1 **Very Fit** – People who are robust, active, energetic and motivated. These people commonly exercise regularly. They are among the fittest for their age.

2 **Well** – People who have **no active disease symptoms** but are less fit than category 1. Often, they exercise or are very **active occasionally**, e.g. seasonally.

3 **Managing Well** – People whose **medical problems are well controlled,** but are **not regularly active** beyond routine walking.

4 **Vulnerable** – While **not dependent** on others for daily help, often **symptoms limit activities.** A common complaint is being "slowed up", and/or being tired during the day.

5 **Mildly Frail** – These people often have **more evident slowing,** and need help in **high order IADLs** (finances, transportation, heavy housework, medications). Typically, mild frailty progressively impairs shopping and walking outside alone, meal preparation and housework.

6 **Moderately Frail** – People need help with **all outside activities** and with **keeping house**. Inside, they often have problems with stairs and need **help with bathing** and might need minimal assistance (cuing, standby) with dressing.

7 **Severely Frail** – **Completely dependent for personal care**, from whatever cause (physical or cognitive). Even so, they seem stable and not at high risk of dying (within ~ 6 months).

8 **Very Severely Frail** – Completely dependent, approaching the end of life. Typically, they could not recover even from a minor illness.

9. **Terminally Ill** - Approaching the end of life. This category applies to people with **a life expectancy <6 months**, who are **not otherwise evidently frail.**

Scoring frailty in people with dementia

The degree of frailty corresponds to the degree of dementia. Common **symptoms in mild dementia** include forgetting the details of a recent event, though still remembering the event itself, repeating the same question/story and social withdrawal.

In **moderate dementia**, recent memory is very impaired, even though they seemingly can remember their past life events well. They can do personal care with prompting.

In **severe dementia**, they cannot do personal care without help.

* 1. Canadian Study on Health & Aging, Revised 2008.
2. K. Rockwood et al. A global clinical measure of fitness and frailty in elderly people. CMAJ 2005;173:489-495.

DALHOUSIE UNIVERSITY *Inspiring Minds*

ISARIC WHO Clinical Characterisation Protocol for Severe Emerging Infections UK
ADMISSION FORM

Date of enrolment [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] **Site Location**_____

CLINICAL INCLUSION CRITERIA

Proven infection with pathogen of Public Health Interest: ☐ YES ☐ NO

OR

High suspicion of exposure to pathogen, noxious agent or harmful energy of Public Health Interest: ☐ YES ☐ NO

*N.B. This does **not** relate to covid-19 exposure. This does include children with hepatitis of unknown cause.*

DEMOGRAPHICS

Sex at Birth: ☐ Male ☐ Female ☐ Not specified **Date of birth** [_D_][_D_]/[_M_][_M_]/[_Y_][_Y_][_Y_][_Y_]

If date of birth is Not Known (N/K) record Age: [___][___][___]years **OR** [___][___]months

Postcode: [___][___][___][___] [___][___][___]

England & Wales NHS number , Scotland CHI: [___][___][___] [___][___][___] [___][___][___][___]
NB Northern Ireland Health & Care Number is not being collected at this time

Ethnic group *(check all that apply)*:

OArab OBlack OEast Asian OSouth Asian OWest Asian OLatin American OWhite OAboriginal/First Nations

OOther: _____ ☐**N/K**

Employed as a Healthcare Worker? ☐YES ☐NO ☐N/K

Pregnant? ☐ YES ☐ NO ☐ N/K If YES: Gestational weeks assessment: [___][___] weeks

POST PARTUM (within six weeks of delivery)? ☐YES ☐NO or ☐N/K *(skip this section - go to INFANT)*

Pregnancy Outcome: ☐Live birth ☐Still birth Delivery date: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]

Has infant(s) been tested for Mother's infection? ☐YES ☐NO ☐N/K If YES: ☐Positive ☐Negative

IF POSITIVE PLEASE COMPLETE A SEPARATE CASE REPORT FORM FOR THE INFANT(s)

INFANT – Less than 1 year old? ☐YES ☐NO *(skip this section)* Birth weight: [___].[___]kg ☐N/K

Gestational: ☐ Term birth (≥37wk GA) ☐Preterm birth (<37wk GA) if <37wk Estimated gestation _____weeks ☐N/K

Breastfed? ☐YES ☐NO ☐N/K If YES: ☐Currently breastfed ☐Breastfeeding discontinued ☐N/K

