

**ISARIC WHO Clinical Characterisation Protocol for Severe Emerging Infections UK (CCP-UK)  
CASE REPORT FORM GUIDANCE FRONT PAGE 1 of 4**

**V10.1 06/05/2021**

**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.

Data can be collected as Tier Zero activity without consent including retrospectively and from deceased cases.

**IMPORTANT CHANGES 1st MAY 2021 UNTILL NEXT NOTICE:**

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| **Tier Zero sites** | Please enrol all cases for admissions who are proven positive (positive test) with COVID-19/ SARS-COV-2 and **any pathogen of Public Health Interest as notified by a public health agency (PHE, PHS, or HSA)**   * Please enrol all admission on and after 1st May until next notice. * Please complete the **ADMISSION CRF** and **DAILY CRF** for the first day of hospital admission (day 1), the **DAILY CRF** again for the first day of any ICU admission, then the **OUTCOME** **CRF** at day 28, discharge, or death (whichever occurs first) * For patients receiving **Remdesivir, Tocilizumab, or Sarilumab** **,** please complete an extra **DAILY CRF** for **first day** that such a drug is dosed and for day 14 after drug initiation (if patient remains admitted). **Collection of this data is requested by the CMOs in all nations.** |
| **Tier 1 & 2**  **sites** | Please enrol all cases as per T0, AND where there is site capacity for Tier 1 / Tier 2 sampling **please only consent and sample** **cases of interest: (See further definitions of criteria on page 4 of this CRF)**   * Suspected vaccine failure (COVID symptom onset >28 days after first vaccination dose) * All children (any under 19y of age) * Re-infection * Co-infection (Influenza A or B virus or respiratory syncytial virus- RSV) * Clinical suspicion of Multi System Inflammatory Syndrome- MIS A or MIS C/ PIMS-TS * Variants of concern (VOCs)- where known |

*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 FRONT PAGE 2 of 4**

**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](mailto:CCP@Liverpool.ac.uk?subject=[ISARIC%20WHO%20CCP%20(UK)%20Site%20Code%20Request])
* 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](https://ncov.medsci.ox.ac.uk/)
* REDCap registration access is obtained by contacting [CCP.REDCap@liverpool.ac.uk](mailto:CCP.REDCap@liverpool.ac.uk)
* Please contact us at [CCP.REDCap@liverpool.ac.uk](mailto:CCP.REDCap@liverpool.ac.uk) for help with database problems.

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| **RULES DEFINING DAYS**   1. Day of Admission = Day of Admission regardless, e.g. even if admitted 2 months ago for a broken hip. 2. For Community Acquired COVID-19 i.e. admitted with symptoms consistent with COVID-19, day 1 = first 24 hours of admission. 3. For those who are already admitted for any other reason and who subsequently test positive, day 1 = day the positive COVID-19 test **was collected**. 4. Rules 2 and 3 are important but we recognise that start of biological sampling for Tier 1 and 2 may be deferred or delayed for several reasons, e.g. due to a delay in the COVID-19 result being reported. If this happens, please take the d1 sample set as soon as possible and then d3 and d9 according to schedule, or as close as possible. 5. For Tier Zero date of enrolment is date on which the act of data collection started (no consent).  For Tier 1 & 2 date of enrolment is date of consent. |

**CASE REPORT FORMS FRONT PAGE 3 of 4**

* 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**](mailto:CCP@liv.ac.uk)using [SECURE] encryption
* The Dalhousie University Clinical Frailty Score is provided below for your reference.![A screenshot of a cell phone

  Description automatically generated]()

**CASE REPORT FORMS FRONT PAGE 4 of 4**

**GENERAL GUIDANCE**

**Definitions:**

**INFLAMMATION - Children and adolescents**

**WHO preliminary criteria Multisystem inflammatory syndrome in children and adolescents temporally related to COVID-19**

Children and adolescents 0–19 years of age with fever > 3 days

**AND** anytwoof the following:

1. Rash or bilateral non-purulent conjunctivitis or muco-cutaneous inflammation signs (oral, hands or feet).
2. Hypotension or shock.
3. Features of myocardial dysfunction, pericarditis, valvulitis, or coronary abnormalities (including ECHO findings or elevated Troponin/NT-proBNP),
4. Evidence of coagulopathy (by PT, PTT, elevated d-Dimers).
5. Acute gastrointestinal problems (diarrhoea, vomiting, or abdominal pain).

