

**ISARIC/WHO Clinical Characterisation Protocol UK (CCP-UK)  
GENERIC CASE REPORT FORM GUIDANCE FRONT PAGE 1 of 3**

**v10.9 31/05/2022**

**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 31st 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.** Restrict to children admitted on or after 01MARCH2022. Retrospective data collection is encouraged. These criteria may be refined as knowledge is gained.  **Any pathogen on the UK-HSA / NHSE High Consequence Infectious Disease List including**  **Monkeypox infection** |
| **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** |

*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 3**

**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/)
* For REDCap registration access or help with database problems, please contact [data@isaric.org](mailto:data@isaric.org)

|  |
| --- |
| **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**](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]()

**ISARIC WHO Clinical Characterisation Protocol UK**

**ADMISSION FORM page 1 of 4**

**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.*  **Which of the following is the individual proven/suspected of having?**  oAndes virus infection (hantavirus) oArgentine haemorrhagic fever (Junin virus) oAvian influenza A H7N9 & H5N1  oAvian influenza A H5N6 & H7N7 oBolivian haemorrhagic fever (Machupo virus) oCrimean Congo haemorrhagic fever (CCHF) oEbola virus disease (EVD) oLassa fever oLujo virus disease oMarburg virus disease (MVD)  oMiddle East respiratory syndrome (MERS) oMonkeypox oNipah virus infection oPneumonic plague (Yersinia pestis) oSevere acute respiratory syndrome (SARS-not COVID-19) oSevere fever with thrombocytopaenia syndrome (SFTS)  oExposure to CBRN agent oExposure to Harmful Energy oPaediatric hepatitis of unknown cause  oOther, specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  oUnknown |

|  |
| --- |
| **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 |

**ADMISSION FORM page 2 of 4**

|  |
| --- |
| **ONSET AND ADMISSION**  **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 |

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

|  |
| --- |
| **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** |

**ADMISSION FORM Page 3 of 4**

|  |  |  |  |
| --- | --- | --- | --- |
| **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-type 1 ☐NO**  **☐YES-type 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-on ARV ☐NO ☐YES-not on ARV ☐N/K** |

|  |
| --- |
| **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**

|  |  |
| --- | --- |
| **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 |

|  |
| --- |
| **MEDICATION ON ADMISSION**  **Record medication the patient was taking just prior to admission and has taken within the past 14 days** |
| Medication name *(generic name preferred-please write in CAPITALS):* |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |

**ISARIC WHO Clinical Characterisation Protocol UK   
DAILY FORM Page 1 of 1**

|  |
| --- |
| **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 PT \_\_\_\_\_\_\_\_\_\_\_ seconds *or***  **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 m2 oCKD-EPI oMDRD oCG  **Most recent HbA1c\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ☐ N/K date of HbA1c [\_D\_][\_D\_]/[\_M\_][\_M\_]/[\_2\_][\_0\_][\_Y\_][\_Y\_]**  Most recent CD4\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_/mm3 ☐ N/K date of CD4 [\_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?**  **If yes, please record the KIT number:** | **☐YES ☐NO**  **KIT NUMBER** [\_C\_] [\_C\_] [\_P\_] [\_\_] [\_\_\_][\_\_\_][\_\_\_][\_\_\_] |

**ISARIC WHO Clinical Characterisation Protocol UK**

**OUTCOME FORM Page 1 of 4**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **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** | | **Monkeypox virus** | **☐ Tested POSITIVE** | **☐ 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\_ | Nasal/NP swab Throat swab  Combined nasal/NP + throat swab  Sputum BAL ETA Lesion swab  Urine Stool/rectal swab Blood  Other, *Specify:* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Positive  Negative  Unknown | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
| \_D\_ \_D\_ /\_M\_ \_M\_ /202 \_Y\_ |  Nasal/NP swab Throat swab  Combined nasal/NP + throat swab  Sputum BAL ETA Lesion swab  Urine Stool/rectal swab Blood  Other, *Specify:* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Positive  Negative  Unknown | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
| \_D\_ \_D\_ /\_M\_ \_M\_ /202 \_Y\_ |  Nasal/NP swab Throat swab  Combined nasal/NP + throat swab  Sputum BAL ETA Lesion swab  Urine Stool/rectal swab Blood  Other, *Specify:* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Positive  Negative  Unknown | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
| \_D\_ \_D\_ /\_M\_ \_M\_ /202 \_Y\_ |  Nasal/NP swab Throat swab  Combined nasal/NP + throat swab  Sputum BAL ETA Lesion swab  Urine Stool/rectal swab Blood  Other, *Specify:* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Positive  Negative  Unknown | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |

**OUTCOME FORM Page 2 of 4**

|  |
| --- |
| **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 oBrincidofovir oTecovirimat  oRibavirin   oOseltamivir (Tamiflu®) oZanamivir  oRemdesivir  oOther or novel antiviral \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Antibiotic?** ☐YES ☐NO ☐N/K If YES: specify type(s):  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Corticosteroid?** ☐YES ☐NO ☐N/K  **Immunoglobulin?** ☐YES ☐NO ☐N/K If YES: specify type:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Antifungal agent? ☐YES ☐NO ☐N/K If YES: which  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Analgesics? ☐YES ☐NO ☐N/K If YES, tick all that apply: oParacetamol oNSAIDs oOpiates oKetamine  **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** |

**OUTCOME FORM Page 3 of 4**

|  |  |  |  |
| --- | --- | --- | --- |
| **COMPLICATIONS: At any time during hospitalisation did the patient experience: No complications ☐** | | | |
| Viral pneumonia | ☐YES ☐NO ☐N/K | Coagulation disorder / Disseminated Intravascular Coagulation | ☐YES ☐NO ☐N/K |
| Bacterial pneumonia | ☐YES ☐NO ☐N/K | Deep vein thrombosis | ☐YES ☐NO ☐N/K |
| Acute Respiratory Distress Syndrome | ☐YES ☐NO ☐N/K | Pulmonary thromboembolism | ☐YES ☐NO ☐N/K |
| Cryptogenic organizing pneumonia (COP) | ☐YES ☐NO ☐N/K | Anaemia | ☐YES ☐NO ☐N/K |
| Pneumothorax | ☐YES ☐NO ☐N/K | Rhabdomyolysis / Myositis | ☐YES ☐NO ☐N/K |
| Pleural effusion | ☐YES ☐NO ☐N/K | Acute renal injury/acute renal failure | ☐YES ☐NO ☐N/K |
| Bronchiolitis | ☐YES ☐NO ☐N/K | Urinary tract infection | ☐YES ☐NO ☐N/K |
| Meningitis / Encephalitis | ☐YES ☐NO ☐N/K | Gastrointestinal haemorrhage | ☐YES ☐NO ☐N/K |
| Seizure | ☐YES ☐NO ☐N/K | Pancreatitis | ☐YES ☐NO ☐N/K |
| Stroke / Cerebrovascular accident | ☐YES ☐NO ☐N/K | Liver dysfunction | ☐YES ☐NO ☐N/K |
| Other neurological complication | ☐YES ☐NO ☐N/K | Hyperglycaemia | ☐YES ☐NO ☐N/K |
| Congestive heart failure | ☐YES ☐NO ☐N/K | Hypoglycaemia | ☐YES ☐NO ☐N/K |
| Endocarditis | ☐YES ☐NO ☐N/K | Bacteraemia | ☐YES ☐NO ☐N/K |
| Myocarditis/Pericarditis | ☐YES ☐NO ☐N/K | Cellulitis | ☐YES ☐NO ☐N/K |
| Cardiomyopathy | ☐YES ☐NO ☐N/K | Skin abscess | ☐YES ☐NO ☐N/K |
| Cardiac arrhythmia | ☐YES ☐NO ☐N/K | Skin tissue loss or eschar | ☐YES ☐NO ☐N/K |
| Cardiac ischemia | ☐YES ☐NO ☐N/K | Other complication(s) | ☐YES ☐NO ☐N/K |
| Cardiac arrest | ☐YES ☐NO ☐N/K | If yes, specify 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 FORM Page 4 of 4**

|  |
| --- |
| **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 UK**

**WITHDRAWAL FORM Page 1 of 1**

|  |
| --- |
| **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 UK**

**Convalescent Sample Page 1 of 1**

|  |  |
| --- | --- |
| **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\_][\_2\_][\_Y\_] |

