



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 <u>COVID-19 assessment</u>. **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 <u>ncov@isaric.org</u> if you need help with databases, if you have comments and to let us know that you are using the forms.





PARTICIPANT IDENTIFICATION #: []	1][][]	[]	II .	lf 1	ſ	
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MODULE 1: PRESENTATION/ADMISSION CASE REPORT FORM

CLINICAL INCLUSION CRITERIA
Suspected or confirmed novel coronavirus (COVID-19) infection: OYES ONO
DEMOGRAPHICS
Clinical centre name:Country:
Enrolmentdate /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: OUnknown
Employed as a Healthcare Worker? OYES ONO OUnknown Employed in a microbiology laboratory? OYES ONO OUnknown
Sex at Birth: OMale OFemale ONot specified/Unknown Age [][]years OR [][]months
Pregnant? OYES ONO OUnknown If YES: Gestational weeks assessment: [][] weeks
POST PARTUM? OYES ONO OUnknown (if NO or Unknown skip this section)
Pregnancy Outcome: OLive birth OStill birth Delivery date: [D][D]/[M][M]/[2][0][Y]
Baby tested for COVID-19/SARS-CoV-2 infection? OYES ONO OUnknown
If YES, result of test: OPositive ONegative OUnknown (If Positive, complete a separate CRF for baby)
INFANT – Less than 1 year old? OYES ONO (If NO skip this section)
Birth weight: []Ckg or Olbs OUnknown
Gestational outcome: O Term birth (≥37wk GA) OPreterm birth (<37wk GA) OUnknown
Breastfed? OYES-currently breastfeeding OYES-breastfeeding discontinued ONO OUnknown
Vaccinations appropriate for age/country? OYES ONO OUnknown
ONSET & ADMISSION
Onset date of first/earliest symptom: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]
Most recent presentation/admission date at this facility: <code>[_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]</code>
Was the patient admitted previously or transferred from any other facility during this illness episode?
OYES-admitted previously to this facility OYES—transferred from other facility ONO OUnknown
SIGNS AND SYMPTOMS AT HOSPITAL ADMISSION (first available data at presentation/admission – within 24 hours)
Temperature: [][].[]O°C or O°F
HR: [][]beats per minute RR: [][]breaths per minute
Systolic BP: [][]mmHg Diastolic BP: [][]mmHg
Oxygen saturation: [][]% On: ORoom air OOxygen therapy OUnknown
Sternal capillary refill time >2sec. OYES ONO OUnknown Height: [][]cm Weight: [][]kg





MODULE 1: PRESENTATION/ADMISSION CASE REPORT FORM

SIGNS AND SYMPTOMS ON ADMISSION (Unk = Unknown)								
History of fever	OYES ONO OUnk	Fatigue / Malaise	OYES ONO OUnk					
Cough OYES-non-productive OYES-productive		Anorexia	OYES ONO OUnk					
OYES-with haemoptys	sis ONO OUnk	Altered consciousness/confusion	OYES ONO OUnk					
Sore throat	OYES ONO OUnk	Muscle aches (myalgia)	OYES ONO OUnk					
Runny nose (rhinorrhoea)	OYES ONO OUnk	Joint pain (arthralgia)	OYES ONO OUnk					
Wheezing	OYES ONO OUnk	Inability to walk	OYES ONO OUnk					
Shortness of breath	OYES ONO OUnk	Abdominal pain	OYES ONO OUnk					
Lower chest wall indrawing	OYES ONO OUnk	Diarrhoea	OYES ONO OUnk					
Chest pain	OYES ONO OUnk	Vomiting / Nausea	OYES ONO OUnk					
Conjunctivitis	OYES ONO OUnk	Skin rash	OYES ONO OUnk					
Lymphadenopathy	OYES ONO OUnk	Bleeding (Haemorrhage)	OYES ONO OUnk					
Headache	OYES ONO OUnk	If YES, specify site(s):						
Loss of smell (Anosmia)	OYES ONO OUnk	Other symptom(s)	OYES ONO OUnk					
Loss of taste (Ageusia)	OYES ONO OUnk	If YES, specify:						
Seizures	OYES ONO OUnk							

PRE-ADMISSION MEDICATION (taken within 14 days of admission/presentation at healthcare facility)									
Angiotensin converting enzyme inhibitors (ACE inhibitors)	OYES ONO OUnk								
Angiotensin II receptor blockers (ARBs)	OYES ONO OUnk								
Non-steroidal anti-inflammatory (NSAIDs)	OYES ONO OUnk								
Oral steroids	OYES ONO OUnk If YES, agent(s):								
Other immunosuppressant agents (not oral steroids)	OYES ONO OUnk If YES, agent(s):								
Antivirals	OYES ONO OUnk If YES, agent(s):								
Antibiotics	OYES ONO OUnk If YES, agent(s):								
Other targeted COVID-19 Medications	OYES ONO OUnk If YES, agent(s):								

CO-MORBIDITIES AND RISK FACTORS (existing prior to admission and ongoing)										
Chronic cardiac disease (not hypertension)	OYES ONO	OUnk	Chronic hematologic disease	OYES ONG	O Unk					
Hypertension	OYES ONO	OUnk	AIDS / HIV OYES-on ART OYES-no	ot on ART ONC	OUnk					
Chronic pulmonary disease (not asthma)	OYES ONO	O Unk	Diabetes Mellitus OYES-Type 1 OYE	S -Type 2 ONC	OUnk					
Asthma (physician diagnosed)	OYES ONO	OUnk	Rheumatologic disorder	OYES ONO	OUnk					
Chronic kidney disease	OYES ONO	OUnk	Dementia	OYES ONO	OUnk					
Obesity (as defined by clinical staff)	OYES ONO	OUnk	Tuberculosis	OYES ONO	OUnk					
Moderate or severe liver disease	OYES ONO	OUnk	Malnutrition	OYES ONO	OUnk					
Mild liver disease	OYES ONO	O Unk	Smoking OYES ONever smoked O	Former smoker	O Unk					
Asplenia	OYES ONO	OUnk	Other relevant risk factor(s)	OYES ONO	OUnk					
Chronic neurological disorder	OYES ONO	OUnk	If YES, specify:							
Malignant neoplasm	OYES ONO	OUnk								





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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 per minute RR: [][] breaths per minute							
Systolic BP: [][]mmHg Diastolic BP: [][]mmHg Oxygen saturation SaO ₂ [][]%							
Any supplemental oxygen: FiO₂ (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							
PaO₂ sample type: OArterial OCapillary OUnknown							
From same blood gas record as PaO₂:							
PCO ₂ OkPa <i>or</i> 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							





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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						

Record the worst value between 00:00 to 24:00 on day of assessment (if Not Available write 'N/A'):

DATE OF ASSESSMENT (DD/MM/YYYY): [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]

Parameter	Value*	Not done	Parameter	Value*	Not done
Haemoglobin (g/L)		0	Urea (BUN) (mmol/L)		0
WBC count (x10 ⁹ /L)		0	Lactate (mmol/L)		0
Lymphocyte count (10 ⁹ /L)		0	Creatinine (µmol/L)		0
Neutrophil count (10 ⁹ /L)		0	Sodium (mmol/L)		0
Haematocrit (%)		0	Potassium (mmol/L)		0
Platelets (x10 ⁹ /L)		0	Procalcitonin (ng/mL)		0
APTT (seconds))		0	CRP (mg/L)		0
APTR		0	LDH (U/L)		0
PT (seconds)		0	Creatine kinase (U/L)		0
INR		0	Troponin I (ng/mL)		0
ALT/SGPT (U/L)		0	D-dimer (mg/L)		0
Total bilirubin (μmol/L)		0	Ferritin (ng/mL)		0
AST/SGOT (U/L)		0	IL-6 (pg/mL)		0
Glucose (mmol/L)		0			





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MODULE 3: OUTCOME CASE REPORT FORM

TREATMENT: At ANY time during hospitalisation, did the patient receive/undergo:									
Any Oxygen therapy? OYES ONO OUnknown If YES, total duration:days OUnknown									
Maximum O ₂ flow volume: O <2 L/min O2-5 L/min O6-10 L/min O11-15 L/min O>15 L/min									
Non-invasive ventilation? (Any)	OYES ONO	OUnknown	If YES, total duration:	_days OUnknown					
Invasive ventilation? (Any)	OYES ONO	OUnknown	If YES, total duration:	_days O Unknown					
Prone Positioning?	OYES ONO	OUnknown	If YES, total duration:	_days O Unknown					
Inhaled Nitric Oxide?	OYES ONO	OUnknown							
Tracheostomy inserted?	OYES ONO	OUnknown							
Extracorporeal support (ECMO)?	OYES ONO	OUnknown	If YES, total duration:	days O Unknown					
Renal replacement therapy (RRT)	or dialysis?	YES ONO OUnknown	1						
Inotropes/vasopressors?	OYES ONO	OUnknown	If YES, total duration:	days O Unknown					
ICU or High Dependency Unit adm	ICU or High Dependency Unit admission? OYES ONO OUnknown If YES, total duration:days OUnknown								
If YES, date of ICU	If YES, date of ICU admission: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]								
date of ICU discharge: [_D_](_M_](_M_]/[_2_](_0_](_Y_](_Y_)									

