

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

**(CCP-UK) Case Report Form FRONT PAGE 1 of 2**

**V9.2 26FEB2020**

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

This CRF is divided into a “**CORE**” form (3 pages) with presentation data, a “**DAILY**” form (2 pages) for daily clinical and laboratory and data, and an “**OUTCOME**” form (3 pages). There is also a **TRAVEL AND ANIMAL EXPOSURE** form (1 page) which should be used when appropriate.

**HOW TO USE THIS CRF**

The CRF is designed to compliment 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. All high-quality data is valuable for analysis.

**Ideally, data and samples will be collected with consent using Tier 2 of the protocol schedule, as outlined below. This will be of greatest public health research value in the early stages of an outbreak.**

**Data can be collected for Tier Zero activity without consent.**

**Consent must be obtained for biological sampling and data collection for Tier 1 and Tier 2 actiivty.**

**Tier Zero** - For sites where caseload or facilities limit research capacity to deliver Tier 1 or Tier 2 activity.

**OR**  
 - For collection of data without consent.  
Please complete the **CORE CRF** and **DAILY** **CRF** for the first day of hospital admission (day 1), the **DAILY** **CRF** for the third (d3), sixth (d6) and ninth (d9) days, then the **OUTCOME CRF** at discharge or death.

**Tier 1** - For sites where facilities limit research capacity to deliver Tier 2 activity. With consent for single timepoint biological sampling. Please complete the **CORE CRF** and **DAILY** **CRF** for the first day of hospital admission (day 1), the **DAILY** **CRF** for the third (d3), sixth (d6) and ninth (d9) days, the **DAILY** **CRF** again for the first day of any ICU admission, and then the **OUTCOME CRF** at discharge or death.

**Tier 2** - For sites with available resources to deliver Tier 2 activity per the protocol schedule.  
With consent for multiple timepoint biological sampling. Please complete the **CORE CRF** and **DAILY** **CRF** on the first day of hospital admission. Please complete the **DAILY CRF** on each subsequent day up to discharge or death. Please complete the **OUTCOME CRF** at discharge or death.

*On each page above here write site code & participant number above as per this example*

I\_R\_I I\_L\_I I\_C\_I I\_3\_I I\_6\_I -- I\_4\_I I\_7\_I I\_2\_I I\_1\_I

**ISARIC/WHO Clinical Characterisation Protocol for Severe Emerging Infections (UK)**

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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.
* Participant Identification Numbers consist of a 5-digit CPMS site code and a 4 digit participant number. You can 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 or incorporating alpha characters. E.g. Ward X will assign numbers from 0001 or A001 onwards and Ward Y will assign numbers from 5001 or B001 onwards. Enter the Participant Identification Number at the top of every page.
* Case Report Form 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 [ncov@isaric.org](mailto:ncov@isaric.org) please state “[CCP-UK REDCap ACCESS]” in the title
* Please contact us at [ncov@isaric.org](mailto:ncov@isaric.org) we can help with database problems
* In the case of a participant transferring between study sites, it is preferred to maintain the same Participant Identification Number across the sites. When this is not possible, space for recording the new number is provided.
* Complete every line of every section, except for where the instructions say to skip a section based on certain responses.
* 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).
* Mark ‘N/A’ for any results of laboratory values that are not available, not applicable or unknown.
* 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.
* Please keep all of the sheets for a single participant together e.g. with a staple or participant-unique folder.
* DO NOT SEND CRFs to anyone by email or post.
* These two FRONT PAGES do not need to be retained.

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

**SARI Case Report Form**

**CORE CASE RECORD FORM page 1 of 3**

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

|  |
| --- |
| **CLINICAL INCLUSION CRITERIA** |
| **Proven or high likelihood of infection with pathogen of Public Health Interest**  ☐ YES ☐ NO  **Experience of the following symptoms during this illness episode: (one or more required for inclusion)**  **A history of self-reported feverishness or measured fever of ≥ 38oC:** ☐ YES ☐ NO  **Cough:** ☐ YES ☐ NO  **Dyspnoea (shortness of breath) OR Tachypnoea\*:** ☐ YES ☐ NO  **Clinical suspicion of ARI despite not meeting criteria above**: ☐ YES ☐ NO  ***\**** *respiratory rate ≥50 breaths/min for <1 year; ≥40 breaths/min for 1-4 years; ≥30 breaths/min for 5-12 years; ≥20 breaths/min for ≥13 years* |
|  |
| **EPIDEMIOLOGICAL FACTORS** |
| **In the 14 days before onset of illness had any of the following:**  **A history of travel to an area with documented cases of infection of a respiratory pathogen of public health Interest in the context of an outbreak, suspected outbreak or incident of a respiratory pathogen of public health interest**  ☐ YES ☐ NO ☐ Not known  **Close contact\* with a confirmed or probable case of infection with the respiratory pathogen of public health interest, while that patient was symptomatic**  ☐ YES ☐ NO ☐ Not known  **Presence in a healthcare facility where infections caused by the respiratory pathogen of public health interest have been managed**  ☐ YES ☐ NO ☐ Not known  **Presence in a laboratory handling samples suspected or confirmed of having the respiratory pathogen of public health interest present**  ☐ YES ☐ NO ☐ Not known  **An otherwise unexplained respiratory illness in the context of an outbreak, suspected outbreak or incident of a respiratory pathogen of public health interest**  ☐ YES ☐ NO ☐ Not known  **Direct contact with animals in countries where the pathogen of public health interest is known to be circulating in animal populations or where human infections have occurred as a result of presumed zoonotic transmission**  ☐ YES ☐ NO ☐ Not known  \* Close contact’ is defined as:  -      Health care associated exposure, including providing direct care for patients, e.g. health care worker, direct exposure to body fluids or specimens including aerosols, working with health care workers infected with the pathogen of public health interest, visiting patients or staying in the same close environment of relevant case.  -      Working together in close proximity or sharing the same classroom environment with a relevant case  -      Traveling together with in any kind of conveyance with a relevant case  -      Living in the same household as a relevant case |

