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 (**O**) 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.

CORE CASE RECORD FORM

CLINICAL INCLUSION CRITERIA

Suspected or proven acute novel Coronavirus (nCoV) infection as main cause for admission: ☐ YES ☐ NO

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 animal populations or where human infections have occurred as a result of presumed zoonotic transmission ☐ YES ☐ NO ☐ Unknown

* 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.

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PARTICIPANT IDENTIFICATION #: [___][___][___]--- [___][___][___][___]

CORE CASE RECORD FORM

DEMOGRAPHICS

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

Enrolment date: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]

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

O Aboriginal/First Nations O Other: _____ ☐Unknown

Employed as a Healthcare Worker? ☐YES ☐NO ☐N/A

Employed in a microbiology laboratory? ☐YES ☐NO ☐N/A

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? ☐YES ☐NO ☐ N/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? ☐YES ☐NO *(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? ☐YES ☐NO ☐N/A **If YES:** ☐Currently breastfed ☐Breastfeeding discontinued at [___][___]weeks☐N/A

Appropriate development for age? ☐YES ☐NO ☐Unknown

Vaccinations appropriate for age/country? ☐YES ☐NO ☐Unknown ☐N/A

CORE CASE RECORD FORM

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	☐YES ☐NO ☐N/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_][_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_] ☐N/A

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? ☐YES ☐NO ☐Unknown

If YES, *state location(s) & date(s):* Country:_____ City/Geographic area:_____

Return Date: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] ☐ 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*

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PARTICIPANT IDENTIFICATION #: [___][___][___]--- [___][___][___][___]

CORE CASE RECORD FORM

SIGNS AND SYMPTOMS AT HOSPITAL ADMISSION *(first available data at presentation/admission – within 24 hours)*	
Temperature: [_][_][_].[_]☐☐°C *or* ☐☐°F **HR:** [_][_][_]beats per minute **RR:** [_][_]breaths per minute	
Systolic BP: [_] [_] [_]mmHg **Diastolic BP:** [_][_][_]mmHg **Severe dehydration:** ☐YES ☐NO ☐Unknown	
Sternal capillary refill time >2seconds ☐YES ☐NO ☐Unknown	
Oxygen saturation: [_][_][_]% **On:** ☐Room air ☐Oxygen therapy ☐N/A	
Admission signs and symptoms *(observed/reported at admission and associated with this 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):	_____ _____ _____

CORE CASE RECORD FORM

PATHOGEN TESTING:

Was pathogen testing done during this illness episode? ☐YES *(complete section)* ☐NO ☐N/A

Influenza : ☐ YES- Confirmed ☐ YES- Probable ☐ NO **If YES:** ☐ A/H3N2 ☐ A/H1N1pdm09 ☐ A/H7N9

☐ A/H5N1 ☐ A, not typed ☐ B ☐ Other:____________________________

Coronavirus: ☐ YES- Confirmed ☐ YES- Probable ☐ NO **If YES:** ☐ Novel CoV ☐ MERS CoV

☐ Other CoV: ______________________

RSV: ☐ YES- Confirmed ☐ YES- Probable ☐ NO

Adenovirus: ☐ YES- Confirmed ☐ YES- Probable ☐ NO

Bacteria: : ☐ Yes – confirmed : ☐ No

Other Infectious Respiratory diagnosis: ☐ YES- Confirmed ☐ YES- Probable ☐ NO

If yes Other Infectious Respiratory diagnosis, specify:____

Clinical pneumonia: ☐ YES ☐ NO ☐ Unknown **If NONE OF THE ABOVE: Suspected Non-infective:** ☐ YES ☐ N/A

Collection Date *(DD/MM/YYYY)*	Biospecimen Type	Laboratory test Method	Result	Pathogen Tested/Detected
___/___/20___	☐Nasal/NP swab ☐Throat swab ☐Combined nasal/NP+throat swab ☐Sputum ☐BAL ☐ETA ☐Urine ☐Feces/rectal swab ☐Blood ☐Other, *Specify:* ____________________	☐PCR ☐Culture ☐Other, *Specify:* _____________	☐Positive ☐Negative ☐N/A	__________________
___/___/20___	☐Nasal/NP swab ☐Throat swab ☐Combined nasal/NP+throat swab ☐Sputum ☐BAL ☐ETA ☐Urine ☐Feces/rectal swab ☐Blood ☐Other, *Specify:* ____________________	☐PCR ☐Culture ☐Other, *Specify:* _____________	☐Positive ☐Negative ☐N/A	__________________
___/___/20___	☐Nasal/NP swab ☐Throat swab ☐Combined nasal/NP+throat swab ☐Sputum ☐BAL ☐ETA ☐Urine ☐Feces/rectal swab ☐Blood ☐Other, *Specify:* ____________________	☐PCR ☐Culture ☐Other, *Specify:* _____________	☐Positive ☐Negative ☐N/A	__________________
___/___/20___	☐Nasal/NP swab ☐Throat swab ☐Combined nasal/NP+throat swab ☐Sputum ☐BAL ☐ETA ☐Urine ☐Faeces/rectal swab ☐Blood ☐Other, *Specify:* ____________________	☐PCR ☐Culture ☐Other, *Specify:* _____________	☐Positive ☐Negative ☐N/A	__________________
___/___/20___	☐Nasal/NP swab ☐Throat swab ☐Combined nasal/NP+throat swab ☐Sputum ☐BAL ☐ETA ☐Urine ☐Feces/rectal swab ☐Blood ☐Other, *Specify:* ____________________	☐PCR ☐Culture ☐Other, *Specify:* _____________	☐Positive ☐Negative ☐N/A	__________________