



ISARIC/WHO Clinical Characterisation Protocol UK (CCP-UK)

CASE REPORT FORM GUIDANCE

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V10.5 04/04/2022

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 4th April 2022

Tier Zero sites	<p>With consent, please enrol all cases of admissions (and those discharged) with confirmed or suspected <u>exposure of Public Health Interest as defined by a public health agency or the CCP-UK study team</u></p> <ul style="list-style-type: none"> 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, or poisoning. Elevated transaminases defined as ALT >400 iU/L and/or AST >400 iU/L. These criteria may be refined as knowledge is gained.
Tier 1 & 2 sites	<p>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</p>

PARTICIPANT ID | | | | | | | | | | | | | | | |

Example: R B S 2 5 -- 0 0 1 6 8

On each page above here write site code & participant number as per this example
(participant number can be 4 or 5 digits depending on number of recruits)

CASE REPORT FORMS

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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 CCP.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.

- 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.

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ISARIC WHO Clinical Characterisation Protocol for Severe Emerging Infections UK

ADMISSION FORM

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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):

☐ Arab ☐ Black ☐ East Asian ☐ South Asian ☐ West Asian ☐ Latin American ☐ White ☐ Aboriginal/First Nations

☐ Other: _____ ☐ 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: | | | | | | | | | | | | | | | | | | | | | | **OR** ☐ **Asymptomatic**
Admission date at this facility: | | | | | | | | | | | | | | | | | | | | | |

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): | | | | | | | | | | | | | | | | | | | | | | ☐ N/K

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

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: | | | | | | | | | | | | | | | | | | | | | | **HR:** | | | | | | | | | | | | | | | | | | | | | | **beats per minute** **RR:** | | | | | | | | | | | | | | | | | | | | | | **breaths per minute**
Systolic BP: | | | | | | | | | | | | | | | | | | | | | | **Diastolic BP:** | | | | | | | | | | | | | | | | | | | | | | **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) ☐

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

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

Is the patient thought to be a member of a CLINICALLY EXTREMELY VULNERABLE GROUP	No <input type="checkbox"/>	NK <input type="checkbox"/>
Solid organ transplant recipients: <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/K		
People with specific cancers: <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/K <ul style="list-style-type: none"> • 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 <u>severe</u> respiratory conditions including all cystic fibrosis, severe asthma requiring daily oral steroid or injectable maintenance therapy and severe chronic obstructive pulmonary requiring oxygen (COPD): <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> 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): <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/K		
People on immunosuppression therapies sufficient to significantly increase risk of infection: <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/K		
Women who are pregnant with significant heart disease, congenital or acquired: <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/K		

<u>CLINICAL FRAILITY SCORE</u> for people age over 18 years With reference to the Dalhousie University Clinical Frailty Score (see guidance page 3 of complete CRF)	
<u>Clinical Frailty Score</u>	[] value 1 to 9 or <input type="checkbox"/> N/K

[illegible]

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DAILY FORM

DAILY TREATMENT <i>(complete every line):</i>	
DATE OF ASSESSMENT (DD/MM/YYYY): [<u> D </u>][<u> D </u>]/[<u> M </u>][<u> M </u>]/[<u> 2 </u>][<u> 0 </u>][<u> Y </u>][<u> Y </u>] <u>Record the worst</u> value between 00:00 to 24:00 on day of assessment <i>(if Not Available write 'N/K'):</i>	
Is the patient in a high-level care area i.e. admitted to ICU/ITU/IMC/HDU <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/K	
Highest Temperature: [<u> </u>][<u> </u>].[<u> </u>] °C <input type="checkbox"/> N/K	
Any Supplemental Oxygen <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/K FiO_2 (0.21-1.0) [<u> </u>].[<u> </u>][<u> </u>] or [<u> </u>][<u> </u>] % or [<u> </u>][<u> </u>] L/min (highest)	
Oxygen saturation <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/K SpO_2 [<u> </u>][<u> </u>][<u> </u>] % (lowest) RR: [<u> </u>][<u> </u>] breaths per minute (highest) <input type="checkbox"/> N/K	
AVPU Alert[<u> </u>] Verbal[<u> </u>] Pain [<u> </u>] Unresponsive[<u> </u>] or <input type="checkbox"/> N/K Glasgow Coma Score (GCS / 15) [<u> </u>][<u> </u>] or <input type="checkbox"/> 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)? <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/K Invasive ventilation? <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/K	
High-flow nasal canula? <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/K ECLS/ECMO? <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/K	
DAILY LABORATORY RESULTS	
Record the values of laboratory results taken between 00:00 to 24:00 on day of assessment <i>(if multiple record the values for the blood draw taken closest to midday)</i>	
Done <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/K Haemoglobin _____ <input type="checkbox"/> g/L or <input type="checkbox"/> g/dL	
Done <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/K WBC count _____ <input type="checkbox"/> $\times 10^9/\text{L}$ or <input type="checkbox"/> $\times 10^3/\mu\text{L}$	
Done <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/K Lymphocyte count _____ <input type="checkbox"/> cells/ μL or <input type="checkbox"/> $\times 10^9/\text{L}$ or <input type="checkbox"/> $\times 10^3/\mu\text{L}$	
Done <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/K Neutrophil count _____ <input type="checkbox"/> cells/ μL or <input type="checkbox"/> $\times 10^9/\text{L}$ or <input type="checkbox"/> $\times 10^3/\mu\text{L}$	
Done <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/K Platelets _____ <input type="checkbox"/> $\times 10^9/\text{L}$ or <input type="checkbox"/> $\times 10^3/\mu\text{L}$ Done <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/K APTT/APTR _____	
Done <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/K PT _____ seconds or Done <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/K INR _____	
Done <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/K ESR _____ mm/hr Done <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/K AST/SGOT _____ iU/L	
Done <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/K Glucose _____ <input type="checkbox"/> mmol/L or <input type="checkbox"/> mg/dL Done <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/K ALT _____ iU/L	
Done <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/K Blood Urea Nitrogen (urea) _____ <input type="checkbox"/> mmol/L or <input type="checkbox"/> mg/dL	
Done <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/K Lactate _____ <input type="checkbox"/> mmol/L or <input type="checkbox"/> mg/dL	
Done <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/K LDH [<u> </u>][<u> </u>][<u> </u>].[<u> </u>] U/L Done <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/K Procalcitonin [<u> </u>][<u> </u>].[<u> </u>][<u> </u>] ng/mL	
Done <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/K CRP [<u> </u>][<u> </u>][<u> </u>].[<u> </u>] mg/L	
Done <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/K eGFR _____ mL/min/1.73 m ² <input type="radio"/> CKD-EPI <input type="radio"/> MDRD <input type="radio"/> CG	
Most recent HbA1c _____ <input type="checkbox"/> N/K date of HbA1c [<u> D </u>][<u> D </u>]/[<u> M </u>][<u> M </u>]/[<u> 2 </u>][<u> 0 </u>][<u> Y </u>][<u> Y </u>]	
Chest X-Ray /CT performed? <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/K IF Yes: Were infiltrates present? <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/K	

ISARIC CCP-UK RESEARCH SAMPLES	
<p><u>Was a biological sample taken for research on this day?</u></p>	<p><input type="checkbox"/> YES <input type="checkbox"/> NO</p>
<p><u>If yes, please record the KIT number:</u></p>	<p>KIT NUMBER [C] [C] [P] [] [] [] [] []</p>

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OUTCOME FORM

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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 (<i>Virus PCR or antigen tests -NOT serology/antibody tests</i>)			
<u>COVID-19 / SARS-CoV-2</u>	<input type="checkbox"/> Tested POSITIVE	<input type="checkbox"/> Tested NEGATIVE	<input type="checkbox"/> NOT TESTED
<u>Influenza virus</u> <i>NB: Please do not enter Haemophilus influenza or parainfluenza virus here – enter them under "other" below</i>	<input type="checkbox"/> Tested POSITIVE , please confirm type: <input type="checkbox"/> A/H3N2 <input type="checkbox"/> A/H1N1pdm09 <input type="checkbox"/> A/H7N9 <input type="checkbox"/> A not typed <input type="checkbox"/> Other A _____ <input type="checkbox"/> B not typed <input type="checkbox"/> Other type (specify): _____	<input type="checkbox"/> Tested NEGATIVE	<input type="checkbox"/> NOT TESTED
<u>Respiratory syncytial virus</u>	<input type="checkbox"/> Tested POSITIVE	<input type="checkbox"/> Tested NEGATIVE	<input type="checkbox"/> NOT TESTED
<u>Adenovirus</u>	<input type="checkbox"/> Tested POSITIVE	<input type="checkbox"/> Tested NEGATIVE	<input type="checkbox"/> NOT TESTED
<u>Hepatitis viruses</u>	<input type="checkbox"/> Tested POSITIVE , please confirm type: <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D <input type="checkbox"/> E <input type="checkbox"/> Other type (specify): _____	<input type="checkbox"/> Tested NEGATIVE	<input type="checkbox"/> NOT TESTED
<u>Poisoning</u>	<input type="checkbox"/> Tested POSITIVE , please confirm type: <input type="checkbox"/> Paracetamol <input type="checkbox"/> Other type (specify): _____	<input type="checkbox"/> Tested NEGATIVE	<input type="checkbox"/> NOT TESTED
<u>Other</u>	<input type="checkbox"/> 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
<div> <div> <div>D</div> <div>D</div> </div> <div>/</div> <div> <div>M</div> <div>M</div> </div> <div>/202_Y</div> </div>	<div> <div> <input type="radio"/> Nasal/NP swab <input type="radio"/> Throat swab </div> <div> <input type="radio"/> Combined nasal/NP + throat swab </div> <div> <div> <input type="radio"/> Sputum <input type="radio"/> BAL <input type="radio"/> ETA </div> <div> <input type="radio"/> Urine <input type="radio"/> Stool/rectal swab <input type="radio"/> Blood </div> </div> <div> <input type="radio"/> Other, Specify: _____ </div> </div>	<div> <input type="radio"/> Positive </div> <div> <input type="radio"/> Negative </div> <div> <input type="radio"/> Unknown </div>	<div> <div></div> </div>
<div> <div> <div>D</div> <div>D</div> </div> <div>/</div> <div> <div>M</div> <div>M</div> </div> <div>/202_Y</div> </div>	<div> <div> <input type="radio"/> Nasal/NP swab <input type="radio"/> Throat swab </div> <div> <input type="radio"/> Combined nasal/NP + throat swab </div> <div> <div> <input type="radio"/> Sputum <input type="radio"/> BAL <input type="radio"/> ETA </div> <div> <input type="radio"/> Urine <input type="radio"/> Stool/rectal swab <input type="radio"/> Blood </div> </div> <div> <input type="radio"/> Other, Specify: _____ </div> </div>	<div> <input type="radio"/> Positive </div> <div> <input type="radio"/> Negative </div> <div> <input type="radio"/> Unknown </div>	<div> <div></div> </div>
<div> <div> <div>D</div> <div>D</div> </div> <div>/</div> <div> <div>M</div> <div>M</div> </div> <div>/202_Y</div> </div>	<div> <div> <input type="radio"/> Nasal/NP swab <input type="radio"/> Throat swab </div> <div> <input type="radio"/> Combined nasal/NP + throat swab </div> <div> <div> <input type="radio"/> Sputum <input type="radio"/> BAL <input type="radio"/> ETA </div> <div> <input type="radio"/> Urine <input type="radio"/> Stool/rectal swab <input type="radio"/> Blood </div> </div> <div> <input type="radio"/> Other, Specify: _____ </div> </div>	<div> <input type="radio"/> Positive </div> <div> <input type="radio"/> Negative </div> <div> <input type="radio"/> Unknown </div>	<div> <div></div> </div>
<div> <div> <div>D</div> <div>D</div> </div> <div>/</div> <div> <div>M</div> <div>M</div> </div> <div>/202_Y</div> </div>	<div> <div> <input type="radio"/> Nasal/NP swab <input type="radio"/> Throat swab </div> <div> <input type="radio"/> Combined nasal/NP + throat swab </div> <div> <div> <input type="radio"/> Sputum <input type="radio"/> BAL <input type="radio"/> ETA </div> <div> <input type="radio"/> Urine <input type="radio"/> Stool/rectal swab <input type="radio"/> Blood </div> </div> <div> <input type="radio"/> Other, Specify: _____ </div> </div>	<div> <input type="radio"/> Positive </div> <div> <input type="radio"/> Negative </div> <div> <input type="radio"/> Unknown </div>	<div> <div></div> </div>

OUTCOME FORM

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

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

☐ Ribavirin ☐ Oseltamivir (Tamiflu®) ☐ Zanamivir ☐ Remdesivir ☐ Other 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 ☐ 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: [] [] [] / [] [] [] / 202[] [] ☐ N/K

ICU/HDU discharge date: [] [] [] / [] [] [] / 202[] [] ☐ 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 ☐ 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 ☐ still on

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

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

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

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

OUTCOME FORM

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

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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

Page 1 of 1

ISARIC CCP-UK RESEARCH SAMPLES	
<u>Was a convalescent sample obtained?</u>	<input type="checkbox"/> YES <input type="checkbox"/> NO
<u>If yes, please record the KIT number:</u>	KIT NUMBER [C][C][P][][][][][]
<u>Date sample obtained:</u>	[D][D]/[M][M]/[2][0][2][Y]