ONSET AND ADMISSION

Date of first/earliest symptom: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] **OR** ☐ **Asymptomatic**

Admission date at this facility: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]

Transfer from other facility? ☐YES-other facility is a study site ☐YES-other facility is not a study site ☐NO ☐N/K

If YES: Name of prior facility:_____ ☐N/K

If YES: Admission date at previous facility *(DD/MM/YYYY)*: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] ☐N/K

If YES-Study Site: Participant ID # at previous facility: I__I I__I I__I I__I I__I -- I__I I__I I__I I__I

OR ☐Same as above

VITAL SIGNS AT HOSPITAL ADMISSION *-first available data at presentation/Admission to the facility.*

(This section should refer to data from the date of admission to this facility)

Temperature: [_][_].[_]°C **HR:** [_][_][_]**beats per minute** **RR:** [_][_]**breaths per minute**

Systolic BP: [_] [_] [_]**mmHg** **Diastolic BP:** [_][_][_]**mmHg** **Severe dehydration:** ☐**YES** ☐**NO** ☐**N/K**

Sternal capillary refill time >2seconds ☐**YES** ☐**NO** ☐**N/K**

Oxygen saturation: [_][_][_]% **On:** ☐**Room air** ☐**Any Oxygen therapy** ☐**N/K**

SIGNS AND SYMPTOMS- *This section should refer to the start of this* episode None (asymptomatic) ☐

History of fever	☐YES ☐NO ☐N/K	Lower chest wall indrawing	☐YES ☐NO ☐N/K
Cough	☐YES ☐NO ☐N/K	Headache	☐YES ☐NO ☐N/K
with sputum production	☐YES ☐NO ☐N/K	Altered consciousness/confusion	☐YES ☐NO ☐N/K
bloody sputum/haemoptysis	☐YES ☐NO ☐N/K	Seizures	☐YES ☐NO ☐N/K
Sore throat	☐YES ☐NO ☐N/K	Abdominal pain	☐YES ☐NO ☐N/K
Runny nose (Rhinorrhoea)	☐YES ☐NO ☐N/K	Vomiting / Nausea	☐YES ☐NO ☐N/K
Ear pain	☐YES ☐NO ☐N/K	Diarrhoea	☐YES ☐NO ☐N/K
Wheezing	☐YES ☐NO ☐N/K	Conjunctivitis	☐YES ☐NO ☐N/K
Chest pain	☐YES ☐NO ☐N/K	Skin rash	☐YES ☐NO ☐N/K
Muscle aches (Myalgia)	☐YES ☐NO ☐N/K	Skin ulcers	☐YES ☐NO ☐N/K
Joint pain (Arthralgia)	☐YES ☐NO ☐N/K	Lymphadenopathy	☐YES ☐NO ☐N/K
Fatigue / Malaise	☐YES ☐NO ☐N/K	Bleeding (Haemorrhage)	☐YES ☐NO ☐N/K
Shortness of breath (Dyspnoea)	☐YES ☐NO ☐N/K	If Bleeding: specify site(s):	_____
Disturbance or loss of taste (Ageusia)	☐YES ☐NO ☐N/K	Disturbance or loss of smell (Anosmia)	☐YES ☐NO ☐N/K
Jaundice	☐YES ☐NO ☐N/K		

CO-MORBIDITIES *(existing prior to admission)*			**No comorbidities ☐**
Chronic cardiac disease, including congenital heart disease. *(not hypertension)*	**☐YES ☐NO ☐N/K**	**Obesity *(as defined by clinical staff)***	**☐YES ☐NO ☐N/K**
Hypertension *(physician diagnosed)*	**☐YES ☐NO ☐N/K**	**Diabetes and Type**	**☐YES ☐NO ☐1 ☐2 ☐N/K**
Chronic pulmonary disease *(not asthma)*	**☐YES ☐NO ☐N/K**	**Diabetes (any) with complications**	**☐YES ☐NO ☐N/K**
Asthma *(physician diagnosed)*	**☐YES ☐NO ☐N/K**	**Diabetes (any) without complications**	**☐YES ☐NO ☐N/K**
Chronic kidney disease	**☐YES ☐NO ☐N/K**	**Rheumatologic disorder**	**☐YES ☐NO ☐N/K**
Moderate / severe liver disease	**☐YES ☐NO ☐N/K**	**Dementia**	**☐YES ☐NO ☐N/K**
Mild liver disease	**☐YES ☐NO ☐N/K**	**Malnutrition**	**☐YES ☐NO ☐N/K**
Chronic neurological disorder	**☐YES ☐NO ☐N/K**	**Smoking ☐YES ☐Never smoked ☐Former smoker ☐N/K**	
Malignant neoplasm	**☐YES ☐NO ☐N/K**	**Other relevant risk factor**	
Chronic hematologic disease	**☐YES ☐NO ☐N/K**	**☐YES ☐NO ☐N/K**	
AIDS / HIV	**☐YES ☐NO ☐N/K**	**If yes, specify_____**	

