World Health Organization ISARIC

COVID-19 CORE CASE REPORT FORM

ACUTE RESPIRATORY INFECTION CLINICAL CHARACTERISATION DATA TOOL

DESIGN OF THIS CASE REPORT FORM (CRF)

This CRF is set up in modules to be used for recording data on the ISARIC_nCov Core Database or for independent studies.

Module 1 and Module 2 complete on the first day of presentation/admission or on first day of COVID-19 assessment.
Module 2 also complete on first day of admission to ICU or high dependency unit. In addition, complete daily for as many days as resources allow up to a maximum of 14 days. Continue to follow-up patients who transfer between wards.
Module 3 (Outcome) complete at 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 prospectively or retrospectively if the patient is enrolled after the admission date.
- Participant Identification Numbers consist of a 5 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.
- Printed paper CRFs may be used for later transfer of the data onto the electronic database.
- For participants who return for re-admission to the same site, **start a new form with the same Participant Identification Number**. Please check "YES-admitted previously" in the ONSET & ADMISSION section. Enter as 2 separate entries in the electronic database.
- For participants who transfer between two sites that are both collecting data on this form, it is preferred to have the data entered by a single site as a single admission, under the same Participant Identification Number. When this is not possible, the first site should record "Transfer to other facility" as an OUTCOME, and the second site should start a new form with a new patient number and indicate "YES-transferred" in ONSET & ADMISSION.
- Complete every line of every section, except where the instructions say to skip a section based on a response.
- Selections with circles (O) are single selection answers (choose one answer only). Selections with square boxes (☐) are multiple selection answers (choose as many answers as are applicable).
- Mark 'Not done' 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 to us. Data are accepted only via secure electronic database.
- Please enter data on the electronic data capture system at https://ncov.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 you need help with databases, if you have comments and to let us know that you are using the forms.

MODULE 1: PRESENTATION/ADMISSION CASE REPORT FORM

CLINICAL INCLUSION CRITERIA

Suspected or confirmed novel coronavirus (COVID-19) infection: O YES O NO

DEMOGRAPHICS

Clinical centre name:_____ **Country:**_____

Enrolment date /first COVID-19 assessment date: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]

Ethnic group *(check all that apply)*: ☐Arab ☐Black ☐East Asian ☐South Asian ☐ West Asian ☐Latin American ☐White

☐Aboriginal/First Nations ☐Other: _____ O Unknown

Employed as a Healthcare Worker? O YES O NO O Unknown **Employed in a microbiology laboratory?** O YES O NO O Unknown

Sex at Birth: O Male O Female O Not specified/Unknown **Age** [___][___][___]years OR [___][___]months

Pregnant? O YES O NO O Unknown **If YES: Gestational weeks assessment:** [___][___] weeks

POST PARTUM? O YES O NO O Unknown *(if NO or Unknown skip this section)*

Pregnancy Outcome: O Live birth O Still birth **Delivery date:** [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]

Baby tested for COVID-19/SARS-CoV-2 infection? O YES O NO O Unknown

If YES, result of test: O Positive O Negative O Unknown (If Positive, complete a separate CRF for baby)

INFANT – Less than 1 year old? O YES O NO *(If NO skip this section)*

Birth weight: [___][___].[___] O kg or O lbs O Unknown

Gestational outcome: O Term birth (≥37wk GA) O Preterm birth (<37wk GA) O Unknown

Breastfed? O YES-currently breastfeeding O YES-breastfeeding discontinued O NO O Unknown

Vaccinations appropriate for age/country? O YES O NO O Unknown

ONSET & ADMISSION

Onset date of first/earliest symptom: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]

Most recent presentation/admission date at this facility: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]

Was the patient admitted previously or transferred from any other facility during this illness episode?

O YES-admitted previously to this facility O YES–transferred from other facility O NO O Unknown

SIGNS AND SYMPTOMS AT HOSPITAL ADMISSION *(first available data at presentation/admission – within 24 hours)*

Temperature: [____][____][____].[____] O °C *or* O °F

HR: [____][____][____]beats/minute **RR:** [____][____]breaths/minute

Systolic BP: [___][___][___]mmHg **Diastolic BP:** [____][____][____]mmHg

Oxygen saturation: [___][___][___]% **On:** O Room air O Oxygen therapy O Unknown

Sternal capillary refill time >2sec. O YES O NO O Unknown **Height:** [___][___][___]cm **Weight:** [___][___][___]kg