**AND**

Elevated markers of inflammation such as ESR, C-reactive protein, or procalcitonin.

**AND**

No other obvious microbial cause of inflammation, including bacterial sepsis, staphylococcal or streptococcal shock syndromes.

**AND**

Evidence of COVID-19 (RT-PCR, antigen test or serology positive), or likely contact with patients with COVID-19

**INFLAMMATION - Adults**

We deliberately do not give criteria to avoid selection bias. Adults with an inflammatory should to be identified at clinical discretion.

If you think a patient meets these criteria or wish to discuss**, please call 0300 365 4423**.

**RE-INFECTION**

To be considered a suspected Covid-19 re-infection the patient should meet one prior Covid-19 criterion and one timing criterion. If you think a patient meets these criteria or wish to discuss, **please call 0300 365 4423**.

*Prior Covid-19 criteria*

* A positive test for virus (PCR or antigen) or antibodies, in the community or in a hospital. Evidence of this can be from the patient’s own recollection, or from medical records.
* Patient-reported symptoms strongly suggestive of Covid-19, including cough, fever and altered taste/smell

*Timing criteria*

* If the patient was previously hospitalised with Covid-19, they must be more than 28 days from discharge from acute hospital (not including rehabilitation hospital).
* If the patient was not hospitalised but had symptoms of Covid-19, they must be more than 28 days from last symptoms.
* If the patient did not have symptoms, they must be more than 28 days from their last positive Covid-19 test.

**VACCINE FAILURE**

* Admission with Covid-19 more than 28 days after vaccination. Please call **0300 365 4423**.

**ISARIC WHO Clinical Characterisation Protocol for Severe Emerging Infections UK**

**ADMISSION FORM page 1 of 4**

**Date of enrolment**[\_D\_][\_D\_]/[\_M\_][\_M\_]/[\_2\_][\_0\_][\_Y\_][\_Y\_] **Site Location**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| **CLINICAL INCLUSION CRITERIA** |
| **Proven infection with pathogen of Public Health Interest**: ☐ YES ☐ NO *N.B. For acute covid-19, please only collect data from proven (laboratory test-positive) people.*  **OR**  **Adult or child who meets Case Definition for Multisystem Inflammatory Syndrome (MIS-C/MIS-A) :** ☐ YES ☐ NO  *N.B. This group should be recruited regardless of covid-19 test as this syndrome can occur after mild disease in the community which has gone untested.* |

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| **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 |
| **VACCINATION STATUS**  **Has the patient received a Covid-19 vaccine (open label licenced product) ☐YES ☐NO ☐N/K**  **date first vaccine given if known: [\_D\_][\_D\_]/[\_M\_][\_M\_]/[\_2\_][\_0\_][\_Y\_][\_Y\_], given but date not known ☐N/K**  **date second vaccine given if known: [\_D\_][\_D\_]/[\_M\_][\_M\_]/[\_2\_][\_0\_][\_Y\_][\_Y\_], given but date not known ☐**  **Vaccine type/ Manufacturer: ☐ Pfizer- BioNTECH ☐ Oxford-AstraZeneca ☐ Moderna ☐ Other** \_\_\_\_\_\_\_\_ **☐N/K**  **has the patient been involved in a vaccine COVID trial? ☐YES ☐NO ☐N/K**  **date if known (first trial vaccination): [\_D\_][\_D\_]/[\_M\_][\_M\_]/[\_2\_][\_0\_][\_Y\_][\_Y\_] (*please complete study participation CRF page 3 of outcome CRF)***  **Has patient received a 2020/21 seasonal influenza vaccine ☐YES ☐NO ☐N/K date if known: [\_D\_][\_D\_]/[\_M\_][\_M\_]/[\_2\_][\_0\_][\_Y\_][\_Y\_] ☐N/K** |