Is the patient thought to be a member of a CLINICALLY EXTREMELY VULNERABLE GROUP **No☐ NK☐**

Solid organ transplant recipients: ☐YES ☐NO ☐N/K

People with specific cancers: ☐YES ☐NO ☐N/K

- people with cancer who are undergoing active chemotherapy
- people with lung cancer who are undergoing radical radiotherapy
- people with cancers of the blood or bone marrow such as leukaemia, lymphoma or myeloma who are at any stage of treatment
- people having immunotherapy or other continuing antibody treatments for cancer
- people having other targeted cancer treatments which can affect the immune system, such as protein kinase inhibitors or PARP inhibitors
- people who have had bone marrow or stem cell transplants in the last 6 months, or who are still taking immunosuppression drugs

People with severe respiratory conditions including all cystic fibrosis, severe asthma requiring daily oral steroid or injectable maintenance therapy and severe chronic obstructive pulmonary requiring oxygen (COPD): ☐YES ☐NO ☐N/K

People with rare diseases and inborn errors of metabolism that significantly increase the risk of infections (such as Severe combined immunodeficiency (SCID), homozygous sickle cell): ☐YES ☐NO ☐N/K

People on immunosuppression therapies sufficient to significantly increase risk of infection: ☐YES ☐NO ☐N/K

Women who are pregnant with significant heart disease, congenital or acquired: ☐YES ☐NO ☐N/K

CLINICAL FRAILTY SCORE for people age over 18 years **With reference to the Dalhousie University Clinical Frailty Score (see guidance page 3 of complete CRF)**	
Clinical Frailty Score	[___] value 1 to 9 or ☐N/K

CURRENT MEDICATION ON ADMISSION **Record medication the patient is currently taking or has taken within the past 14 days**
Medication name *(generic name preferred-please write in CAPITALS):*

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DAILY FORM

DAILY TREATMENT *(complete every line)*:

DATE OF ASSESSMENT *(DD/MM/YYYY):* [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]
Record the worst value between 00:00 to 24:00 on day of assessment *(if Not Available write 'N/K')*:

Is the patient in a high-level care area i.e. admitted to ICU/ITU/IMC/HDU ☐YES ☐NO ☐N/K

Highest Temperature: |_ |[__].[__] °C ☐N/K

Any Supplemental Oxygen ☐YES ☐NO ☐N/K **FiO_2 *(0.21-1.0)*** [___].[___][___] or [___][___] % or [___][___] L/min (highest)

Oxygen saturation ☐YES ☐NO ☐N/K **SpO_2** [___][___][___]% (lowest) RR: [___][___]breaths per minute (highest) ☐N/K

AVPU Alert[___] Verbal[___] Pain [___] Unresponsive[___] or ☐N/K Glasgow Coma Score (GCS / 15) [___][___] or ☐N/K

Is the patient currently receiving, or has received (from 00:00 to 24:00) on day of assessment:
Non-invasive respiratory support *(e.g. NIV, BIPAP, CPAP)*? ☐YES ☐NO ☐N/K **Invasive ventilation?** ☐YES ☐NO ☐N/K
High-flow nasal canula? ☐YES ☐NO ☐N/K **ECLS/ECMO?** ☐YES ☐NO ☐N/K

DAILY LABORATORY RESULTS

Record the values of laboratory results taken between 00:00 to 24:00 on day of assessment *(If multiple record the values for the blood draw taken closest to midday)*

Done ☐YES ☐NO ☐N/K **Haemoglobin** _____ ☐g/L *or* ☐g/dL

Done ☐YES ☐NO ☐N/K **WBC count** _____ ☐$x10^9$/L *or* ☐$x10^3$/µL

Done ☐YES ☐NO ☐N/K **Lymphocyte count** _____ ☐cells/µL *or* ☐$x10^9$/L *or* ☐$x10^3$/µL

