DESIGN OF THIS CASE RECORD FORM (CRF)

This CRF has 3 modules:

Module 1 to be completed on the first day of admission to the health centre.

Module 2 to be completed on first day of admission to ICU or high dependency unit. Module 2 should also be completed daily for as many days as resources allow. Continue to follow-up patients who transfer between wards.

Module 3 to be completed at discharge or death.

ADMINISTRATION GUIDANCE

- The CRF is designed to collect data obtained through examination, interview and review of hospital notes for the period from hospital admission to discharge, transfer, death, or continued hospitalization without possibility of continued data collection. Data may be collected retrospectively if the patient is enrolled after the admission date. Participant Identification Numbers consist of a site code and a participant number. You can obtain a site code and registration on the data management system by contacting ncov@isaric.org. Participant numbers should be assigned sequentially for each site beginning with 00001. 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 by incorporating alpha characters (e.g. Ward X assigns A0001, Ward Y assigns B0001 onwards). Enter the Participant Identification Number at the top of every page.

- Data are entered on 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 section. Questions marked ‘If yes, …’ should be left blank when they do not apply (i.e. when the answer is not yes).

- 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 ‘Unknown’ for any data 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 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 can be stored by the institution responsible for them. All data should be transferred to the 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 we can help with databases, if you have comments and to let us know that you are using the forms.
GENERAL GUIDANCE AND DEFINITIONS

Coinfections
Any coinfections should be entered in Module 3 under 15. DIAGNOSTIC/PATHOGEN TESTING

Comorbidities
Comorbidities present before the onset of COVID-19 and are still present. Do not include those that developed following the onset of COVID-19 symptoms. More detailed guidance is provided.

Hospital admission
For patients who were admitted to hospital with COVID-19 or symptoms consistent with possible COVID-19 infection, please enter details for the date of hospital admission. For patients with a clear alternative diagnosis leading to admission who subsequently acquired COVID-19, original admission date should be provided, but all subsequent references to admission should be taken as referring to the first 24 hours after first day of onset of symptoms of suspected or confirmed COVID-19 infection.

Where a patient was admitted via multiple hospital departments, count admission from the time they came to the first department during the visit that led to their admission (e.g. arrival at the Emergency Department).

Oxygen therapy
Include any form of supplemental oxygen received using any methods. Then complete all data on type of delivery and duration. If the exact delivery device used is not listed, please select the most similar option. If multiple different flow rates and interfaces have been used, please select the one delivering the greatest oxygen flow. If a venturi valve is used, please record the fraction of inspired oxygen (FiO₂) in preference to the flow rate of oxygen.

Invasive ventilation
Please include any mechanical ventilation delivered following intubation or via a tracheostomy. Do not include patients who are breathing independently via a tracheostomy.

Non-invasive ventilation
Please include any positive-pressure treatment given via a tight-fitted mask. This can be continuous positive pressure (CPAP) or bi-level positive pressure (BIPAP).

Oral/orogastric fluids
Please include any fluids/nutrients delivered artificially to the gastrointestinal tract (e.g. nasogastric tube, nasojejunal tube, gastrostomy) but not patients taking normal oral intake.

Renal replacement therapy or dialysis
Please include any form of continuous renal replacement therapy or intermittent haemodialysis.

Worst result
References to ‘worst result’ refer to those furthest from the normal physiological range or laboratory normal range.

Results that were rejected by the clinical team (e.g. pulse oximetry on poorly perfused extremities, haemolysed blood samples, contaminated microbiology results) should not be reported.

Blood pressure: Please report the systolic and diastolic blood pressure from the observation with the lowest mean arterial pressure (if mean arterial pressure has not been calculated, report the measurement with lowest systolic blood pressure).

Respiratory rate: If both abnormal low and high rate observed, record the abnormally high rate.
Enter participant ID on each page.

1. CLINICAL INCLUSION CRITERIA
Proven or suspected infection with pathogen of Public Health Interest
Select yes if patient has either clinically suspected or laboratory-confirmed SARS-CoV-2 /COVID-19 infection.