Viral pneumonia/pneumonitis	OYES ONO	O Unk	Stroke / Cerebrovascular accident		ONO	OUnk
Bacterial pneumonia	OYES ONO	OUnk	Meningitis / Encephalitis	O YES	ONO	OUnk
Acute Respiratory Distress Syndrome	OYES ONO	OUnk	Bacteremia	O YES	ONO	OUnk
If YES, specify: O Mild O Modera	te O Severe	O Unk	Coagulation disorder / DIC	O YES	ONO	OUnk
Pneumothorax	OYES ONO	OUnk	Pulmonary embolism	O YES	ONO	O Unk
Pleural effusion	OYES ONO	OUnk	Anemia	O YES	ONO	OUnk
Cryptogenic organizing pneumonia (COP)	OYES ONO	OUnk	Rhabdomyolysis / Myositis	O YES	ONO	O Unk
Bronchiolitis	OYES ONO	O Unk	Acute renal injury/ Acute renal failure	O YES	ONO	OUnk
Cardiac arrest	OYES ONO	OUnk	Gastrointestinal haemorrhage	O YES	ONO	OUnk
Myocardial infarction	OYES ONO	O Unk	Pancreatitis	O YES	ONO	O Unk
Cardiac ischaemia	OYES ONO	O Unk	Liver dysfunction	O YES	ONO	OUnk
Cardiac arrhythmia	OYES ONO	O Unk	Hyperglycemia	O YES	ONO	O Unk
Myocarditis / Pericarditis	OYES ONO	OUnk	Hypoglycemia	O YES	ONO	OUnk
Endocarditis	OYES ONO	OUnk	Other			
Cardiomyopathy	OYES ONO	OUnk	If YES specify:	•		
Congestive heart failure	OYES ONO	OUnk				
Seizure	OYES ONO	Olink				





MODULE 3: OUTCOME CASE REPORT FORM

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DIAGNOSTICS								
Was patient clinically dia	agnosed with COVID-19? OYES ONO	OUnknown						
Was pathogen testing do	one during this illness episode? OYE	S (complete section)	ONO OUnk	nown				
Coronavirus: OPositive	ONegative ONot done If Positive: OCC	OVID-2019/ SARS-Co\	/2 OMERS C	CoV				
	OOt	her CoV:	O	Jnknown				
Influenza : O Positive C	Negative ONot done If Positive: OA/H3N	2 O A/H1N1pdm09 O	A/H7N9 O A/H	5N1 O A-not typed O B				
		OOther:		OUnknown				
RSV: OPositive ONega	itive ONot done							
Adenovirus: OPositive	ONegative ONot done							
Bacteria: OPositive C	Negative ONot done If Positive, specify:	:		OUnknown				
Other pathogen/s detected: OYES ONO OUnknown If YES, specify all:								
*******	*****							
Clinical pneumonia diagnos	sed? 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 OCombined nasal/NP+throat swab OSputum OBAL OFECES/rectal swab OOther, Specify:	OPCR OCulture OOther, Specify:	O Positive O Negative O Unknown					
D D / M M /20 Y Y	ONasal/NP swab OCombined nasal/NP+throat swab OSputum OBAL OFECES/rectal swab OOther, Specify:	OPCR OCulture Other, Specify:	O Positive O Negative O Unknown					
D D / M M /20 Y Y	ONasal/NP swab OCombined nasal/NP+throat swab OSputum OBAL OFECES/rectal swab OOther, Specify:	OPCR OCulture Other, Specify:	O Positive O Negative O Unknown					
<u>D D / M M /20 Y Y</u>	ONasal/NP swab OCombined nasal/NP+throat swab OSputum OBAL OFACES/rectal swab OOther, Specify:	OPCR OCulture Other, Specify:	OPositive ONegative OUnknown					
D D / M M /20 Y Y	ONasal/NP swab OCombined nasal/NP+throat swab OSputum OBAL OFeces/rectal swab 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 [□][□]/[M][M]/[2][0][Y][Y] Duration: days OUnk							
□ Lopinavir/Ritonavir Date commenced [□][□]/[M][M]/[2][0][Y][Y] Duration: days OUnk							
□Remdesivir Date commenced [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] Duration: days ○Unk							
□Interferon alpha Date commenced [□][□]/[M][M]/[2][0][Y][Y] Duration: days ○Unk							
□Interferon beta Date commenced [□][□]/[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 [□][□]/[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:							
Agent:							
Corticosteroid? OYES ONO OUnk If YES, Route: Oral Ontravenous (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 ○Unk 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_]							
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							