**CORE CASE RECORD FORM Page 2 of 3**

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| **DEMOGRAPHICS** |
| **Sex at Birth:**  ☐ Male ☐Female ☐Not specified \***Date of birth** [\_D\_][\_D\_]/[\_M\_][\_M\_]/[\_ Y \_][\_ Y \_][\_Y\_][\_Y\_]    **\* WHERE DATA IS BEING COLLECTED WITHOUT CONSENT FOR TIER ZERO, ONLY RECORD AGE AND NOT DATE OF BIRTH**  If date of birth is unknown or for Tier Zero, record Age [\_\_\_][\_\_\_][\_\_\_]years OR [\_\_\_][\_\_\_]months  **Ethnic group** *(check all that apply)*:  oArab oBlack oEast Asian oSouth Asian oWest Asian oLatin American oWhite oAboriginal/First Nations oOther: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 🞎N/A  **Employed as a Healthcare Worker?** 🞎YES 🞎NO 🞎N/A  **Employed in a Microbiology laboratory?** 🞎YES 🞎NO 🞎N/A  **Pregnant?** ☐YES ☐ NO ☐ Unknown ☐N/A **If YES:** **Gestational weeks assessment:** [\_\_\_][\_\_\_] weeks |
| **POST PARTUM (within six weeks of delivery)?** 🞎YES 🞎NO or N/A *(skip this section - go to INFANT)*  **Pregnancy Outcome:** 🞎Live birth 🞎Still birth  **Delivery date:** [\_D\_][\_D\_]/[\_M\_][\_M\_]/[\_2\_][\_0\_][\_Y\_][\_Y\_]  **Baby tested for Mother’s ARI infection?** 🞎YES 🞎NO 🞎N/A **If YES:** 🞎Positive 🞎Negative **Method:** 🞎PCR 🞎Other:\_\_\_\_\_\_\_\_\_ |
| **INFANT – Less than 1 year old?** 🞎YES 🞎NO *(skip this section)* **Birth weight:** [\_\_\_][\_\_\_]**.**[\_\_\_]🞎kg or 🞎lbs🞎N/A  **Gestational:**🞎 Term birth (≥37wk GA) 🞎Preterm birth (<37wk GA**) if <37wk** Estimated gestation \_\_\_\_\_\_\_\_\_weeks 🞎N/A  **Breastfed?** 🞎YES 🞎NO 🞎N/A **If YES:**🞎Currently breastfed  🞎Breastfeeding discontinued at [\_\_\_][\_\_\_]weeks🞎N/A  **Appropriate development for age?** 🞎YES 🞎NO 🞎N/A  **Vaccinations appropriate for age/country?** 🞎YES 🞎NO 🞎Unknown 🞎N/A |

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| **ONSET AND ADMISSION** |
| **Symptom onset date of first/earliest symptom:**[\_D\_][\_D\_]/[\_M\_][\_M\_]/[\_2\_][\_0\_][\_Y\_][\_Y\_]  **Admission date at this facility:**  [\_D\_][\_D\_]/[\_M\_][\_M\_]/[\_2\_][\_0\_][\_Y\_][\_Y\_]  **Time of admission (24-hour format):**[\_H\_][\_H\_]/[\_M\_][\_M\_]  **Transfer from other facility?** 🞎YES-facility is a study site 🞎YES-facility is not a study site 🞎NO 🞎N/A  If YES: **Name of transfer facility**:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 🞎N/A  If YES: **Admission date at transfer facility** *(DD/MM/YYYY)*: [\_D\_][\_D\_]/[\_M\_][\_M\_]/[\_2\_][\_0\_][\_Y\_][\_Y\_] 🞎N/A  If YES-Study Site: **Participant ID # at transfer facility:** 🞎Same as above  🞎Different: [\_\_\_][\_\_\_][\_\_\_]–[\_\_\_][\_\_\_][\_\_\_][\_\_\_] 🞎N/A  **Travel in the 14 days prior to first symptom onset?** 🞎YES 🞎NO 🞎N/A *If YES, complete the*  **If YES, *state location(s) & date(s):*** Country:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ City/Geographic area:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Return Date: [\_D\_][\_D\_]/[\_M\_][\_M\_]/[\_2\_][\_0\_][\_Y\_][\_Y\_] 🞎 N/A *(if more use TRAVEL EXPOSURE CRF)*  **Contact with animals, raw meat or insect bites in the 14 days prior to symptom onset?**  🞎YES 🞎NO 🞎Unknown 🞎 N/A *If YES, complete the ANIMAL EXPOSURE CRF* |

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| **SIGNS AND SYMPTOMS AT HOSPITAL ADMISSION** *(first available data at presentation/admission – within 24 hours)* |
| **Temperature:** [\_ ][\_ ][\_ ]**.**[\_ ]°C *or* °F **HR:** [\_ ][\_ ][\_ ]beats per minute **RR:** [\_ ][\_ ]breaths per minute  **Systolic BP:** [\_ ][\_ ][\_ ]mmHg **Diastolic BP:** [\_ ][\_ ][\_ ]mmHg **Severe dehydration:** 🞎YES 🞎NO 🞎Unknown  **Sternal capillary refill time >2seconds** 🞎YES 🞎NO 🞎Unknown    **Oxygen saturation:** [\_ ][\_ ][\_ ]% **On:** Room air Oxygen therapy N/A |

**CORE CASE RECORD FORM Page 3 of 3**

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| **CO-MORBIDITIES** *(existing prior to admission)* | | | |
| Chronic cardiac disease, including congenital heart disease  *(not hypertension)* | 🞎YES 🞎NO 🞎N/A | Obesity *(as defined by clinical staff)* | 🞎YES 🞎NO 🞎N/A |
| Chronic pulmonary disease  *(not asthma)* | 🞎YES 🞎NO 🞎N/A | Diabetes with complications | 🞎YES 🞎NO 🞎N/A |
| Asthma *(physician diagnosed)* | 🞎YES 🞎NO 🞎N/A | Diabetes without complications | 🞎YES 🞎NO 🞎N/A |
| Chronic kidney disease | 🞎YES 🞎NO 🞎N/A | Rheumatologic disorder | 🞎YES 🞎NO 🞎N/A |
| Moderate or severe liver disease | 🞎YES 🞎NO 🞎N/A | Dementia | 🞎YES 🞎NO 🞎N/A |
| Mild liver disease | 🞎YES 🞎NO 🞎N/A | Malnutrition | 🞎YES 🞎NO 🞎N/A |
| Chronic neurological disorder | 🞎YES 🞎NO 🞎N/A | Smoking 🞎YES 🞎Never smoked 🞎Former smoker | |
| Malignant neoplasm | 🞎YES 🞎NO 🞎N/A | Other relevant risk factor | 🞎YES 🞎NO 🞎N/A |
| Chronic hematologic disease | 🞎YES 🞎NO 🞎N/A | If yes, specify:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | |
| AIDS / HIV | 🞎YES 🞎NO 🞎N/A |
| **Pre-admission treatment** | | | |
| Treated with immunosuppressants, including oral (not inhaled) corticosteroids prior to admission? | | 🞎YES 🞎NO 🞎 N/A | |
| Treated with anti-infectives for this illness episode prior to admission? | | 🞎YES 🞎NO 🞎 N/A If yes, specify:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |

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| **Admission signs and symptoms***(observed/reported at admission and associated with this episode of acute illness)* | | | |
| 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) | 🞎YES 🞎NO 🞎Unknown  🞎YES 🞎NO 🞎 Unknown  🞎YES 🞎NO 🞎 Unknown  🞎YES 🞎NO 🞎 Unknown  🞎YES 🞎NO 🞎 Unknown  🞎YES 🞎NO 🞎 Unknown  🞎YES 🞎NO 🞎 Unknown  🞎YES 🞎NO 🞎 Unknown  🞎YES 🞎NO 🞎 Unknown  🞎YES 🞎NO 🞎 Unknown  🞎YES 🞎NO 🞎 Unknown  🞎YES 🞎NO 🞎 Unknown  🞎YES 🞎NO 🞎 Unknown | 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): | 🞎YES 🞎NO 🞎 Unknown  🞎YES 🞎NO 🞎 Unknown  🞎YES 🞎NO 🞎 Unknown  🞎YES 🞎NO 🞎 Unknown  🞎YES 🞎NO 🞎 Unknown  🞎YES 🞎NO 🞎 Unknown  🞎YES 🞎NO 🞎 Unknown  🞎YES 🞎NO 🞎 Unknown  🞎YES 🞎NO 🞎 Unknown  🞎YES 🞎NO 🞎 Unknown  🞎YES 🞎NO 🞎 Unknown  🞎YES 🞎NO 🞎 Unknown  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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

**SARI Case Report Form**

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| **CURRENT MEDICATION**  **Record medication the patient is currently taking or has taken within the past 14 days** | | | |
| **Medication name**  ***(generic name preferred)*** | **Dose** | ***Dose Frequency*** | **Route of administration** |
|  |  | 🞎**q.d - once a day** 🞎**b.i.d - twice a day**  🞎**t.i.d - three times a day** 🞎**q.i.d - four times a day** 🞎**q.h.s - before bed** 🞎**5X a day - five times a day**  🞎 **q.4h - every four hours** 🞎 **q.6h - every six hours**  🞎**q.o.d - every other day** 🞎**prn - as needed**  🞎**Other frequency Specify Other:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | 🞎**IV** 🞎**oral** 🞎**inhaled**  🞎**other** 🞎**unknown**  **Specify Other:\_\_\_\_\_\_\_\_\_\_\_** |
|  |  | 🞎**q.d - once a day** 🞎**b.i.d - twice a day**  🞎**t.i.d - three times a day** 🞎**q.i.d - four times a day** 🞎**q.h.s - before bed** 🞎**5X a day - five times a day**  🞎 **q.4h - every four hours** 🞎 **q.6h - every six hours**  🞎**q.o.d - every other day** 🞎**prn - as needed**  🞎**Other frequency Specify Other:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | 🞎**IV** 🞎**oral** 🞎**inhaled**  🞎**other** 🞎**unknown**  **Specify Other:\_\_\_\_\_\_\_\_\_\_\_** |
|  |  | 🞎**q.d - once a day** 🞎**b.i.d - twice a day**  🞎**t.i.d - three times a day** 🞎**q.i.d - four times a day** 🞎**q.h.s - before bed** 🞎**5X a day - five times a day**  🞎 **q.4h - every four hours** 🞎 **q.6h - every six hours**  🞎**q.o.d - every other day** 🞎**prn - as needed**  🞎**Other frequency Specify Other:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | 🞎**IV** 🞎**oral** 🞎**inhaled**  🞎**other** 🞎**unknown**  **Specify Other:\_\_\_\_\_\_\_\_\_\_\_** |
|  |  | 🞎**q.d - once a day** 🞎**b.i.d - twice a day**  🞎**t.i.d - three times a day** 🞎**q.i.d - four times a day** 🞎**q.h.s - before bed** 🞎**5X a day - five times a day**  🞎 **q.4h - every four hours** 🞎 **q.6h - every six hours**  🞎**q.o.d - every other day** 🞎**prn - as needed**  🞎**Other frequency Specify Other:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | 🞎**IV** 🞎**oral** 🞎**inhaled**  🞎**other** 🞎**unknown**  **Specify Other:\_\_\_\_\_\_\_\_\_\_\_** |
|  |  | 🞎**q.d - once a day** 🞎**b.i.d - twice a day**  🞎**t.i.d - three times a day** 🞎**q.i.d - four times a day** 🞎**q.h.s - before bed** 🞎**5X a day - five times a day**  🞎 **q.4h - every four hours** 🞎 **q.6h - every six hours**  🞎**q.o.d - every other day** 🞎**prn - as needed**  🞎**Other frequency Specify Other:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | 🞎**IV** 🞎**oral** 🞎**inhaled**  🞎**other** 🞎**unknown**  **Specify Other:\_\_\_\_\_\_\_\_\_\_\_** |

**CORE CASE RECORD FORM Page 2 of 3**

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| **ADMISSION AND 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/A’)*: |
| Current admission to ICU/ITU/IMC/HDU? 🞎YES 🞎NO 🞎N/A  **Done** 🞎YES 🞎NO FiO2 *(0.21-1.0)* [\_\_\_].[\_\_\_][\_\_\_] or [\_\_\_][\_\_\_]L/min  **Done** 🞎YES 🞎NO SaO2 [\_\_\_][\_\_\_][\_\_\_]%  **Done** 🞎YES 🞎NO PaO2 *at time of FiO2 above* [\_\_\_][\_\_\_][\_\_\_] 🞎kPa *or* 🞎mmHg  **Done** 🞎YES 🞎NO PaO2 sample type: 🞎 Arterial 🞎 Venous 🞎 Capillary 🞎N/A  **Done** 🞎YES 🞎NO From same blood gas record as PaO2 PCO2 \_\_\_\_\_\_\_\_\_\_\_\_🞎kPa *or* 🞎mmHg  **Done** 🞎YES 🞎NO pH \_\_\_\_\_\_\_\_\_\_\_\_\_  **Done** 🞎YES 🞎NO HCO3- \_\_\_\_\_\_\_\_\_\_\_mEq/L  **Done** 🞎YES 🞎NO Base excess \_\_\_\_\_\_\_\_\_\_ mmol/L  **Done** 🞎YES 🞎NO AVPU Alert[\_\_\_] Verbal[\_\_\_] Pain [\_\_\_] Unresponsive[\_\_\_] Glasgow Coma Score (GCS / 15) [\_\_\_][\_\_\_]  **Done** 🞎YES 🞎NO Systolic Blood Pressure [\_\_\_][\_\_\_][\_\_\_]mmHg  **Done** 🞎YES 🞎NO Diastolic Blood Pressure [\_\_\_][\_\_\_][\_\_\_]mmHg  **Done** 🞎YES 🞎NO Mean Arterial Blood Pressure [\_\_\_][\_\_\_][\_\_\_]mmHg  **Done** 🞎YES 🞎NO Urine flow rate [\_\_\_][\_\_\_][\_\_\_][\_\_\_][\_\_\_]mL/24 hours 🞎 Check if estimated |
| Is the patient currently receiving, or has received (from 00:00 to 24:00) on day of assessment) *(apply to all questions in this section)*  **Non-invasive ventilation** *(e.g. BIPAP, CPAP)*? 🞎 YES 🞎 NO 🞎 N/A **Invasive ventilation?** 🞎 YES 🞎 NO 🞎N/A  **High-flow nasal canula oxygen therapy?**  🞎YES 🞎NO 🞎N/A **ECLS/ECMO?** 🞎 YES 🞎 NO 🞎 N/A  **Dialysis/Hemofiltration**? 🞎YES 🞎NO 🞎N/A  **Any vasopressor/inotropic support?** ☐ YES ☐ NO *(if NO, answer the next 3 questions NO)* 🞎N/A  Dopamine <5µg/kg/min OR Dobutamine OR milrinone OR levosimendan: ☐ YES ☐ NO  Dopamine 5-15µg/kg/min OR Epinephrine/Norepinephrine < 0.1µg/kg/min OR vasopressin OR phenylephrine: ☐ YES ☐ NO  Dopamine >15µg/k/min OR Epinephrine/Norepinephrine > 0.1µg/kg/min: ☐ YES ☐ NO  **Neuromuscular blocking agents?** 🞎 YES 🞎 NO 🞎 N/A **Inhaled Nitric Oxide?** 🞎YES 🞎NO 🞎N/A  **Prone positioning?** 🞎 YES 🞎 NO 🞎 N/A **Tracheostomy inserted?** 🞎YES 🞎NO 🞎N/A  **Other intervention or procedure:** 🞎 YES 🞎 NO 🞎 N/A **If YES, Specify**: |

**DAILY CASE RECORD FORM Page 3 of 3**

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| **DAILY LABORATORY RESULTS** |
| *(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/A’)*: |
| **Done** 🞎YES 🞎NO **Haemoglobin** \_\_\_\_\_\_\_ 🞎g/L *or*🞎g/dL  **Done** 🞎YES 🞎NO **WBC count** \_\_\_\_\_\_\_\_\_\_\_ 🞎x109/L *or*🞎x103/µL  **Done** 🞎YES 🞎NO **Lymphocyte count** \_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_ 🞎cells/ μL  **Done** 🞎YES 🞎NO **Neutrophil count** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_ 🞎 cells/ μL  **Done** 🞎YES 🞎NO **Haematocrit** [\_\_\_][\_\_\_]%  **Done** 🞎YES 🞎NO **Platelets** \_\_\_\_\_\_\_\_\_\_\_ 🞎x109/L *or* 🞎x103/μL **Done** 🞎YES 🞎NO **APTT/APTR** \_\_\_\_\_\_\_\_\_\_  **Done** 🞎YES 🞎NO **PT \_\_\_\_\_\_\_\_\_\_\_** seconds *or* **Done** 🞎YES 🞎NO **INR**\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Done** 🞎YES 🞎NO **ALT/SGPT** \_\_\_\_\_\_\_\_\_ U/L  **Done** 🞎YES 🞎NO **Total Bilirubin** \_\_\_\_\_\_\_🞎µmol/L *or*🞎mg/dL  **Done** 🞎YES 🞎NO **AST/SGOT** \_\_\_\_\_\_\_\_\_ U/L **Done** 🞎YES 🞎NO  **Glucose** \_\_\_\_\_\_\_\_\_🞎mmol/L *or* 🞎mg/dL  **Done** 🞎YES 🞎NO **Blood Urea Nitrogen (urea)** \_\_\_\_\_\_\_\_\_\_\_\_ 🞎mmol/L *or*🞎mg/dL  **Done** 🞎YES 🞎NO **Lactate** \_\_\_\_\_\_\_\_\_\_\_🞎mmol/L *or* 🞎mg/dL  **Done** 🞎YES 🞎NO **LDH**  [\_\_\_][\_\_\_][\_\_\_].[\_\_\_]\_U/L  **Done** 🞎YES 🞎NO **Creatinine Kinase (CPK)**  [\_\_\_][\_\_\_][\_\_\_].[\_\_\_]\_U/L  **Done** 🞎YES 🞎NO **Creatinine** \_\_\_\_\_\_\_\_\_\_\_\_\_ 🞎μmol/L *or*🞎mg/dL  **Done** 🞎YES 🞎NO **Sodium**  [\_\_\_][\_\_\_][\_\_\_][\_\_\_] mEq/L  **Done** 🞎YES 🞎NO **Potassium** [\_\_\_][\_\_\_].[\_\_\_] mEq/L  **Done** 🞎YES 🞎NO **Procalcitonin** [\_\_\_][\_\_\_].[\_\_\_][\_\_\_]ng/mL  **Done** 🞎YES 🞎NO **CRP** [\_\_\_][\_\_\_][\_\_\_].[\_\_\_] mg/L  **Chest X-Ray /CT performed?** 🞎YES 🞎NO 🞎N/A  **IF Yes: Were infiltrates present?** 🞎YES 🞎NO 🞎N/A |

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

**SARI Case Report Form**

**OUTCOME CASE RECORD FORM Page 1 of 5**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **PATHOGEN TESTING** | | | | | |
| **Was pathogen testing done during this illness episode?** 🞎YES 🞎NO 🞎N/A  **Influenza :** ☐YES- Confirmed ☐ YES- Probable ☐ NO **If** YES**:** ☐A/H3N2 ☐A/H1N1pdm09 ☐A/H7N9  ☐A/H5N1 ☐A not typed, other A ☐\_\_\_\_\_\_\_\_\_\_\_\_\_☐B not typed ☐ Other type (specify):\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Coronavirus:** ☐ YES- Confirmed ☐ YES- Probable ☐ NO **If** YES**:** ☐ MERS CoV☐ 2019nCoV  ☐ Other CoV (specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **RSV:** ☐ YES- Confirmed ☐ YES- Probable ☐ NO  **Adenovirus:** ☐ YES- Confirmed ☐ YES- Probable ☐ NO  **Bacteria:** **:** ☐ YES – confirmed: specify **:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ☐ No  **Other :** ☐YES- Confirmed ☐ YES- Probable ☐ NO  **If yes Other, specify\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Clinical pneumonia:** ☐ YES ☐ NO☐ Unknown **If NONE OF THE ABOVE: Suspected Non-infective:** ☐ YES | | | | | |
| **LIMS Number** | **Collection Date** *(DD/MM/YYYY)* | **Bio specimen Type** | **Laboratory Test Method** | **Result** | **Pathogen Tested/Detected** |
|  | \_\_ \_\_ /\_\_ \_\_ /20\_\_ \_\_ | 🞎Nasal/NP swab 🞎Throat swab 🞎Combined nasal/NP+throat swab  🞎Sputum 🞎BAL 🞎ETA 🞎Urine 🞎Feces/rectal swab 🞎Blood  🞎Other, *Specify:* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | 🞎PCR  🞎Culture  🞎Other, *Specify:*  \_\_\_\_\_\_\_\_\_\_\_\_\_\_ | 🞎Positive  🞎Negative  🞎N/A | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  | \_\_ \_\_ /\_\_ \_\_ /20\_\_ \_\_ | 🞎Nasal/NP swab 🞎Throat swab 🞎Combined nasal/NP+throat swab  🞎Sputum 🞎BAL 🞎ETA 🞎Urine 🞎Feces/rectal swab 🞎Blood  🞎Other, *Specify:* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | 🞎PCR  🞎Culture  🞎Other, *Specify:*  \_\_\_\_\_\_\_\_\_\_\_\_\_\_ | 🞎Positive  🞎Negative  🞎N/A | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  | \_\_ \_\_ /\_\_ \_\_ /20\_\_ \_\_ | 🞎Nasal/NP swab 🞎Throat swab 🞎Combined nasal/NP+throat swab  🞎Sputum 🞎BAL 🞎ETA 🞎Urine 🞎Feces/rectal swab 🞎Blood  🞎Other, *Specify:* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | 🞎PCR  🞎Culture  🞎Other, *Specify:*  \_\_\_\_\_\_\_\_\_\_\_\_\_\_ | 🞎Positive  🞎Negative  🞎N/A | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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**OUTCOME CASE RECORD FORM Page 2 of 5**