**ADMISSION FORM Page 2 of 4**

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| **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\_]**  Is the patient being readmitted with Covid-19? *(Please only add re-admission episodes for COVID patients remaining positive or new positive COVID test- Please assign new subject ID)* ☐YES ☐NO ☐N/K  Previous participant ID: I\_\_I I\_\_I I\_\_I I\_*\_*I I\_\_I -- I\_\_I I\_\_I I\_\_I I\_\_I ☐ NK  Please provide reason for readmission: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ☐N/K  Is this a suspected re-infection with COVID-19? Defined as proven (PCR or antibody test) or highly probable (clinical case definition met) more than 28 days prior to this new laboratory proven covid-19 infection ☐YES ☐NO ☐N/K  If yes, please complete REINFECTION FORM and seek consent for biological sampling, ideally at Tier 2)  Is this a NIGHTINGALE or other SURGE FACILITY ☐YES ☐NO ☐N/K  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 |

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| **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** |

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| **SIGNS AND SYMPTOMS- *This section should refer to the start of the COVID* episode None (asymptomatic) ☐** | | | |
| **History of fever**  **Cough**  **with sputum production**  **bloody sputum/haemoptysis**  **Sore throat**  **Runny nose (Rhinorrhoea)**  **Ear pain**  **Wheezing**  **Chest pain**  **Muscle aches (Myalgia)**  **Joint pain (Arthralgia)**  **Fatigue / Malaise**  **Shortness of breath (Dyspnoea)**  **Disturbance or loss of taste (Ageusia )** | **YES NO N/K**  **YES NO N/K**  **YES NO N/K**  **YES NO N/K**  **YES NO N/K**  **YES NO N/K**  **YES NO N/K**  **YES NO N/K**  **YES NO N/K**  **YES NO N/K**  **YES NO N/K**  **YES NO N/K**  **YES NO N/K**  **YES NO N/K** | **Lower chest wall indrawing**  **Headache**  **Altered consciousness/confusion**  **Seizures**  **Abdominal pain**  **Vomiting / Nausea**  **Diarrhoea**  **Conjunctivitis**  **Skin rash**  **Skin ulcers**  **Lymphadenopathy**  **Bleeding (Haemorrhage)**  **If Bleeding: specify site(s):**  **Disturbance or loss of smell (Anosmia)** | **YES NO N/K**  **YES NO N/K**  **YES NO N/K**    **YES NO N/K**  **YES NO N/K**  **YES NO N/K**  **YES NO N/K**  **YES NO N/K**  **YES NO N/K**  **YES NO N/K**  **YES NO N/K**  **YES NO N/K**  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **YES NO N/K** |

**ADMISSION FORM Page 3 of 4**

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| **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**  **☐YES ☐NO ☐N/K**  **If yes, specify\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | |
| **Chronic hematologic disease** | **☐YES ☐NO ☐N/K** |
| **AIDS / HIV** | **☐YES ☐NO ☐N/K** |

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| **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 |

**ADMISSION FORM Page 4 of 4**

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| **PRE-ADMISSION MEDICATION Were any of the following taken within 14 days of admission?** | | |
| Immunosuppressant e.g. oral (not inhaled) corticosteroids (not low dose hydrocortisone) ☐YES ☐NO ☐N/K | Angiotensin converting enzyme inhibitors (ACEI)? | ☐YES ☐NO ☐N/K |
| Anti-infectives for this illness episode prior to admission?  ☐YES ☐NO ☐N/K If yes, specify:\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Angiotensin II receptor blockers (ARBs)? | ☐YES ☐NO ☐N/K |
| Non-steroidal anti-inflammatory (NSAID)? | ☐YES ☐NO ☐N/K |

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| **CLINICAL FRAILTY SCORE  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 |

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| **CURRENT MEDICATION ON ADMISSION**  **Record medication the patient is currently taking or has taken within the past 14 days** |
| Medication name *(generic name preferred):* |
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**ISARIC WHO Clinical Characterisation Protocol for Severe Emerging Infections UK**