MODULE 1: PRESENTATION/ADMISSION CASE REPORT FORM

SIGNS AND SYMPTOMS ON ADMISSION *(Unk = Unknown)*			
History of fever	O YES O NO O Unk	Fatigue / Malaise	O YES O NO O Unk
Cough O YES-non-productive O YES-productive O YES-with haemoptysis O NO O Unk		Anorexia	O YES O NO O Unk
		Altered consciousness/confusion	O YES O NO O Unk
Sore throat	O YES O NO O Unk	Muscle aches (myalgia)	O YES O NO O Unk
Runny nose (rhinorrhoea)	O YES O NO O Unk	Joint pain (arthralgia)	O YES O NO O Unk
Wheezing	O YES O NO O Unk	Inability to walk	O YES O NO O Unk
Shortness of breath	O YES O NO O Unk	Abdominal pain	O YES O NO O Unk
Lower chest wall indrawing	O YES O NO O Unk	Diarrhoea	O YES O NO O Unk
Chest pain	O YES O NO O Unk	Vomiting / Nausea	O YES O NO O Unk
Conjunctivitis	O YES O NO O Unk	Skin rash	O YES O NO O Unk
Lymphadenopathy	O YES O NO O Unk	Bleeding (Haemorrhage) O YES O NO O Unk If YES, specify site(s):	
Headache	O YES O NO O Unk		
Loss of smell (Anosmia)	O YES O NO O Unk	Other symptom(s) O YES O NO O Unk If YES, specify:	
Loss of taste (Ageusia)	O YES O NO O Unk		
Seizures	O YES O NO O Unk		

PRE-ADMISSION MEDICATION *(taken within 14 days of admission/presentation at healthcare facility)*	
Angiotensin converting enzyme inhibitors (ACE inhibitors)	O YES O NO O Unk
Angiotensin II receptor blockers (ARBs)	O YES O NO O Unk
Non-steroidal anti-inflammatory (NSAIDs)	O YES O NO O Unk
Oral steroids	O YES O NO O Unk If YES, agent(s):
Other immunosuppressant agents (not oral steroids)	O YES O NO O Unk If YES, agent(s):
Antivirals	O YES O NO O Unk If YES, agent(s):
Antibiotics	O YES O NO O Unk If YES, agent(s):
Other targeted COVID-19 Medications	O YES O NO O Unk If YES, agent(s):

CO-MORBIDITIES AND RISK FACTORS *(existing prior to admission and ongoing)*			
Chronic cardiac disease *(not hypertension)*	O YES O NO O Unk	Chronic hematologic disease	O YES O NO O Unk
Hypertension	O YES O NO O Unk	AIDS / HIV O YES-on ART O YES-not on ART O NO O Unk	
Chronic pulmonary disease *(not asthma)*	O YES O NO O Unk	Diabetes Mellitus O YES-Type 1 O YES -Type 2 O NO O Unk	
Asthma *(physician diagnosed)*	O YES O NO O Unk	Rheumatologic disorder	O YES O NO O Unk
Chronic kidney disease	O YES O NO O Unk	Dementia	O YES O NO O Unk
Obesity *(as defined by clinical staff)*	O YES O NO O Unk	Tuberculosis	O YES O NO O Unk
Moderate or severe liver disease	O YES O NO O Unk	Malnutrition	O YES O NO O Unk
Mild liver disease	O YES O NO O Unk	Smoking O YES O Never smoked O Former smoker O Unk	
Asplenia	O YES O NO O Unk	Other relevant risk factor(s) O YES O NO O Unk If YES, specify:	
Chronic neurological disorder	O YES O NO O Unk		
Malignant neoplasm	O YES O NO O Unk		

MODULE 2: DAILY CASE REPORT FORM

Complete on the day of admission or first COVID-19 investigation, and on the first day of ICU admission (if different from day of admission). In addition, depending on available resources, complete every day for a maximum of 14 days, or for days when biochemical results are available.