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| --- | --- | --- | --- | --- | --- |
|  | \_\_ \_\_ /\_\_ \_\_ /20\_\_ \_\_ | 🞎Nasal/NP swab 🞎Throat swab 🞎Combined nasal/NP+throat swab  🞎Sputum 🞎BAL 🞎ETA 🞎Urine 🞎Feces/rectal swab 🞎Blood  🞎Other, *Specify:* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | 🞎PCR  🞎Culture  🞎Other, *Specify:*  \_\_\_\_\_\_\_\_\_\_\_\_\_\_ | 🞎Positive  🞎Negative  🞎N/A | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  | \_\_ \_\_ /\_\_ \_\_ /20\_\_ \_\_ | 🞎Nasal/NP swab 🞎Throat swab 🞎Combined nasal/NP+throat swab  🞎Sputum 🞎BAL 🞎ETA 🞎Urine 🞎Feces/rectal swab 🞎Blood  🞎Other, *Specify:* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | 🞎PCR  🞎Culture  🞎Other, *Specify:*  \_\_\_\_\_\_\_\_\_\_\_\_\_\_ | 🞎Positive  🞎Negative  🞎N/A | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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| **MEDICATION: While hospitalised or at discharge, were any of the following administered**? |
| **Antiviral agent?** 🞎YES 🞎NO 🞎 N/A **If YES, specify:** oRibavirin   oLopinavir/Ritonavir  oInterferon alpha oInterferon beta  oNeuraminidase inhibitor **if YES:** Which \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_   oOther \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Antibiotic?** 🞎YES 🞎NO 🞎N/A **If YES:** specify type(s):  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_  **Corticosteroid?** 🞎YES 🞎NO 🞎N/A **If YES, Route:** 🞎 Oral 🞎 Intravenous 🞎 Inhaled  **If YES, please provide type and dose: \_\_\_\_\_\_\_\_\_\_\_**  **Antifungal agent?** 🞎YES 🞎NO 🞎N/A  **If YES:** which  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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| **TREATMENT: At ANY time during hospitalisation, did the patient receive/undergo:** |
| **ICU or High Dependency Unit admission?** 🞎YES 🞎NO 🞎N/A……..….… If YES, total duration: \_\_\_\_\_\_\_\_\_days  Date of ICU admission:[\_D\_][\_D\_]/[\_M\_][\_M\_]/[\_2\_][\_0\_][\_Y\_][\_Y\_] 🞎N/A  ICU discharge date: [\_D\_][\_D\_]/[\_M\_][\_M\_]/[\_2\_][\_0\_][\_Y\_][\_Y\_] 🞎N/A  **Oxygen therapy?** 🞎YES 🞎NO 🞎N/A  **Non-invasive ventilation?** *(e.g. BIPAP, CPAP)* 🞎YES 🞎NO 🞎N/A  **Invasive ventilation** *(Any)***?** 🞎YES 🞎NO 🞎N/A If YES, total duration: \_\_\_\_\_\_\_\_\_days  **Prone Ventilation?** 🞎YES 🞎NO 🞎N/A  **Inhaled Nitric Oxide?** 🞎YES 🞎NO 🞎N/A  **Tracheostomy inserted?** 🞎YES 🞎NO 🞎N/A  **Extracorporeal (ECMO) support?** 🞎YES 🞎NO 🞎N/A If YES, total duration: \_\_\_\_\_\_\_\_\_days  **Renal replacement therapy (RRT) or dialysis?** 🞎YES 🞎NO 🞎N/A  **Inotropes/vasopressors?** 🞎YES 🞎NO 🞎N/A If YES, total duration: \_\_\_\_\_\_\_\_\_days  **OTHER intervention or procedure** *(please specify)***:** |

**OUTCOME CASE RECORD FORM Page 3 of 5**

**OUTCOME CASE RECORD FORM Page 4 of 5**

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| **COMPLICATIONS: At any time during hospitalisation did the patient experience:** |
| |  |  |  |  | | --- | --- | --- | --- | | Viral pneumonia | 🞎YES 🞎NO 🞎N/A | Cardiac arrest | 🞎YES 🞎NO 🞎N/A | | Bacterial pneumonia | 🞎YES 🞎NO 🞎N/A | Bacteraemia | 🞎YES 🞎NO 🞎N/A | | Acute Respiratory Distress Syndrome | 🞎YES 🞎NO 🞎N/A | Coagulation disorder / Disseminated Intravascular Coagulation | 🞎YES 🞎NO 🞎N/A | | Cryptogenic organizing pneumonia (COP) | 🞎YES 🞎NO 🞎N/A | Anaemia | 🞎YES 🞎NO 🞎N/A | | Pneumothorax | 🞎YES 🞎NO 🞎N/A | Rhabdomyolysis / Myositis | 🞎YES 🞎NO 🞎N/A | | Pleural effusion | 🞎YES 🞎NO 🞎N/A | Acute renal injury/acute renal failure | 🞎YES 🞎NO 🞎N/A | | Bronchiolitis | 🞎YES 🞎NO 🞎N/A | Gastrointestinal haemorrhage | 🞎YES 🞎NO 🞎N/A | | Meningitis / Encephalitis | 🞎YES 🞎NO 🞎N/A | Pancreatitis | 🞎YES 🞎NO 🞎N/A | | Seizure | 🞎YES 🞎NO 🞎N/A | Liver dysfunction | 🞎YES 🞎NO 🞎N/A | | Stroke / Cerebrovascular accident | 🞎YES 🞎NO 🞎N/A | Hyperglycaemia | 🞎YES 🞎NO 🞎N/A | | Congestive heart failure | 🞎YES 🞎NO 🞎N/A | Hypoglycaemia | 🞎YES 🞎NO 🞎N/A | | Endocarditis/Myocarditis/  Pericarditis | 🞎YES 🞎NO 🞎N/A | Other | 🞎YES 🞎NO 🞎N/A | | Cardiac arrhythmia | 🞎YES 🞎NO 🞎N/A | If yes, specify:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | Cardiac ischemia | 🞎YES 🞎NO 🞎N/A | |

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| **STUDY PARTICIPATION** |
| Is / Has the participant being 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 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**Page 5 of 5**

**OUTCOME CASE RECORD FORM Page 5 of 5**

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| **OUTCOME** |
| **Outcome:** ☐ Discharged alive expected to survive ☐ Hospitalization ☐ Transfer to other facility ☐ Death  ☐ Palliative discharge ☐ Unknown  **Outcome date:** [\_D\_][\_D\_]/[\_M\_][\_M\_]/[\_2\_][\_0\_][\_Y\_][\_Y\_] ☐N/A  **If Discharged alive:**  **Ability to self-care at discharge versus before illness:** 🞎 Same as before illness 🞎 Worse 🞎 Better ☐N/A  **If Discharged alive: Post-discharge treatment:**  **Oxygen therapy?** 🞎 YES 🞎 NO 🞎 N/A **Dialysis/renal treatment?** 🞎 YES 🞎 NO 🞎 N/A  **Other intervention or procedure?** 🞎 YES 🞎 NO 🞎 N/A  **If YES: Specify** *(multiple permitted): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*  **If Transferred: Facility name:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 🞎 N/A  **If Transferred: Is the transfer facility a study site?** 🞎 YES 🞎 NO 🞎 N/A  **If a Study Site: Participant ID # at new facility:** 🞎 Same as above  🞎 Different: [\_\_\_][\_\_\_][\_\_\_] – [\_\_\_][\_\_\_][\_\_\_][\_\_\_] 🞎N/A |

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| **TRAVEL (addition countries to those listed on COR CRF page 2 of 3) Did the patient travel in the 14 days prior to first symptom onset*:*** |
| Country:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ City/Geographic area: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Return Date *(DD/MM/20YY):* \_\_\_\_ /\_\_\_\_ /20\_\_\_\_\_  Country:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ City/Geographic area: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Return Date *(DD/MM/20YY):* \_\_\_\_ /\_\_\_\_ /20\_\_\_\_\_  Country:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ City/Geographic area: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Return Date *(DD/MM/20YY):* \_\_\_\_ /\_\_\_\_ /20\_\_\_\_\_  Country:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ City/Geographic area: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Return Date *(DD/MM/20YY):* \_\_\_\_ /\_\_\_\_ /20\_\_\_\_\_  Country:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ City/Geographic area: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Return Date *(DD/MM/20YY):* \_\_\_\_ /\_\_\_\_ /20\_\_\_\_\_ |

**TRAVEL AND ANIMAL EXPOSURE CASE RECORD FORM Page 1 of 1**

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| **ANIMAL EXPOSURES:**  **Did the patient have contact with live/dead animals, raw meat or insect bites in the 14 days prior to first symptom onset?**  If YES, specify the animal/insect, type of contact and date of exposure (DD/MM/YYYY). *(Complete each line)* | | |
| Bird/Aves (e.g. chickens, turkeys, ducks) | 🞎YES 🞎NO 🞎N/A |  |
| Bat | 🞎YES 🞎NO 🞎N/A |  |
| Livestock (e.g. goats, cattle, camels) | 🞎YES 🞎NO 🞎N/A |  |
| Horse | 🞎YES 🞎NO 🞎N/A |  |
| Hare/ Rabbit | 🞎YES 🞎NO 🞎N/A |  |
| Pigs | 🞎YES 🞎NO 🞎N/A |  |
| Non-human primates | 🞎YES 🞎NO 🞎N/A |  |
| Rodent (e.g. rats, mice, squirrels) | 🞎YES 🞎NO 🞎N/A |  |
| Insect or tick bite (e.g. tick, flea, mosquito) | 🞎YES 🞎NO 🞎N/A |  |
| Reptile / Amphibian | 🞎YES 🞎NO 🞎N/A |  |
| Domestic animals living in his/her home (e.g. cats, dogs, other) | 🞎YES 🞎NO 🞎N/A |  |
| Animal faeces or nests | 🞎YES 🞎NO 🞎N/A |  |
| Sick animal or dead animal | 🞎YES 🞎NO 🞎N/A |  |
| Raw animal meat / animal blood | 🞎YES 🞎NO 🞎N/A |  |
| Skinned, dressed or eaten wild game | 🞎YES 🞎NO 🞎N/A |  |
| Visit to live animal market, farm or zoo | 🞎YES 🞎NO 🞎N/A |  |
| Participated in animal surgery or necropsy | 🞎YES 🞎NO 🞎N/A |  |
| Other animal contacts: | 🞎YES 🞎NO 🞎N/A |  |