**REINFECTION FORM PAGE 1 OF 1**

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| **SUSPECTED RE-INFECTION WITH COVID-19: DETAILS OF PREVIOUS INFECTION** |  |
| Was the patient previously enrolled? ☐YES ☐NO ☐N/K, If No/ NK please confirm:  Did the patient have a positive PCR (virus) test for SARS-CoV-2?    If yes, enter date of positive test: [\_D\_][\_D\_]/[\_M\_][\_M\_]/[\_2\_][\_0\_][\_Y\_][\_Y\_]  Did the patient have a positive antigen (virus) test for SARS-CoV-2?  If yes, enter date of positive test: [\_D\_][\_D\_]/[\_M\_][\_M\_]/[\_2\_][\_0\_][\_Y\_][\_Y\_]  Did the patient have a positive serology (antibody) test for SARS-CoV-2?  If yes, enter date of positive test: [\_D\_][\_D\_]/[\_M\_][\_M\_]/[\_2\_][\_0\_][\_Y\_][\_Y\_]  Symptom onset date of first/earliest symptom for previous infection: [\_D\_][\_D\_]/[\_M\_][\_M\_]/[\_2\_][\_0\_][\_Y\_][\_Y\_]  OR ☐ Asymptomatic | ☐YES ☐NO ☐N/K  ☐YES ☐NO ☐N/K  ☐YES ☐NO ☐N/K |

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| **SIGNS AND SYMPTOMS for PREVIOUS COVID-19 episode None (Asymptomatic) ☐** | | | |
| History of fever  Cough  with sputum production  bloody sputum/haemoptysis  Sore throat  Runny nose (Rhinorrhoea)  Ear pain  Wheezing  Chest pain  Muscle aches (Myalgia)  Joint pain (Arthralgia)  Fatigue / Malaise  Shortness of breath (Dyspnoea)  Disturbance or loss of taste (Ageusia ) | YES NO N/K  YES NO N/K  YES NO N/K  YES NO N/K  YES NO N/K  YES NO N/K  YES NO N/K  YES NO N/K  YES NO N/K  YES NO N/K  YES NO N/K  YES NO N/K  YES NO N/K  YES NO N/K | Lower chest wall indrawing  Headache  Altered consciousness/confusion  Seizures  Abdominal pain  Vomiting / Nausea  Diarrhoea  Conjunctivitis  Skin rash  Skin ulcers  Lymphadenopathy  Bleeding (Haemorrhage)  If Bleeding: specify site(s):  Disturbance or loss of smell (Anosmia)  None | YES NO N/K  YES NO N/K  YES NO N/K  YES NO N/K  YES NO N/K  YES NO N/K  YES NO N/K  YES NO N/K  YES NO N/K  YES NO N/K  YES NO N/K  YES NO N/K  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  YES NO N/K  YES NO N/K |
| **TREATMENT: During the previous episode, was the patient: None ☐** | | | |
| Admitted to hospital:  Treated with oxygen:  Admitted to HDU/ICU:  Receive invasive ventilation:  Receive extracorporeal membrane oxygenation (ECMO) | YES NO N/K  YES NO N/K  YES NO N/K  YES NO N/K  YES NO N/K | Treated with:  Dexamethasone  Any other steroid  Tocilizumab  Remdesivir  Convalescent plasma  Lopinavir/Ritonavir  Interferon  Chloroquine/Hydroxychloroquine | YES NO N/K  YES NO N/K  YES NO N/K  YES NO N/K  YES NO N/K  YES NO N/K  YES NO N/K  YES NO N/K |

**ISARIC WHO Clinical Characterisation Protocol for Severe Emerging Infections UK   
DAILY FORM complete per Tier of activity AND if research samples are collected Page 1 of 1**

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| **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 FiO2 *(0.21-1.0)* [\_\_\_].[\_\_\_][\_\_\_] or [\_\_\_][\_\_\_] %or[\_\_\_][\_\_\_] L/min (highest)**  **Oxygen saturation ☐YES ☐NO ☐N/K SpO2 [\_\_\_][\_\_\_][\_\_\_]% (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 \_\_\_\_\_\_\_\_\_\_\_ ☐x109/L *or* ☐x103/µL**  **Done ☐YES ☐NO ☐N/K Lymphocyte count \_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_ ☐cells/ μL  *or* ☐x109/L *or* ☐x103/µL**  **Done ☐YES ☐NO ☐N/K Neutrophil count \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_ ☐ cells/ μL  *or* ☐x109/L *or* ☐x103/µL**  **Done ☐YES ☐NO ☐N/K Platelets \_\_\_\_\_\_\_\_\_\_\_ ☐x109/L *or* ☐x103/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 \_\_\_\_\_\_\_\_\_ U/L**  **Done ☐YES ☐NO ☐N/K Glucose \_\_\_\_\_\_\_\_\_ ☐mmol/L *or* ☐mg/dL**  **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 m2 **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 |