Done ☐YES ☐NO ☐N/K **Neutrophil count** _____ ☐cells/µL *or* ☐$x10^9$/L *or* ☐$x10^3$/µL

Done ☐YES ☐NO ☐N/K **Platelets** _____ ☐$x10^9$/L *or* ☐$x10^3$/µL Done ☐YES ☐NO ☐N/K **APTT/APTR** _____

Done ☐YES ☐NO ☐N/K **PT** _____ seconds *or* Done ☐YES ☐NO ☐N/K **INR**_____

Done ☐YES ☐NO ☐N/K **ESR** _____ mm/hr Done ☐YES ☐NO ☐N/K **AST/SGOT** _____ iU/L

Done ☐YES ☐NO ☐N/K **Glucose** _____ ☐mmol/L *or* ☐mg/dL Done ☐YES ☐NO ☐N/K **ALT** _____ iU/L

Done ☐YES ☐NO ☐N/K **Blood Urea Nitrogen (urea)** _____ ☐mmol/L *or* ☐mg/dL

Done ☐YES ☐NO ☐N/K **Lactate** _____☐mmol/L *or* ☐mg/dL

Done ☐YES ☐NO ☐N/K **LDH** [___][___][___].[___]_U/L Done ☐YES ☐NO ☐N/K **Procalcitonin** [___][___].[___][___]ng/mL

Done ☐YES ☐NO ☐N/K **CRP** [___][___][___].[___] mg/L

Done ☐YES ☐NO ☐N/K eGFR _____ mL/min/1.73 m^2 **O**CKD-EPI **O**MDRD **O**CG

Most recent HbA1c _____ ☐ N/K **date of HbA1c** [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]

Chest X-Ray /CT performed? ☐YES ☐NO ☐N/K IF Yes: Were infiltrates present? ☐YES ☐NO ☐N/K

ISARIC CCP-UK RESEARCH SAMPLES

Was a biological sample taken for research on this day?	☐YES ☐NO
If yes, please record the KIT number:	**KIT NUMBER** [_C_] [_C_] [_P_] [__] [___][___][___][___]

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OUTCOME FORM

DIAGNOSTIC TESTING

Was diagnostic testing done during this illness episode? ☐YES* ☐NO ☐N/K **Should be YES as this is key eligibility criteria*

**Please record the detail of any COVID-19 / SARS2-CoV-2 test which may have been done in the community*

Section 1: Diagnosis Summary *(Virus PCR or antigen tests -NOT serology/antibody tests)*			
COVID-19 / SARS-CoV-2	☐ Tested POSITIVE	☐ Tested NEGATIVE	☐ NOT TESTED
Influenza virus *NB: Please do not enter Haemophilus influenza or parainfluenza virus here – enter them under "other" below*	☐ Tested POSITIVE, please confirm type: ☐ A/H3N2 ☐ A/H1N1pdm09 ☐ A/H7N9 ☐ A not typed ☐ Other A ________________ ☐ B not typed ☐ Other type (specify): _________________	☐ Tested NEGATIVE	☐ NOT TESTED
Respiratory syncytial virus	☐ Tested POSITIVE	☐ Tested NEGATIVE	☐ NOT TESTED
Adenovirus	☐ Tested POSITIVE	☐ Tested NEGATIVE	☐ NOT TESTED
Hepatitis viruses	☐ Tested POSITIVE, please confirm type: ☐ A ☐ B ☐ C ☐ D ☐ E ☐ Other type (specify): _________________	☐ Tested NEGATIVE	☐ NOT TESTED
Poisoning	☐ Tested POSITIVE, please confirm type: ☐ Paracetamol ☐ Other type (specify): _________________	☐ Tested NEGATIVE	☐ NOT TESTED
Other	☐ Tested POSITIVE Please specify : ____		

Section 2: Pathogen Testing Details

(Please record the details of all tests carried out during this illness episode -including the details of the tests indicated above).

