

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.
- DO NOT INPUT ANY PATIENT IDENTIFIERS: THIS INCLUDES NAMES, ADDRESSES, DATE OF BIRTH OR PLACE OF BIRTH.
- Step 1: Contact <u>EDCARN@who.int</u> to become a contributor to the nCoV global platform.
- Step 2: You will be contacted by ISARIC, platform manager, for assignment informational pack and instructions on how to use the REDCap nCoV platform.
- Step 3: Participant Identification Numbers will include a 3-digit country code, a 3 digit site code and a 4 digit participant number. 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.
- Step 4: Data should be entered to the central electronic 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.
- The contributor will:
 - 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.
- If your site would like to collect data independently, establishment of locally hosted database is possible.
- Standard reports will be provided on regular basis to all contributors. Additional analysis for operational public health purposes will be determined by an independent WHO clinical advisory group.



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	animal populations or where
 * Close contact' is defined as: Health care associated exposure, including providing direct care for novel coronavirus patients, e.g. heac care workers infected with novel coronavirus, visiting patients or staying in the same close environme 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:			
Enrolmentdate: [_D_][_D_]/[_M_][_A_]/[_2_][_0_][_Y_][_Y_]			
Ethnic group (check all that apply): OArab OBlack OEast Asian OSouth Asian O West Asian O Latin American O White			
O 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 (if NO or N/A skip this section - go to INFANT)			
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	e 🛛 🗠 🗠 YES 🗆 NO 🗆 N/A 🕹 If yes, specify:			
AIDS / HIV				
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_][_H_]/[_M_][_M_]			
Transfer from other facility? YES-facility is a study site YES-facility is not a study site NO N/A				
If YES: Name of transfer facility:		□N/A		
If YES: Admission date at transfer facility (DD/MM/YYYY): [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]				
If YES-Study Site: Participant ID # at transfer facility: Same as above Different: [][][][][][] N/A				
Travel in the 14 days prior to first symptom onset? UYES UNO Unknown				
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: $[][][][].].].].].]. Cor \square 0°F HR: [][][].].].].]. Direction of the set of th$			
Systolic BP: [_] [_] mmHg Diastolic BP: [_][_] mmHg Severe dehydration: □YES	□NO □Unknown		
Sternal capillary refill time >2seconds			
Oxygen saturation: [][]% On: \Box Room air \Box Oxygen therapy \Box 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? UYES (complete section) NO N/A					
	med □ YES- Probable □ NO If YES: □ A		dm09 🗆 A/H7	N9	
	firmed I YES- Probable I NO If YES: I		Sel /		
			.0V		
□ Other CoV	:				
RSV: 🗆 YES- C	onfirmed 🛛 YES- Probable 🗆 NO				
Adenovirus: 🗆 YES- Co	onfirmed 🛛 YES- Probable 🗌 NO				
Bacteria: 🗆 🗆 Yes – c	onfirmed : 🗆 No				
Other Infectious Respira	tory diagnosis: 🗆 YES- Confirmed 🛛 YES- Pro	bable 🗆 NO			
If yes Other Infectious R	espiratory diagnosis, specify:			_	
Clinical pneumonia: 🗆 Y	ES 🗆 NO 🗆 Unknown 🛛 If NONE OF THE ABO	OVE: Suspected Non-	infective: 🗆 YI	es 🗆 N/A	
Collection Date (DD/MM/YYYY)	Biospecimen Type	Laboratory test Method	Result	Pathogen Tested/Detected	
Image: Normal Symbol Content of the					
Image: Nasal/NP swab Image: Nasal/NP swab <td< td=""></td<>					
	□Nasal/NP swab □Throat swab	□PCR			

□Culture

□PCR

□PCR

□Culture

□Culture

□Other, Specify:

□Other, *Specify*:

□Other, Specify:

□Positive

□Negative

□Positive

□Negative

□Positive

□Negative

□n/A

□n/a

□n/a

□Combined nasal/NP+throat swab

□Combined nasal/NP+throat swab

Combined nasal/NP+throat swab

□BAL

ΔΕΤΑ

ΠΕΤΑ

ΔΕΤΑ

□Blood

□Blood

□Blood

□Throat swab

□Throat swab

□Urine

□Urine

□Urine

□Sputum □BAL

□Feces/rectal swab

□Sputum □BAL

□Faeces/rectal swab

□Other*, Specify:* _ □Nasal/NP swab

□Feces/rectal swab

□Other, Specify: _

□Sputum

□Other*, Specify:* _ □Nasal/NP swab

/20

/20__

/___/20__



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 \Box YES \Box NO PaO ₂ at time of FiO ₂ above [][] \Box kPa or \Box mmHg				
Done □YES □NO PaO ₂ sample type: □ Arterial □ Venous □ Capillary □N/A				
Done \Box YES \Box NO From same blood gas record as PaO ₂ PCO ₂ \Box kPa <i>or</i> \Box mmHg				
Done _YES _NO pH				
Done 🗆 YES 🖾 NO HCO3mEq/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 UYES 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?				
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? 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): [_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 TYES TNO Haemoglobin Tg/L or Tg/dL				
Done □YES □NO WBC count □x10 ⁹ /L <i>or</i> □x10 ³ /μL				
Done 🗆 YES 🖾 NO Lymphocyte count 🔤 🗆 Cells/ µL				
Done □YES □NO Neutrophil count □ cells/ μL				
Done YES NO Haematocrit []%				
Done □YES □NO Platelets □x10 ⁹ /L <i>or</i> □x10 ³ /µL				
Done IYES INO APTT/APTR				
Done IYES INO PT seconds				
Done YES NO INR				
Done IYES INO ALT/SGPT U/L				
Done 🗆 YES 🖾 NO Total Bilirubin □µmol/L <i>or</i> □mg/dL				
Done 🗆 YES 🖾 NO AST/SGOT U/L				
Done 🗆 YES 🖾 NO Glucose 🗆 mmol/L <i>or</i> 🗆 mg/dL				
Done YES NO Blood Urea Nitrogen (urea) mmol/L or mmol/L or mg/dL				
Done YES NO Lactate mmol/L or mg/dL				
Done YES NO Creatinine Dµmol/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? UYES NO N/A IF Yes: Were infiltrates present? UYES 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	D NO	□n/A	Coagulation disorder / Disseminated Intravascular Coagulation	□ YES	D NO	□n/a
IF yes, specify: □ Mild □ Unkr	☐ Mode nown	erate 🛛] Severe	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		□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				



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 IG	CU admission: [_D_][_D_]/[_M_](_2_][_0_][_Y_] □N/A				
date of I	CU discharge: [_D_]/[_M_]/[_A_]/[_2_][_0_][_Y_][_Y_] □N/A				
Oxygen therapy? DYES DNO					
Non-invasive ventilation? (e.g. E	BIPAP, CPAP) □YES □NO □N/A				
Invasive ventilation (Any)?	Invasive ventilation (Any)?				
Prone Ventilation?					
Inhaled Nitric Oxide? DYES DNO DN/A					
Tracheostomy inserted					
Extracorporeal support?					
Renal replacement therapy (RRT) or dialysis? UYES NO N/A					
Inotropes/vasopressors? UYES NO N/A					
If YES: First/Start date: [_D_](_D_]/[_M_]/[_2_][_0_](_Y_](_Y_] □N/A					
Last/End date: _D_/[_M_](_A_](_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? DYES DNO DN/A

If YES, please provide type and dose: _





OUTCOME
Outcome: Discharged alive Hospitalization Transfer to other facility Death
□ Palliative discharge □ Unknown
Outcome date: [_D_](_D_]/[_M_](_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? \Box YES \Box NO \Box 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

prior to first symptom onset? DYES	have contact with live/dead animals, raw meat or insect bites in the 14 days □NO □N/A If yes, Complete each line below. of contact and date of exposure (DD/MM/YYYY)
Bird/Aves (e.g. chickens, turkeys, ducks)	
Bat	
Livestock (e.g. goats, cattle, camels)	
Horse	
Hare/ Rabbit	
Pigs	
Non-human primates	
Rodent (e.g. rats, mice, squirrels)	
Insect or tick bite (e.g. tick, flea, mosquito)	□YES □NO □N/A
Reptile / Amphibian	
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	
Skinned, dressed or eaten wild game	
Visit to live animal market, farm or zoo	
Participated in animal surgery or necropsy	□YES □NO □N/A
Other animal contacts:	□YES □NO □N/A