**PAEDIATRIC HEPATITIS MODULE Page 1 of 1**

*Complete this module at admission*

|  |
| --- |
| **Additional Recent Illness History** |
| **In the last 3 months, has your child had a diarrhoea and vomiting / gastroenteritis illness? ☐YES ☐NO ☐N/K**  **If yes, approximate date of this illness: [\_D\_][\_D\_]/[\_M\_][\_M\_]/[\_2\_][\_0\_][\_Y\_][\_Y\_]**  **If yes, did these symptoms persist for more than a week? ☐YES ☐NO ☐N/K**  If yes, what persistent symptoms did they have in the last three months?  History of fever **☐YES ☐NO ☐N/K.** Vomiting / Nausea **☐YES ☐NO ☐N/K**  Diarrhoea **☐YES ☐NO ☐N/K** Abdominal pain **☐YES ☐NO ☐N/K**  Weight loss **☐YES ☐NO ☐N/K** Tiredness **☐YES ☐NO ☐N/K**  Other (free text) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**MONKEYPOX MODULE Page 1 of 1**

*Complete this module at admission and daily during hospital admission*

|  |  |  |  |
| --- | --- | --- | --- |
| **DAILY SIGNS AND SYMPTOMS None (asymptomatic) ☐** | | | |
| **Sore throat**  **Lower respiratory tract symptoms** (productive cough, wheezing, respiratory distress)  **Muscle aches (Myalgia)**  **Joint pain (Arthralgia)**  **Weight loss**  **Vomiting / Nausea**  **Diarrhoea**  **Abdominal pain**  **Constipation**  **Urinary retention**  **Jaundice**  **Fatigue / Malaise**  **Headache**  **Altered consciousness/confusion**  **Psychological disturbance**  **Seizures** | **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**  **YES NO N/K**  **YES NO N/K** | **Keratitis**  **Conjunctivitis**  **Pruritis**  **Lymphadenopathy**  **If yes, Painful lymph nodes**  **If yes, Axillary (arm pits)**  **If yes, Cervical (neck)**  **If yes, Inguinal (groin)**  **If yes, Other site**  **Specify site:**  **Bleeding (Haemorrhage)**  **If bleeding, specify site(s)**  **Other symptom(s)**  **If yes, specify other:** | **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**  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |

|  |
| --- |
| **DAILY LESION ASSESSMENT** |
| **Have new lesions appeared in the previous 24 hours?** (patients may be best placed to assess this)  **☐YES  ☐NO  ☐N/K**  **LESION ASSESSMENT:**  **Estimate total number of lesions on the body: ☐None ☐1-5 ☐6-25 ☐26-100 ☐ >100 ☐N/K**  **Are there active lesions in the following areas?**   |  |  |  |  | | --- | --- | --- | --- | | Head, face, neck | YES NO N/K | External genitalia | YES NO N/K | | Inside of mouth | YES NO N/K | Perianal | YES NO N/K | | Torso | YES NO N/K | Vaginal canal | YES NO N/K | | Arms and/or hands | YES NO N/K | Rectum | YES NO N/K | | Legs and/or feet | YES NO N/K | Other | YES NO N/K | |  | YES NO N/K | Specify where: | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |   **Are these types of lesions on the body today?**   |  |  |  |  | | --- | --- | --- | --- | | Vesicle | YES NO N/K | Crusted/scabbed mature lesion | YES NO N/K | | Pustule | YES NO N/K | Residual evidence of resolved lesions (scar/discoloration) | YES NO N/K | | Ulcerated lesion | YES NO N/K | Haemorrhagic / bleeding lesions | YES NO N/K |   **Pain at lesion site: ☐YES ☐NO ☐N/K**  **If yes, score: [\_\_\_] [\_\_\_]/10 where zero means “no pain,” and 10 means “the worst possible pain.”**  Printable pain scale assessment chart that can be printed and used in order for people and kids to be able to point to the current pain level they are feeling.  **Describe any other lesion complications: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |