NOVEL CORONAVIRUS (nCoV)

ACUTE RESPIRATORY INFECTION CLINICAL CHARACTERISATION DATA TOOL

DESIGN OF THIS CASE RECORD FORM (CRF)

This CRF is divided into a "CORE" form and a "DAILY" form for daily laboratory and clinical data.

Complete the CORE CRF + complete the DAILY CRF on the first day of hospital admission and on ICU admission, and daily upto discharge or death.

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 3 digit site code and a 4 digit participant number.
  You can obtain a site code and registering on the data management system by contacting *ncov@isaric.org*.
  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.
- Data should be entered to the central electronic REDCap database at https://ncov.medsci.ox.ac.uk or to your site/network's independent database. Printed paper CRFs may be used for later transfer of the data onto the electronic database.
- In the case of a participant transferring between 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.
- If using paper CRFs, we recommend writing clearly in 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.
- Please transfer all paper CRF data to the electronic database. All paper CRFs needs to be stored locally, do not send any forms with patient identifiable information to us via e-mail or post. All data should be transferred to the secure electronic database.
- Please enter data on the electronic data capture system at https://redcap.medsci.ox.ac.uk/. If your site would like to collect data independently, we are happy to support the establishment of locally hosted databases.
- Please contact us at *ncov@isaric.org* If we can help with databases, if you have comments and to let us know that you are using the forms.

CORE CASE RECORD FORM

COMPLICATIONS: At any time during hospitalisation did the patient experience:							
Viral pneumonitis	☐ YES	☐ NO	☐N/A	**Cardiac arrest**	☐ YES	☐ NO	☐N/A
Bacterial pneumonia	☐ YES	☐ NO	☐N/A	**Bacteremia**	☐ YES	☐ NO	☐N/A
Acute Respiratory Distress Syndrome	☐ YES	☐ NO	☐N/A	**Coagulation disorder / Disseminated Intravascular Coagulation**	☐ YES	☐ NO	☐N/A
IF yes, specify: ☐ Mild ☐ Moderate ☐ Severe ☐ Unknown				**Anemia**	☐ 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
Cryptogenic organizing pneumonia (COP)	☐ YES	☐ NO	☐N/A	**Gastrointestinal haemorrhage**	☐ YES	☐ NO	☐N/A
Bronchiolitis	☐ YES	☐ NO	☐N/A	**Pancreatitis**	☐ YES	☐ NO	☐N/A
Meningitis / Encephalitis	☐ YES	☐ NO	☐N/A	**Liver dysfunction**	☐ YES	☐ NO	☐N/A
Seizure	☐ YES	☐ NO	☐N/A	**Hyperglycemia**	☐ YES	☐ NO	☐N/A
Stroke / Cerebrovascular accident	☐ YES	☐ NO	☐N/A	**Hypoglycemia**	☐ YES	☐ NO	☐N/A
Congestive heart failure	☐ YES	☐ NO	☐N/A	**Other**	☐ YES	☐ NO	☐N/A
Endocarditis / Myocarditis / Pericarditis	☐ YES	☐ NO	☐N/A	**If yes specify**: _____			
Cardiac arrhythmia	☐ YES	☐ NO	☐N/A	_____			
Cardiac ischaemia	☐ YES	☐ NO	☐N/A				

CORE CASE RECORD FORM

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

If yes, date of ICU admission: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] ☐N/A

date of ICU discharge: [_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 support? ☐YES ☐NO ☐N/A

Renal replacement therapy (RRT) or dialysis? ☐YES ☐NO ☐N/A

Inotropes/vasopressors? ☐YES ☐NO ☐N/A

If YES: First/Start date: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] ☐N/A

Last/End date: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] ☐N/A

OTHER intervention or procedure *(please specify)***:** _____

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

Antiviral agent? ☐YES ☐NO ☐N/A **If YES:** ☐Ribavirin ☐Lopinavir/Ritonavir ☐Interferon alpha ☐Interferon beta

☐ Neuraminidase inhibitor ☐Other _____

Antibiotic? ☐YES ☐NO ☐N/A

Corticosteroid? ☐YES ☐NO ☐N/A **If YES, Route:** ☐Oral ☐Intravenous ☐Inhaled

If YES, please provide type and dose: _____

Antifungal agent? ☐YES ☐NO ☐N/A

CORE CASE RECORD FORM

OUTCOME

Outcome: ☐ Discharged alive ☐ 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

CORE CASE RECORD FORM

TRAVEL: Did the patient travel in the 14 days prior to first symptom onset? If > 1 *location & date list:*
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_____

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? ☐YES ☐NO ☐N/A If yes, *Complete each line below.* *If YES, specify the animal/insect, type of contact and date of exposure (DD/MM/YYYY)* ⬇ *here:*		
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 feces 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	