



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 <u>ncov@isaric.org</u>.
 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 <u>ncov@isaric.org</u> If we can help with databases, if you have comments and to let us know that you are using the forms.



CLINICAL INCLUSION CRITERIA

Suspected or proven acute novel Coronavirus (nCoV) infection as main cause for admission:

EPIDEMIOLOGICAL FACTORS	
In the 14 days before onset of illness had the patient any of the following:	
A history of travel to an area with documented cases of nCoV infection	🗆 YES 🗆 NO 🗆 Unknown
Close contact* with a confirmed or probable case of nCoV infection, while that patient was symptomatic	□ YES □ NO □ Unknown
Presence in a healthcare facility where nCoV infections have been managed	🗆 YES 🗆 NO 🗆 Unknown
Presence in a laboratory handling suspected or confirmed nCoV samples	🗆 YES 🗆 NO 🗆 Unknown
Direct contact with animals in countries where the nCoV is known to be circulating in human infections have occurred as a result of presumed zoonotic transmission	• •
* Close contact' is defined as:	

- Health care associated exposure, including providing direct care for novel coronavirus patients, e.g. health care worker, working with health care workers infected with novel coronavirus, visiting patients or staying in the same close environment of a novel coronavirus patient, or direct exposure to body fluids or specimens including aerosols.

- Working together in close proximity or sharing the same classroom environment with a novel coronavirus patient.

- Traveling together with novel coronavirus patient in any kind of conveyance.
- Living in the same household as a novel coronavirus patient.



DEMOGRAPHICS
Clinical centre name:Country:
Enrolment date: [_D_][_D_]/[_M_]/[_2_][_0_][_Y_][_Y_]
Ethnic group (check all that apply): OArab OBlack OEast Asian OSouth Asian O West Asian O Latin American O White
• Aboriginal/First Nations • O Other: Unknown
Employed as a Healthcare Worker?
Employed in a microbiology laboratory?
Sex at Birth: Male Female Not specified
Estimated Age [][]years OR][]months
Pregnant? YES NO Unknown N/A If YES: Gestational weeks assessment: [][] weeks
POST PARTUM? DYES DNO DN/A (<i>if NO or N/A skip this section - go to INFANT</i>)
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? TYES INO (If NO skip this section)
Birth weight: [][]□kg or □lbs □N/A
Gestational outcome: □ Term birth (≥37wk GA) □Preterm birth (<37wk GA) □N/A
Breastfed? TYES NO N/A If YES: Currently breastfed Breastfeeding discontinued at [][]weeks N/A
Appropriate development for age? UYES UNO UNknown
Vaccinations appropriate for age/country?



CO-MORBIDITIES				
Co-morbidities and risk factors – Charlson Index will be calculated for each patient at analysis.				
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 DYES DNO DN/A				
ONSET & ADMISSION				
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-hr format):[_H_](_M_][_M_]				
Transfer from other facility? \Box YES-facility is a study site \Box YES-facility is not a study site \Box NO \Box N/A				
If YES: Name of transfer facility:				
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:				
Travel in the 14 days prior to first symptom onset?				
If YES, state location(s) & date(s): Country: City/Geographic area:				
Return Date: $[D][D]/[M][M]/[2][0][Y][Y] \square N/A$ (more space at the end if required)				
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 section				