2. DEMOGRAPHICS
If date of birth is unknown, please record age in years, or if <1 year old, record age in months.
If pregnant or recently delivered within 14 days of onset of symptoms, please complete the optional Pregnancy Module CRF.

3. DATE OF ONSET AND ADMISSION VITAL SIGNS
Please provide the date of patient reported onset of the first symptom that you clinically believe was related to this episode of COVID-19 infection. Please provide details of clinical observations made on admission (including if data recording takes place subsequently). For observations not made at admission, please record the first available data (patient reported and/or from medical records) after admission measured within 24 hours of admission.
For patients with a clear alternative diagnosis leading to admission who subsequently developed COVID-19, provide dates as they occurred but complete observations for the 24 hours after onset of symptoms of suspected or confirmed COVID-19 infection.
Please ensure all measurements are provided using the units specified.

4. CO-MORBIDITIES
Please record if any of these comorbidities existed prior to admission.
Do not include past comorbidities that are cured. Additional details are given below. Where example conditions are given, these are not intended to be exhaustive. Other significant comorbidities and risk factors not listed should be specified as ‘Others’.

Chronic cardiac disease (not hypertension)
Please include any of coronary artery disease, heart failure, congenital heart disease, cardiomyopathy, rheumatic heart disease.

Chronic pulmonary disease
Please include any of chronic obstructive pulmonary disease (chronic bronchitis, emphysema), cystic fibrosis, bronchiectasis, interstitial lung disease, pre-existing requirement for long term oxygen therapy.
Do not include asthma.
4. CO-MORBIDITIES (CONTINUED)

**Asthma**
Clinician-diagnosed asthma.

**Chronic kidney disease**
Please include any of clinician-diagnosed chronic kidney disease, chronic estimated glomerular filtration rate < 60 mL/min/1.73m², history of kidney transplantation

**Chronic neurological disorder**
Please include any of cerebral palsy, multiple sclerosis, motor neurone disease, muscular dystrophy, myasthenia gravis, Parkinson’s disease, stroke, severe learning difficulty

**HIV**
History of laboratory-confirmed HIV infection. (Note, ART: anti-retroviral therapy).

**Diabetes**
Type 1 or type 2 diabetes mellitus requiring oral or subcutaneous treatment.

**Current smoking**
Smoking at least one cigarette, cigar, pipe or equivalent per day before the onset of the current illness. Do not include smoke-free tobacco products such as chewed tobacco or electronic nicotine delivery devices.

**Tuberculosis**
Patients currently receiving treatment for tuberculosis. Do not include latent tuberculosis.

**Asplenia**
Please include any of splenectomy, non-functional spleen, and congenital asplenia.

**Malignant neoplasm**
Current solid organ or haematological malignancy. Please do not include malignancies that have been declared ‘cured’ ≥5 years ago with no evidence of ongoing disease. Do not include non-melanoma skin cancers. Do not include benign growths or dysplasia.

**Other**
Please include other comorbidities that the clinical team feels may affect the patient’s physiological reserves or response to this disease or treatment. Please specify these other comorbidities.

5. PRE-ADMISSION & CHRONIC MEDICATION

Please state whether any of these medications were taken in the 14 days before admission for any reason.
6. SIGNS AND SYMPTOMS ON ADMISSION
Please provide details of clinical observations made within 24 hours of admission. For observations not made immediately at admission, please record the first available data (patient reported and/or from medical records) within 24 hours of admission.

For patients with a clear alternative diagnosis leading to admission who subsequently acquired COVID-19, provide dates as they occurred but complete observations for the 24 hours after onset of symptoms of suspected or confirmed COVID-19 infection.

7. MEDICATION ON ADMISSION
Please record if the patient was administered any of these medications at the time of admission or within 24 hours of admission. For patients who were admitted for another reason and subsequently developed COVID-19, provide complete for the 24 hours after COVID-19 was first suspected.

Please specify all agent. When entering data on to the electronic CRF a drop-down list of different agents will be provided.

8. SUPPORTIVE CARE ON ADMISSION
Please record all treatments received on the day of or within the first 24 hours of admission.