Collection Date *(DD/MM/YYYY)*	Biospecimen Type	Result	Pathogen Tested/Detected
_D_ _D_ /_M_ _M_ /202 _Y_	O Nasal/NP swab O Throat swab O Combined nasal/NP + throat swab O Sputum O BAL O ETA O Urine O Stool/rectal swab O Blood O Other, *Specify:* ____________________	O Positive O Negative O Unknown	________________________
_D_ _D_ /_M_ _M_ /202 _Y_	O Nasal/NP swab O Throat swab O Combined nasal/NP + throat swab O Sputum O BAL O ETA O Urine O Stool/rectal swab O Blood O Other, *Specify:* ____________________	O Positive O Negative O Unknown	________________________
_D_ _D_ /_M_ _M_ /202 _Y_	O Nasal/NP swab O Throat swab O Combined nasal/NP + throat swab O Sputum O BAL O ETA O Urine O Stool/rectal swab O Blood O Other, *Specify:* ____________________	O Positive O Negative O Unknown	________________________
_D_ _D_ /_M_ _M_ /202 _Y_	O Nasal/NP swab O Throat swab O Combined nasal/NP + throat swab O Sputum O BAL O ETA O Urine O Stool/rectal swab O Blood O Other, *Specify:* ____________________	O Positive O Negative O Unknown	________________________

MEDICATION: While hospitalised or at discharge, were any of the following administered?

Antiviral agent? ☐YES ☐NO ☐N/K If YES, tick all that apply: OCidofovir

ORibavirin OOseltamivir (Tamiflu®) OZanamivir ORemdesivir OOther or novel antiviral _____

Antibiotic? ☐YES ☐NO ☐N/K If YES: specify type(s): _____ _____ _____

Corticosteroid? ☐YES ☐NO ☐N/K

Antifungal agent? ☐YES ☐NO ☐N/K If YES: which _____

Off-label / Compassionate Use medications? ☐YES ☐NO ☐N/K If YES: which _____

TREATMENT: At ANY time during hospitalisation, did the patient receive/undergo:

ICU or High Dependency Unit admission? ☐YES ☐NO ☐N/K If YES, total duration: _____days O still in ICU/HDU

If NO, ☐Not indicated ☐Not appropriate*

(*Advanced care plan/discussion documented in notes regarding not for escalation of care beyond ward)

Date of ICU/HDU admission: [_D_][_D_]/[_M_][_M_]/202[_Y_] ☐N/K

ICU/HDU discharge date: [_D_][_D_]/[_M_][_M_]/202[_Y_] ☐N/K

Any Oxygen therapy? ☐YES ☐NO ☐N/K High-flow nasal canula? ☐YES ☐NO ☐N/K

Non-invasive ventilation? *(e.g. BIPAP, CPAP)* ☐YES ☐NO ☐N/K

Invasive ventilation *(Any intubation)*? ☐YES ☐NO ☐N/K If YES, total duration: _____days O still on

Prone Ventilation? ☐YES ☐NO ☐N/K

Inhaled Nitric Oxide? ☐YES ☐NO ☐N/K

Tracheostomy inserted? ☐YES ☐NO ☐N/K

Extracorporeal (ECMO) support? ☐YES ☐NO ☐N/K If YES, total duration: _____days O still on

Renal replacement therapy (RRT) or dialysis? ☐YES ☐NO ☐N/K If YES, total duration: _____days O still on

Inotropes/vasopressors? ☐YES ☐NO ☐N/K If YES, total duration: _____days O still on

Liver Transplant ☐YES ☐NO ☐N/K If YES, date [_D_][_D_]/[_M_][_M_]/ 202[_Y_] ☐N/K

Kidney Transplant ☐YES ☐NO ☐N/K If YES, date [_D_][_D_]/[_M_][_M_]/ 202[_Y_] ☐N/K