SIGNS AND SYMPTOMS AT HOSPITAL ADMISSION (first available data at presentation/admission – within 24 hours)				
Temperature: $[][][].].].].].]. Cor \square O^F HR: [][].].].]. Beats per minute RR: [][].].].]. Decomposition of the second seco$				
Systolic BP: [_] [_] [_] mmHg Diastolic BP: [_][_] mmHg Severe dehydration: □YES □NO □Unknown				
Sternal capillary refill time >2seconds				
Oxygen saturation: [][]% On: □Room air □Oxygen therapy □N/A				
Admission signs and symptoms (observed/reported at admission and associated with this e	episode of acute illness)			
History of fever	□YES □NO □Unknown			
Cough	□YES □NO □ Unknown			
with sputum production	□YES □NO □ Unknown			
bloody sputum/haemoptysis	□YES □NO □ Unknown			
Sore throat	□YES □NO □ Unknown			
Runny nose (Rhinorrhoea)	□YES □NO □ Unknown			
Ear pain	□YES □NO □ Unknown			
Wheezing	□YES □NO □ Unknown			
Chest pain	□YES □NO □ Unknown			
Muscle aches (Myalgia)	□YES □NO □ Unknown			
Joint pain (Arthralgia)	□YES □NO □ Unknown			
Fatigue / Malaise	□YES □NO □ Unknown			
Shortness of breath (Dyspnea)	□YES □NO □ Unknown			
Lower chest wall indrawing	□YES □NO □ Unknown			
Headache	□YES □NO □ Unknown			
Altered consciousness/confusion	□YES □NO □ Unknown			
Seizures	□YES □NO □ Unknown			
Abdominal pain	□YES □NO □ Unknown			
Vomiting / Nausea	□YES □NO □ Unknown			
Diarrhoea	□YES □NO □ Unknown			
Conjunctivitis	□YES □NO □ Unknown			
Skin rash	□YES □NO □ Unknown			
Skin ulcers	□YES □NO □ Unknown			
Lymphadenopathy	□YES □NO □ Unknown			
Bleeding (Haemorrhage)	□YES □NO □ Unknown			
If Bleeding: specify site(s):				



PATHOGEN TESTING:					
Was pathogen testing done during this illness episode?					
Influenza : 🗆 YES- Confir	Influenza : 🗆 YES- Confirmed 🗇 YES- Probable 🗇 NO 🛛 If YES: 🗆 A/H3N2 🗇 A/H1N1pdm09 🗇 A/H7N9				
□ A/H5N1 [□ A, not typed □ B □ Other:				
Coronavirus: 🗆 YES- Cor	ifirmed 🛛 YES- Probable 🗆 NO 🛛 If YES: 🗆	Novel CoV 🗆 MERS (CoV		
□ Other CoV	':				
RSV: □ YES- C	onfirmed 🛛 YES- Probable 🗆 NO				
Adenovirus: 🗆 YES- C	onfirmed 🛛 YES- Probable 🗆 NO				
	confirmed : \Box No				
	tory diagnosis: 🗆 YES- Confirmed 🛛 YES- Pro				
If yes Other Infectious R	espiratory diagnosis, specify:			-	
Clinical pneumonia: 🗆 Y	ES 🗆 NO 🗆 Unknown 🛛 If NONE OF THE AB	OVE: Suspected Non-	infective: 🗆 Y	ES □ N/A	
Collection Date Laboratory test Pathogen (DD/MM/VYYY) Biospecimen Type Method Tested/Detected					
Collection Date (DD/MM/YYYY)	Biospecimen Type	Laboratory test Method	Result	Pathogen Tested/Detected	
	Biospecimen Type	-	Result	_	
(DD/MM/YYYY)	□Nasal/NP swab □Throat swab □Combined nasal/NP+throat swab □Sputum □BAL □ETA □Urine □Feces/rectal swab □Blood	Method	□Positive □Negative	_	
(DD/MM/YYYY)	Image: Construct of the symbol Image: Construct of the symbol Image: Construct of the symbol Image: Construct of the symbol Image: Construct of the symbol Image: Construct of the symbol Image: Construct of the symbol Image: Construct of the symbol Image: Construct of the symbol Image: Construct of the symbol Image: Construct of the symbol Image: Construct of the symbol Image: Construct of the symbol Image: Construct of the symbol Image: Construct of the symbol Image: Construct of the symbol Image: Construct of the symbol Image: Construct of the symbol Image: Construct of the symbol Image: Construct of the symbol Image: Construct of the symbol Image: Construct of the symbol Image: Construct of the symbol Image: Construct of the symbol Image: Construct of the symbol Image: Construct of the symbol Image: Construct of the symbol Image: Construct of the symbol Image: Construct of the symbol Image: Construct of the symbol Image: Construct of the symbol Image: Construct of the symbol Image: Construct of the symbol Image: Construct of the symbol Image: Construct of the symbol Image: Construct of the symbol Image: Construct	Method PCR Culture Other, Specify: PCR Culture Culture Culture	□Positive □Negative □N/A □Positive □Negative	_	

□Nasal/NP swab

□Feces/rectal swab

Other, Specify: _

/___/20___

□Combined nasal/NP+throat swab

□Sputum □BAL □ETA

□Throat swab

□Blood

□Urine

□PCR

□Culture

□Other, Specify:

□Positive

□Negative

□n/A



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): [_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?
Record the worst value (within the previous 24 hours (if Not Available write 'N/A')):
Done 🗆 YES 🖾 NO FiO ₂ (0.21-1.0) [].[] or []L/min
Done □YES □NO SaO ₂ [][]%
Done YES NO PaO ₂ at time of FiO ₂ above [][]
Done □YES □NO PaO ₂ sample type: □ Arterial □ Venous □ Capillary □N/A
Done YES NO From same blood gas record as PaO ₂ PCO ₂
Done YES
Done UYES HCO ₃ 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 TYES NO Systolic Blood Pressure [][]mmHg
Done YES
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 INO 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? UYES NO N/A
Any vasopressor/inotropic support? \Box YES \Box NO (if NO, answer the next 3 questions NO) \Box N/A
Dopamine <5µg/kg/min OR Dobutamine OR milrinone OR levosimendan:
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:
Neuromuscular blocking agents? YES NO N/A Inhaled Nitric Oxide? YES NO N/A
Tracheostomy inserted? \[
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): [_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 UYES NO Haemoglobin g/L or g/dL
Done \Box YES \Box NO WBC count \Box x10 ⁹ /L or \Box x10 ³ /µL
Done □YES □NO Lymphocyte count □cells/ μL
Done □YES □NO Neutrophil count □ cells/ μL
Done UYES NO Haematocrit []%
Done UYES NO Platelets L x10 ⁹ /L or x10 ³ /µL
Done TYES TNO APTT/APTR
Done TYES 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
Done 🗆 YES 🖾 NO Blood Urea Nitrogen (urea) 🖾 mmol/L <i>or</i> 🗆 mg/dL
Done 🗆 YES 🖾 NO Lactate 🗆 mmol/L <i>or</i> 🗆 mg/dL
Done UYES NO Creatinine
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



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	D NO	□n/a
Acute Respiratory Distress Syndrome	□ YES	□ NO	□n/a	Coagulation disorder / Disseminated Intravascular Coagulation	□ YES	□ NO	□n/A
	F yes, specify: Mild I Moderate Severe Anemia YES INO N/A Unknown						□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		□n/a
Endocarditis / Myocarditis / Pericarditis	□ YES	□ NO	□n/a	If yes specify:			I
Cardiac arrhythmia	🗆 YES	□ NO	□n/a	·			
Cardiac ischaemia	□ YES	□ NO	□n/a				



TREATMENT: At ANY time during hospitalisation, did the patient receive/undergo:			
ICU or High Dependency Unit ac	dmission?		
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?	JN/A		
Non-invasive ventilation? (e.g. B	IPAP, CPAP) □YES □NO □N/A		
Invasive ventilation (Any)?	□YES □NO □N/A If YES, total duration:days		
Prone Ventilation?			
Inhaled Nitric Oxide?			
Tracheostomy inserted	\Box YES \Box NO \Box N/A,		
Extracorporeal support?			
Renal replacement therapy (RRT) or dialysis? 🗆 YES 💷 NO 💷 N/A		
Inotropes/vasopressors?			
If YES: First/Start date: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] □N/A			
Last/End date: [_D_](_D_]/(_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?

If YES, please provide type and dose: _____

Antifungal agent? □YES □NO □N/A





OUTCOME
Outcome: Discharged alive Hospitalization Transfer to other facility Death Palliative discharge Unknown
Outcome date: [_D_][_D_]/[_M_][_A_]/[_2_][_0_][_Y_][_Y_]
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



TRAVEL: Did the patient travel in the 14 days prior to first symptom onset? If > 1 <i>location & date list:</i>			
Country:	_ City/Geographic area:	Return Date (<i>DD/MM/20YY</i>): /20	
Country:	_ City/Geographic area:	Return Date (<i>DD/MM/20YY</i>): /20	
Country:	_ City/Geographic area:	Return Date (<i>DD/MM/20YY</i>): / /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? UYES UNO UN/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)				
Bat	□YES □NO □N/A			
Livestock (e.g. goats, cattle, camels)				
Horse				
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				
Sick animal or dead animal				
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			