9. LABORATORY RESULTS ON ADMISSION
Please include results taken on presentation, admission or within the first 24 hours following admission or in existing in-patients on the day or within 24 hours of first symptoms of suspected or confirmed COVID-19 infection.

Please ensure all measurements are provided using the units specified or if other units are used specify the unit used. When transferring data on to the electronic database there will be a drop-down list of different units used globally.
**Date of follow-up**
This module is to be completed on the first day of admission to ICU or high dependency unit (HDU), and also daily for as many days as resources allow. For patients admitted to ICU/HDU or other critical care unit, please also complete the Critical Care Module. Please state the date of follow-up for this form. All data should refer to that calendar date, from midnight to midnight.

**10. VITAL SIGNS**
Please see General Guidance and Definitions

**Severe dehydration**
Please record if severe dehydration was present at any point during the follow-up day. Signs of severe dehydration include thirst, dry mucous membranes, low volumes of dark-coloured urine, sunken eyes, reduced skin elasticity.

**Glasgow Coma Scale (GCS)**
Please state the lowest GCS recorded. For intubated patients and patients with a non-fenestrated tracheostomy, give 1 point for the voice component and calculate the total as usual. Suffixes such as ‘t’ for tracheostomy cannot be entered on to the database.

**Level of consciousness (AVPU)**
Alert – responding to voice – responding to pain – unresponsive: please state the least responsive condition of the patient during the calendar day (not counting normal sleep).

**11. DAILY CLINICAL FEATURES**
Record “yes” for all that were present at any time during the date of follow-up stated on the form.

**12. LABORATORY RESULTS**
Please state all laboratory results from the day of follow-up. The day of follow-up for this form should correspond to the date of sample collection, not the date when the laboratory reported the result. Please note the units provided for each measure. If your laboratory reports these results with different units, please state the unit used in the Value column. There is a drop-down menu available to record any unit used in the electronic database.

**13. MEDICATION**
Please record if the patient received any of these medications on the date stated on this follow-up form. Please select as many treatments as are applicable. Please record generic names of agents administered. There is a drop-down menu available to record any unit used in the electronic database.

**14. SUPPORTIVE CARE**
Please record all treatments received on this day of follow-up (midnight to midnight), no matter how long they were used for.
This page should be completed once a patient is discharged or has died using all available data throughout their admission and stay in hospital.

**15. DIAGNOSTIC / PATHOGEN TESTING**

Chest x-ray / CT
Please select ‘Yes’ if a chest x-ray or thoracic CT was performed at any point during the patient’s hospital stay.

Infiltrates present
Please tick that infiltrates are present if they are reported as present by a radiologist. You can also select ‘Yes’ if you are qualified to assess the images, or if a senior member of the clinical team looking after the patient has documented that the images showed ‘infiltrates’, ‘consolidation’, ‘opacities’ or ‘radiological signs of pneumonia/pneumonitis/ARDS’.

Pathogen testing
For each pathogen, select whether the test was positive (the pathogen was found), negative (the pathogen was not found) or not known if the test was done.

Where a pathogen was identified, please specify the organism identified as precisely as possible.

**16. COMPLICATIONS**

Please select all that were clinically identified at any time during the hospital admission.

Do not include known comorbidities (e.g. previous atrial fibrillation should not be included but new onset during this admission should)

Shock
Hypotension non-responsive to intravenous fluid resuscitation requiring vasoactive drugs to maintain adequate perfusion.

Seizure
A seizure, convulsion or ‘fit’ is an involuntary rhythmic contraction of muscles. Select ‘yes’ for any seizure regardless of cause (e.g. febrile or due to epilepsy)

Meningitis / encephalitis
Inflammation of the meninges or the brain parenchyma. Select yes if diagnosed clinically, radiologically or microbiologically.
Global COVID-19 Clinical Platform | Rapid Version CRF Completion Guidance