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| **ISARIC CCP-UK RESEARCH SAMPLES** | |
| **Was a biological sample taken for research on this day?**  **If yes, please record the KIT number:** | **☐YES ☐NO**  **KIT NUMBER** [\_C\_] [\_C\_] [\_P\_] [\_ \_] [\_ \_][\_ \_][\_ \_][\_ \_] |

**ISARIC WHO Clinical Characterisation Protocol for Severe Emerging Infections UK**

**OUTCOME FORM Page 1 of 4**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| **PATHOGEN TESTING**  **Was pathogen testing done during this illness episode? ☐YES ☐NO ☐N/K (\*NB Should be a YES as this is key eligibility criteria)**  **\*please record the detail of any COVID-19 / SARS2-CoV-2 which may have been done in the community**   |  |  |  |  | | --- | --- | --- | --- | | **Section 1: Pathogen Diagnosis Summary *(Respiratory virus PCR or antigen tests -NOT serology/antibody tests)*** | | | | |  | **Tested and POSITIVE**  **(please tick)** | **Tested and NEGATIVE (Please tick)** | **NOT TESTED (please tick)** | | **COVID-19 / SARS-CoV-2** | **Yes☐** | **☐** | **☐** | | **Influenza virus**  *NB: Please do not enter Haemophilus influenza or parainfluenza virus here – enter them under "other" below* | **Yes ☐**  **Please confirm type:**  **☐ A/H3N2 ☐ A/H1N1pdm09 ☐ A/H7N9**  **☐ A not typed other A ☐\_\_\_\_\_\_\_\_\_\_\_\_\_**  **☐ B not typed**  **☐ Other type** **(specify):\_\_\_\_\_\_\_\_\_\_\_\_** | **☐** | **☐** | | **Respiratory syncytial virus (RSV)** | **Yes ☐** | **☐** | **☐** | | **Adenovirus** | **Yes ☐** | **☐** | **☐** | | **Other** | **Yes ☐ please specify :\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | | |  |  |  |  |  | | --- | --- | --- | --- | | **Section 2: Pathogen Testing Details**  ***(Please record the details of all tests carried out during this illness episode below -including the details of the tests indicated above).*** | | | | |  | Select one: | **Organism** | **Date sample obtained** | | **Nasal and/ or throat swab** | **☐** Obtained: positive  **☐** Obtained: negative  **☐** Not obtained | …………………..  …………………..  …………………..  ………………….. | …………………..  …………………..  …………………..  ………………….. | | **Blood culture** | **☐** Obtained: positive  **☐** Obtained: negative  **☐** Not obtained | …………………..  …………………..  …………………..  ………………….. | …………………..  …………………..  …………………..  ………………….. | | **Sputum** | **☐** Obtained: positive  **☐** Obtained: negative  **☐** Not obtained | …………………..  …………………..  …………………..  ………………….. | …………………..  …………………..  …………………..  ………………….. | | **Deep respiratory sample (BAL/ETA)** | **☐** Obtained: positive  **☐** Obtained: negative  **☐** Not obtained | …………………..  …………………..  …………………..  ………………….. | …………………..  …………………..  …………………..  ………………….. | |