COMPLICATIONS: At any time during hospitalisation did the patient experience:				**No complications ☐**
Viral pneumonia	☐YES ☐NO ☐N/K		Cardiac ischemia	☐YES ☐NO ☐N/K
Bacterial pneumonia	☐YES ☐NO ☐N/K		Cardiac arrest	☐YES ☐NO ☐N/K
Acute Respiratory Distress Syndrome	☐YES ☐NO ☐N/K		Bacteraemia	☐YES ☐NO ☐N/K
Cryptogenic organizing pneumonia (COP)	☐YES ☐NO ☐N/K		Coagulation disorder / Disseminated Intravascular Coagulation	☐YES ☐NO ☐N/K
Pneumothorax	☐YES ☐NO ☐N/K		Deep vein thrombosis	☐YES ☐NO ☐N/K
Pleural effusion	☐YES ☐NO ☐N/K		Pulmonary thromboembolism	☐YES ☐NO ☐N/K
Bronchiolitis	☐YES ☐NO ☐N/K		Anaemia	☐YES ☐NO ☐N/K
Meningitis / Encephalitis	☐YES ☐NO ☐N/K		Rhabdomyolysis / Myositis	☐YES ☐NO ☐N/K
Seizure	☐YES ☐NO ☐N/K		Acute renal injury/acute renal failure	☐YES ☐NO ☐N/K
Stroke / Cerebrovascular accident	☐YES ☐NO ☐N/K		Gastrointestinal haemorrhage	☐YES ☐NO ☐N/K
Other neurological complication	☐YES ☐NO ☐N/K		Pancreatitis	☐YES ☐NO ☐N/K
Congestive heart failure	☐YES ☐NO ☐N/K		Liver dysfunction	☐YES ☐NO ☐N/K
Endocarditis	☐YES ☐NO ☐N/K		Hyperglycaemia	☐YES ☐NO ☐N/K
Myocarditis/Pericarditis	☐YES ☐NO ☐N/K		Hypoglycaemia	☐YES ☐NO ☐N/K
Cardiomyopathy	☐YES ☐NO ☐N/K		Other, if yes specify below	☐YES ☐NO ☐N/K
Cardiac arrhythmia	☐YES ☐NO ☐N/K		Other:	

STUDY PARTICIPATION

Is / Has the participant being/ been recruited to a trial or multi-centre study during the period of their current illness (including initiation in the community and hospital)? ☐ YES ☐ NO

If YES , specify
Name of study_____
Study Participant ID _____

Add another study? ☐ YES ☐ NO
If YES , specify
Name of study_____
Study Participant ID _____

Add another study? ☐ YES ☐ NO
If YES , specify
Name of study_____
Study Participant ID _____

OUTCOME: (complete at discharge, transfer death or DAY 28, whichever occurs first)

Outcome: ☐ **Discharged alive expected to survive**

☐ **Hospitalisation = Remains in Hospital ≥ Day 28 after symptom onset**

- if Hospitalisation ☐ **Ongoing health care needs relating to this admission**

OR

☐ **Ongoing health care needs NOT related to this episode**

OR

☐ **Medically fit for discharge but remains in hospital for other reason (e.g. awaiting suitable care in community, resident in long term health care or mental health facility)**

☐ **Transfer to other facility** ☐ **Palliative discharge** ☐ **Death** ☐ **N/K**

Outcome date: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_2_][_Y_] ☐ **N/K**

If Discharged alive:

Ability to self-care at discharge versus before illness: ☐ Same as before illness ☐ Worse ☐ Better ☐ N/K

If Discharged alive: Post-discharge treatment:

Oxygen therapy? ☐ YES ☐ NO ☐ N/K

If Transferred: Facility name: _____ ☐ N/K

If Transferred: Is the transfer facility a study site? ☐ YES ☐ NO ☐ N/K

If a Study Site: Participant ID # at new facility: ☐ Same as above

☐ Different: [___][___][___][___][___]- [___][___][___][___] ☐N/K

PREGNANCY OUTCOME: If delivered during admission, please confirm:

POST PARTUM (within six weeks of delivery)? ☐YES ☐NO or ☐N/K

Pregnancy Outcome: ☐Live birth ☐Still birth Delivery date: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_2_][_Y_]

Has infant(s) been tested for Mother's infection? ☐YES ☐NO ☐N/K If YES: ☐Positive ☐Negative

IF POSITIVE PLEASE COMPLETE A SEPARATE CASE REPORT FORM FOR THE INFANT(s)

ISARIC WHO Clinical Characterisation Protocol for Severe Emerging Infections UK

WITHDRAWAL FORM

WITHDRAWAL
Date of withdrawal: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_2_][_Y_] ☐ N/K Type of withdrawal: ☐ Withdrawal from samples only ☐ Other Please specify: _____ Reason for withdrawal: _____

ISARIC WHO Clinical Characterisation Protocol for Severe Emerging Infections UK

Convalescent Sample

ISARIC CCP-UK RESEARCH SAMPLES	
Was a convalescent sample obtained?	☐**YES** ☐**NO**
If yes, please record the KIT number:	**KIT NUMBER** [_C_] [_C_] [_P_] [_ _] [_ _][_ _][_ _][_ _]
Date sample obtained:	[_D_][_D_]/[_M_][_M_]/[_2_][_0_][_2_][_Y_]