SIGNS AND SYMPTOMS *(Record the worst value between 00:00 to 24:00 on day of assessment)(worst=furthest from normal range)*

DATE OF ASSESSMENT *(DD/MM/YYYY):* [_D_][_D_]/[_M_][_M_]/[__2_][__0_][_Y_][_Y_]

Temperature: [___][___][___].[___] O°C *or* O°F **HR:** [___][___][___]beats/minute **RR:** [___][___][___]breaths/minute

Systolic BP: [___][___][___]mmHg **Diastolic BP:** [___][___][___]mmHg **Oxygen saturation SaO_2** [___][___][___]%

Any supplemental oxygen: FiO_2 *(0.21-1.0)* [___].[___][___] or [___][___] % or [___][___]L/min

Sternal capillary refill time >2seconds OYES ONO OUnknown

AVPU: Alert [___] Verbal[___] Pain [___] Unresponsive [___] **Glasgow Coma Score (GCS / 15)** [___][___]

Is the patient currently receiving, or has received *(between 00:00 to 24:00 on day of assessment)*

High-flow nasal cannula oxygen therapy? OYES ONO OUnknown

Non-invasive ventilation *(Any)*? OYES ONO OUnknown **If YES:** OBIPAP OCPAP OOther OUnknown

Invasive ventilation? OYES ONO OUnknown

Prone positioning? OYES ONO OUnknown

Inhaled Nitric Oxide? OYES ONO OUnknown

Tracheostomy inserted? OYES ONO OUnknown

Extra corporeal life support (ECLS/ ECMO)? OYES ONO OUnknown **If YES:** OVV OAV OCentral OUnknown

Renal replacement therapy (RRT) or dialysis? OYES ONO OUnknown

Any vasopressor/inotropic support? OYES ONO OUnknown *(if NO, select NO for the next 3 questions)*

Dopamine <5µg/kg/min OR Dobutamine OR milrinone OR levosimendan: OYES ONO

Dopamine 5-15µg/kg/min OR Epinephrine/Norepinephrine < 0.1µg/kg/min OR vasopressin OR phenylephrine: OYES ONO

Dopamine >15µg/k/min OR Epinephrine/Norepinephrine > 0.1µg/kg/min: OYES ONO

Neuromuscular blocking agents? OYES ONO OUnknown

Other intervention(s) or procedure(s)? OYES ONO OUnknown If YES, Specify: _____

_____

Current admission to ICU/ITU/IMC/HDU? OYES ONO OUnknown ***(Record the worst value on day of assessment)***

PaO_2 *(at time nearest to the FiO_2 recorded at top of page)* [___][___][___]OkPa *or* OmmHg ONot done

PaO_2 sample type: OArterial OCapillary OUnknown

From same blood gas record as PaO_2:

PCO_2 _____OkPa *or* OmmHg **| pH** _____ **| HCO_3-** _____mEq/L | **Base excess** _____ mmol/L

Richmond Agitation-Sedation Scale (RASS) [___] or **Riker Sedation-Agitation Scale (SAS)** [___] OUnknown

Mean Arterial Blood Pressure [___][___][___]mmHg OUnknown

Urine flow rate [___][___][___][___][___]mL/24 hours O Check if estimated OUnknown

MODULE 2: DAILY CASE REPORT FORM

Complete on the day of admission or first COVID-19 investigation, and on the first day of ICU admission (if different from day of admission). In addition, depending on available resources, complete every day for a maximum of 14 days, or for days when biochemical results are available.

LABORATORY RESULTS (on admission, on any admission to ICU, then daily) – 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'):

LABORATORY RESULTS (**record units if different from those listed)*

Parameter	Value*	Not done	Parameter	Value*	Not done
Haemoglobin (g/L)		O	Urea (BUN) (mmol/L)		O
WBC count (x10^9/L)		O	Lactate (mmol/L)		O
Lymphocyte count (10^9/L)		O	Creatinine (µmol/L)		O
Neutrophil count (10^9/L)		O	Sodium (mmol/L)		O
Haematocrit (%)		O	Potassium (mmol/L)		O
Platelets (x10^9/L)		O	Procalcitonin (ng/mL)		O
APTT (seconds)*)*		O	CRP (mg/L)		O
APTR		O	LDH (U/L)		O
PT (seconds)		O	Creatine kinase (U/L)		O
INR		O	Troponin I (ng/mL)		O
ALT/SGPT (U/L)		O	D-dimer (mg/L)		O
Total bilirubin (µmol/L)		O	Ferritin (ng/mL)		O
AST/SGOT (U/L)		O	IL-6 (pg/mL)		O
Glucose (mmol/L)		O			

MODULE 3: OUTCOME CASE REPORT FORM

TREATMENT: At ANY time during hospitalisation, did the patient receive/undergo:

Any Oxygen therapy? O YES O NO O Unknown **If YES, total duration:** _____days O Unknown

Maximum O_2 flow volume: O <2 L/min O 2-5 L/min O 6-10 L/min O 11-15 L/min O >15 L/min

Non-invasive ventilation? *(Any)* O YES O NO O Unknown **If YES, total duration:** _____days O Unknown

Invasive ventilation? *(Any)* O YES O NO O Unknown **If YES, total duration:** _____days O Unknown

Prone Positioning? O YES O NO O Unknown **If YES, total duration:** _____days O Unknown

Inhaled Nitric Oxide? O YES O NO O Unknown

Tracheostomy inserted? O YES O NO O Unknown

Extracorporeal support (ECMO)? O YES O NO O Unknown **If YES, total duration:** _____days O Unknown

Renal replacement therapy (RRT) or dialysis? O YES O NO O Unknown

Inotropes/vasopressors? O YES O NO O Unknown **If YES, total duration:** _____days O Unknown

ICU or High Dependency Unit admission? O YES O NO O Unknown **If YES, total duration:** _____days O Unknown

If YES, date of ICU admission: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] O Unknown

date of ICU discharge: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] O Unknown

COMPLICATIONS: At any time during hospitalisation did the patient experience: *(Unk = Unknown)*

Viral pneumonia/pneumonitis	O YES O NO O Unk	Stroke / Cerebrovascular accident	O YES O NO O Unk
Bacterial pneumonia	O YES O NO O Unk	Meningitis / Encephalitis	O YES O NO O Unk
Acute Respiratory Distress Syndrome	O YES O NO O Unk	Bacteremia	O YES O NO O Unk
If YES, specify: O Mild O Moderate O Severe O Unk		Coagulation disorder / DIC	O YES O NO O Unk
Pneumothorax	O YES O NO O Unk	Pulmonary embolism	O YES O NO O Unk
Pleural effusion	O YES O NO O Unk	Anemia	O YES O NO O Unk
Cryptogenic organizing pneumonia (COP)	O YES O NO O Unk	Rhabdomyolysis / Myositis	O YES O NO O Unk
Bronchiolitis	O YES O NO O Unk	Acute renal injury/ Acute renal failure	O YES O NO O Unk
Cardiac arrest	O YES O NO O Unk	Gastrointestinal haemorrhage	O YES O NO O Unk
Myocardial infarction	O YES O NO O Unk	Pancreatitis	O YES O NO O Unk
Cardiac ischaemia	O YES O NO O Unk	Liver dysfunction	O YES O NO O Unk
Cardiac arrhythmia	O YES O NO O Unk	Hyperglycemia	O YES O NO O Unk
Myocarditis / Pericarditis	O YES O NO O Unk	Hypoglycemia	O YES O NO O Unk
Endocarditis	O YES O NO O Unk	Other	
Cardiomyopathy	O YES O NO O Unk	If YES specify:	
Congestive heart failure	O YES O NO O Unk		
Seizure	O YES O NO O Unk		

MODULE 3: OUTCOME CASE REPORT FORM

DIAGNOSTICS

Was patient clinically diagnosed with COVID-19? OYES ONO OUnknown

Was pathogen testing done during this illness episode? OYES *(complete section)* ONO OUnknown

Coronavirus: OPositive ONegative ONot done **If Positive:** OCOVID-2019/ SARS-CoV2 OMERS CoV
OOther CoV: ____________________ OUnknown

Influenza : OPositive ONegative ONot done **If Positive:** OA/H3N2 OA/H1N1pdm09 OA/H7N9 OA/H5N1 OA-not typed OB
OOther:__________________________ OUnknown

RSV: OPositive ONegative ONot done

Adenovirus: OPositive ONegative ONot done

Bacteria: OPositive ONegative ONot done **If Positive, specify**: _________________ ________________ OUnknown

Other pathogen/s detected: OYES ONO OUnknown **If YES, specify all:**_________________________________OUnknown

****

Clinical pneumonia diagnosed? OYES ONO OUnknown

Chest X-Ray performed? OYES ONO OUnknown **If Yes: Were infiltrates present?** OYES ONO OUnknown

CT performed? OYES ONO OUnknown **If Yes: Were infiltrates present?** OYES ONO OUnknown

Collection Date *(DD/MM/YYYY)*	Biospecimen Type	Laboratory test Method	Result	Pathogen Tested/Detected
_D_ _D_ /_M_ _M_ /20_Y_ _Y_	ONasal/NP swab OThroat swab OCombined nasal/NP+throat swab OSputum OBAL OETA OUrine OFeces/rectal swab OBlood OOther, *Specify:* ___________________	OPCR OCulture OOther, *Specify:* _____________	OPositive ONegative OUnknown	________________
_D_ _D_ /_M_ _M_ /20_Y_ _Y_	ONasal/NP swab OThroat swab OCombined nasal/NP+throat swab OSputum OBAL OETA OUrine OFeces/rectal swab OBlood OOther, *Specify:* ___________________	OPCR OCulture OOther, *Specify:* _____________	OPositive ONegative OUnknown	________________
_D_ _D_ /_M_ _M_ /20_Y_ _Y_	ONasal/NP swab OThroat swab OCombined nasal/NP+throat swab OSputum OBAL OETA OUrine OFeces/rectal swab OBlood OOther, *Specify:* ___________________	OPCR OCulture OOther, *Specify:* _____________	OPositive ONegative OUnknown	________________
_D_ _D_ /_M_ _M_ /20_Y_ _Y_	ONasal/NP swab OThroat swab OCombined nasal/NP+throat swab OSputum OBAL OETA OUrine OFaeces/rectal swab OBlood OOther, *Specify:* ___________________	OPCR OCulture OOther, *Specify:* _____________	OPositive ONegative OUnknown	________________
_D_ _D_ /_M_ _M_ /20_Y_ _Y_	ONasal/NP swab OThroat swab OCombined nasal/NP+throat swab OSputum OBAL OETA ☐Urine OFeces/rectal swab OBlood OOther, *Specify:* ___________________	OPCR OCulture OOther, *Specify:* _____________	OPositive ONegative OUnknown	________________

MODULE 3: OUTCOME CASE REPORT FORM

MEDICATION: While hospitalised or at discharge, were any of the following administered? *(Unk=Unknown)*

Antiviral or COVID-19 targeted agent? OYES ONO OUnknown **If YES, specify all agents and duration:**

☐**Ribavirin** **Date commenced** [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] **Duration**: _____ days OUnk

☐ **Lopinavir/Ritonavir** **Date commenced** [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] **Duration**: _____ days OUnk

☐**Remdesivir** **Date commenced** [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] **Duration**: _____ days OUnk

☐**Interferon alpha** **Date commenced** [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] **Duration**: _____ days OUnk

☐**Interferon beta** **Date commenced** [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] **Duration**: _____ days OUnk

☐ **Chloroquine/hydroxychloroquine** **Date commenced** [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] **Duration**: _____days OUnk

☐**Other** _____ **Date commenced** [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] **Duration**: _____days OUnk

****

Antibiotic? OYES ONO OUnk **If yes, specify all:**

Agent:_____ **Date commenced** [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] **Duration**: ____ days OUnk

Agent:_____ **Date commenced** [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] **Duration**: ____ days OUnk

Agent:_____ **Date commenced** [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] **Duration**: ____ days OUnk

****

Corticosteroid? OYES ONO OUnk **If YES, Route:** ☐Oral ☐Intravenous (IV) ☐Inhaled OUnk

If YES Oral or IV, please provide agent: _____ **and max. daily dose & unit**:_____

Date commenced [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] OUnk **Duration**: _____ days OUnk

****

Heparin? OYES ONO OUnk **If YES, Route:** ☐Subcutaneous ☐Intravenous (IV) OUnk

If YES: ☐Unfractionated ☐Low molecular weight ☐Fondaparinux OUnk **Maximum daily dose & unit**:_____

Date commenced [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] OUnk **Duration**: _____ days OUnk

****

Antifungal agent? OYES ONO OUnk

****

Other treatments administered for COVID-19 including experimental or compassionate use? OYES ONO OUnk

If yes, specify agent, maximum daily does and duration:

Agent: _____ **Maximum daily dose & unit**: _____ OUnk

Date of commencement [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] OUnk **Duration**: _____ days OUnk

Agent:_____ **Maximum daily dose & unit**: _____ OUnk

Date of commencement [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] OUnk **Duration**: _____ days OUnk

OUTCOME

Outcome: ODischarged alive OHospitalised OTransfer to other facility ODeath OPalliative discharge OUnknown

Outcome date: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] OUnknown

If Discharged alive:

Ability to self-care at discharge versus before illness: OSame as before illness OWorse OBetter OUnknown

Post-discharge treatment: Oxygen therapy? OYES ONO OUnknown