**Anaemia**
Select ‘yes’ if haemoglobin levels were lower than age- and sex-specific thresholds listed below.

<table>
<thead>
<tr>
<th>Age and sex</th>
<th>Haemoglobin threshold</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>g /L</td>
</tr>
<tr>
<td>Age 6 months to 5 years</td>
<td>110</td>
</tr>
<tr>
<td>Age 5–12 years</td>
<td>115</td>
</tr>
<tr>
<td>Age 12–15 years</td>
<td>120</td>
</tr>
<tr>
<td>Age &gt; 15 years, non-pregnant women</td>
<td>120</td>
</tr>
<tr>
<td>Pregnant women</td>
<td>110</td>
</tr>
<tr>
<td>Age &gt; 15 years, men</td>
<td>130</td>
</tr>
</tbody>
</table>

**Cardiac arrhythmia**
If a cardiac arrhythmia is identified and there is no previous record of it, select ‘yes’.

**Pneumonia**
Select ‘yes’ if radiologically diagnosed pneumonia or if the patient’s discharge diagnosis is recorded as pneumonia.

**Bronchiolitis**
This is a clinical diagnosis, generally in children <2 years old.

**Acute respiratory distress syndrome (ARDS)**
Defined according to Berlin criteria as:
- Occurring within 1 week of a known clinical insult or worsening respiratory symptoms
- Bilateral radiological opacities not fully explained by effusions, lobar/lung collapse, or nodules
- Respiratory failure not fully explained by cardiac failure or fluid overload

**Bacteraemia**
Growth of bacteria on a blood culture. Select ‘no’ if the only bacteria grown were believed to be skin contaminants (e.g. coagulase negative Staphylococci or diphtheroids).

**Bleeding**
Please record ‘yes’ for haemorrhage from any site.

**Endocarditis**
Bacterial or sterile inflammation and vegetation formation on endocardium, native valves or prosthetic valves.
Myocarditis / pericarditis
Inflammation of the heart or pericardium (outer lining of the heart). Diagnosis can be clinical, biochemical (cardiac enzymes) or radiological.

Acute renal injury
Acute renal injury is defined as any of:
- Increase in serum creatinine by ≥0.3 mg/dL (≥26.5 µmol/L) within 48 hours
- Increase in serum creatinine to ≥1.5 times baseline, which is known or presumed to have occurred within the prior 7 days
- Urine volume <0.5 mL/kg/hour for 6 hours

Pancreatitis
Inflammation of the pancreas, diagnosed from clinical, biochemical, radiological or histological evidence.

Liver dysfunction
Defined by any of:
- Clinical jaundice
- Hyperbilirubinaemia (blood bilirubin level twice the upper limit of the normal range)
- An increase in alanine transaminase or aspartate transaminase that is twice the upper limit of the normal range

Cardiomyopathy
Please record yes if cardiomyopathy diagnosed during this admission.

Other
Please report any other serious complications during this patient’s stay in hospital.

17. MEDICATION
Please record if the patient received any of these medications during their stay in hospital up to and including day of discharge.

18. SUPPORTIVE CARE
For all questions of duration, please count the number of calendar days that the patient received the treatment. For treatments that were stopped and restarted, count those days on which the treatment was given but not any calendar days on which it was not.

ICU or high dependency unit admission
If they died in ICU/HDU or were transferred from your site’s ICU/HDU to another hospital’s ICU/HDU, please select ‘in ICU at outcome’, otherwise please record the date they were discharged from ICU/HDU.
**19. OUTCOME**

**Outcome**

Please select only one outcome.

**Discharged alive** can mean discharge to their usual place of residence before their illness, to the home of a relative or friend, or to a social care facility, because their illness is no longer severe enough to warrant treatment in a medical facility.

**Hospitalized** means they are still in hospital but have recovered from COVID-19 infection and the form has been completed as the patient is in a part of the hospital for care of other conditions and where the form will not be completed at a later date.

**Transfer to other facility** means they have been transferred to another facility that provides medical care. This could be a specialist centre for more intensive treatment or a step-down for rehabilitation. It does not include facilities that solely provide social care (these patients should be listed as discharged alive).

**Death** means the patient died in the hospital.

**Palliative discharge** means the patient has been discharged with the expectation that they will not recover from this or other co-existing illness. This could be to a specialist hospice facility, or to their usual home address with anticipatory end of life medications.

**Outcome date**

Please state the date for the outcome listed above.