

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 () 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.

DAILY CASE RECORD FORM (complete one form on admission, one form on admission to ICU, and daily up to 14 days or until discharge or death if earlier)

DAILY ASSESSMENT FORM (on admission, on any admission to ICU, then daily) – complete every line

DATE OF ASSESSMENT (DD/MM/YYYY): [_] [_] [_] / [_] [_] [_] / [_] [_] [_] [_] [_] [_]

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

Record the worst value (within the previous 24 hours (if Not Available write '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

AVPU Alert [_] Verbal [_] Pain [_] Unresponsive [_]

Glasgow Coma Score (GCS / 15) [_] [_]

Done YES NO Richmond Agitation-Sedation Scale (RASS) [_]

Done YES NO Riker Sedation-Agitation Scale (SAS) [_]

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 (between 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

Extra corporeal life support (ECLS)? YES NO N/A

High-flow nasal canula oxygen therapy 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

Tracheostomy inserted? YES NO N/A Prone positioning? YES NO N/A

Other intervention or procedure: YES NO N/A If YES, Specify: _____

DAILY CASE RECORD FORM (complete one form on admission, one form on admission to ICU, and daily up to 14 days or till discharge or death if earlier)

DAILY LABORATORY RESULTS (on admission, on any admission to ICU, then daily) – complete every line

DATE OF ASSESSMENT (DD/MM/YYYY): [_] [_] [_] [_] / [_] [_] [_] [_] / [_] [_] [_] [_]

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

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 **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 performed? YES NO N/A

IF Yes: Were infiltrates present? YES NO N/A