**OUTCOME FORM Page 2 of 4**

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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: oRibavirin   oLopinavir/Ritonavir  oInterferon alpha oInterferon beta oChloroquine / Hydroxychloroquine oOseltamivir (Tamiflu®) oZanamivir**  **oOther or novel antiviral \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **oRemdesivir  If YES**: first dose: [\_D\_][\_D\_]/[\_M\_][\_M\_]/[\_ Y \_][\_ Y \_] and last dose [\_D\_][\_D\_]/[\_M\_][\_M\_]/[\_ Y \_][\_ Y \_]  **o IL6 inhibitor   IF YES which ☐ Tocilizumab ☐ Other IL6 inhibitor\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **IL6 inhibitor**  first dose: [\_D\_][\_D\_]/[\_M\_][\_M\_]/[\_ Y \_][\_ Y \_] and last dose [\_D\_][\_D\_]/[\_M\_][\_M\_]/[\_ Y \_][\_ Y \_]  **Antibiotic? ☐YES ☐NO ☐N/K If YES: specify type(s):  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_**  **Corticosteroid? ☐YES ☐NO ☐N/K**  **If yes, please confirm type: ☐ Dexamethasone ☐ Methylprednisolone ☐ Prednisolone ☐ Other, please specify \_\_\_\_\_\_\_\_\_\_\_**  **Route: ☐ Oral ☐ Intravenous ☐ Inhaled, maximum daily dose: \_\_\_\_\_\_\_\_\_\_\_**  **If given Dexamethasone, was this given as 6mg once per day (od) ? ☐YES ☐NO ☐N/K, for how many days \_\_\_\_\_\_\_\_\_\_\_**  **If no, another dosing regimen used please confirm:**     |  |  |  |  | | --- | --- | --- | --- | | **Other Dexamethasone route** | **Other Dexamethasone Dose** | **Other Dexamethasone Frequency** | **Number of days given** | | **☐ Oral ☐ Intravenous** | **\_\_\_\_\_\_\_\_\_\_\_ mg** | **☐ BD ☐ TDS ☐QDS ☐Other\_\_\_\_\_\_** |  | | **☐ Oral ☐ Intravenous** | **\_\_\_\_\_\_\_\_\_\_\_ mg** | **☐ BD ☐ TDS ☐QDS ☐Other\_\_\_\_\_\_** |  | | **☐ Oral ☐ Intravenous** | **\_\_\_\_\_\_\_\_\_\_\_ mg** | **☐ BD ☐ TDS ☐QDS ☐Other\_\_\_\_\_\_** |  |   **Antifungal agent? ☐YES ☐NO ☐N/K**  **If YES:** **which**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Off-label / Compassionate Use medications?** ☐YES ☐NO ☐N/K  **If YES:** which  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Interleukin inhibitors** ☐YES ☐NO ☐N/K  **If YES:** which  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_   **Convalescent plasma** ☐YES ☐NO ☐N/K |

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| **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\_]/[\_2\_][\_0\_][\_Y\_][\_Y\_] ☐N/K**  **ICU/HDU discharge date: [\_D\_][\_D\_]/[\_M\_][\_M\_]/[\_2\_][\_0\_][\_Y\_][\_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**  Blood Group (please check past as well as current medical record): **o**A **o**B **o**AB **o**O **o**N/K |

**OUTCOME FORM Page 3 of 4**

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| **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: | |

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| **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 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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| **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\_][\_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)* |

**OUTCOME FORM Page 4 of 4**

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| **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 so ☐ Ongoing health care needs relating to this admission for COVID-19**  **OR**  **☐ Ongoing health care needs NOT related to COVID episode**  **OR**  **☐ Medically fit for discharge (COVID-19 resolved) 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\_][\_Y\_][\_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 |

**ISARIC WHO Clinical Characterisation Protocol for Severe Emerging Infections UK**

**WITHDRAWAL FORM Page 1 of 1**

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| **WITHDRAWAL** |
| Date of withdrawal:[\_D\_][\_D\_]/[\_M\_][\_M\_]/[\_2\_][\_0\_][\_Y\_][\_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**

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| **ISARIC CCP-UK RESEARCH SAMPLES** | |
| **Was a convalescent sample obtained?**  **If yes, please record the KIT number:**  **Date sample obtained:** | **☐YES ☐NO**  **KIT NUMBER** [\_C\_] [\_C\_] [\_P\_] [\_ \_] [\_ \_][\_ \_][\_ \_][\_ \_]  [\_D\_][\_D\_]/[\_M\_][\_M\_]/[\_2\_][\_0\_][\_Y\_][\_Y\_] |