Instructions for Completion of the Human Infection with 2019 Novel Coronavirus (2019-nCoV) Case Report Form

Purpose: This document describes the procedures for completing the 2019 Novel Coronavirus (2019-nCoV) Case Report Form (CRF) for laboratory-confirmed cases of 2019-nCoV.

General:

1. All dates should be formatted MM/DD/YYYY.
2. Enter the CDC 2019-nCoV ID on each page of the form.
3. Use an "X" to mark boxes; make sure to carefully mark boxes so that the "X" does not cross multiple boxes.
4. If additional space is needed to record information, use the "Notes" items; located at item #47.

Header:

THE FOLLOWING INFORMATION IS NOT TRANSMITTED TO CDC.

Patient first name: Enter case's first name.
Patient last name: Enter case's last name.
Date of birth (MM/DD/YYYY): Enter date of birth in MM/DD/YYYY.

ID information:

State: Enter the state where the case was identified / is being reported.
Case state/local ID: Enter the ID assigned by the state/local health department.
State/local health dept: Enter the name of the state/local health department name that is completing the form.
CDC 2019-nCoV ID: Enter the CDC 2019-nCoV ID assigned to the case.

If the person was previously under investigation in collaboration with CDC, or was part of a contact investigation in which CDC was collaborating with state/local health departments, or CDC conducted all specimen testing, this CDC 2019-nCoV ID should have already been assigned. If any of the above scenarios are true, enter the CDC 2019-nCoV ID that has been provided by CDC. In some cases, this is the same as the CDC PUI ID. **Do not assign a new 2019-nCoV ID**.

If this is a new case that was not previously reported, under investigation, or whose lab samples were not tested by CDC, and the state is conducting their own testing of 2019-nCoV laboratory samples, the CDC 2019-nCoV ID should be assigned by the state at the time that specimens are collected, a person is identified as a PUI or contact, or when confirmed as a case, whichever comes first. The state should assign the CDC 2019-nCoV ID, and use this ID for all information related to the case that is transmitted to CDC.

The structure of the ID should be as follows:

A L 0 0 0 0 0 1

Standard state code — Number of case

This ID will be used to track information about the case-patient in CDC data systems and **must** be provided in all forms or specimens related to the case-patient.

Contact ID: Only fill out this field if a case-patient is a known contact of another case-patient. Enter the Contact ID assigned to the case when he/she was a contact. If the person was previously under investigation in collaboration with CDC, or was part of a contact investigation in which CDC was collaborating with state/local health departments, this Contact ID may already have been assigned.

NNDSS loc. rec. ID/Case ID: For NNDSS reporters, enter the GenV2 or NETSS patient identifier.

State/local Specimen IDs: Provide specimen IDs from state/local laboratories for specimens tested for 2019-nCoV. If needed, prioritize listing of specimens testing positive for 2019-nCoV, regardless of specimen type.

Interviewer information

Name of interviewer: Enter the last name and first name of the person performing the interview.

Affiliation/Organization: Enter the interviewer's affiliation/organization.

Telephone: Enter the interviewer's telephone number.

Email: Enter the interviewer's email address.

Date of interview: Enter the date of the interview with the laboratory-confirmed case in MM/DD/YYYY format.

Date of medical chart abstraction: Enter the date the medical chart abstraction of the laboratory-confirmed case was performed in MM/DD/YYYY format. If multiple medical record abstraction dates occur, enter / update to be the last date of medical record abstraction.

Basic case information

Report date to CDC: Enter date the case-patient was initially reported to CDC **as a case** in MM/DD/YYYY format.

Is this a 2019-nCoV laboratory-confirmed case?: Select appropriate response. If "no", then do not complete the case report form. This person would not be considered a case.

Race: Check all race categories that apply. If other, please specify in free text.

Date of first positive specimen collection: Enter date of this person's first positive specimen collection, regardless of specimen collection type, in MM/DD/YYYY format.

Ethnicity: Select appropriate response. If unknown, select not specified.

Date of birth: Enter the case-patient's date of birth in MM/DD/YYYY format. Only enter data in this field if data are able to be transmitted to CDC per state/local policy.

Age: Enter age.

Age units (year/month/day): Select age units.

Sex: Select appropriate response.

Symptom status (ever): This question refers to the case-patient's symptom status related to their entire duration of illness related to 2019-nCoV. If the case-patient was ever symptomatic as part of this illness with 2019-nCoV, select "symptomatic." If the case-patient was asymptomatic (never experienced symptoms as part of this illness), please select "asymptomatic." If symptom status unknown, select unknown.

- If symptomatic, record symptom onset date in MM/DD/YYYY format or mark unknown.
- If the case-patient was previously symptomatic and symptoms are currently resolved, list date of symptom resolution in MM/DD/YYYY format. If exact dates of symptom resolution are not known, but there is a known approximate date, enter this in the text field. If still symptomatic at time of interview, mark "still symptomatic." If the case-patient had symptoms, and the symptoms are resolved, but had an no information about the time frame of symptom resolution, mark "Symptoms resolved, unknown date." If the interviewer and patient do not know the symptom status, mark "Unknown symptom status."

In the 14 days prior to illness onset, did the patient have any of the following exposures: Check all that apply. For healthcare contact with another lab-confirmed 2019-nCoV case-patient, check if the case-patient identified

in the current form was a patient, a visitor (e.g., accompanying family member who was seeking care), or a healthcare worker, when they contacted a lab-confirmed 2019-nCoV case-patient.

Was the patient hospitalized? Select appropriate response. If yes, provide date of first admission and discharge from the hospital in MM/DD/YYYY format. Additional hospitalizations will be captured later in the form.

Was the patient admitted to an intensive care unit (ICU)? Select appropriate response.

Did the patient receive mechanical ventilation (MV)/intubation? Select the appropriate response. If yes, count the total number of days with mechanical ventilation. Round up to whole number.

Did the patient die as a result of this illness? Select appropriate response. If yes, then enter date of death in MM/DD/YYYY format. If unknown date of death, then mark "Unknown date of death."

Patient interview:

Who is providing information for this form? Mark all that apply; if both the case-patient and another person are used as sources, please select "case-patient" and "other, specify relationship to case". Then, please provide the relationship of case-patient to the source case (i.e. mother, father, brother, sister, neighbor, etc.; do not provide identifiable information or names).

Case-patient's primary language: Enter the case-patient's primary language.

Was this form administered via a translator?: Select appropriate response.

Case-patient demographic information:

1. **Was this case a known patient under investigation (PUI) prior to lab confirmation?** Select appropriate response.
2. **Under what process was the case first identified?** Select all that apply.
3. **County of residence and State of residence:** Record the case-patient's county and state of residence.
4. **Current status:** Select the current hospital or isolation status of the case-patient.
5. **Occupation:** Enter the occupation of the case-patient.
   If student, what grade level and what school?: If the case-patient is a student, enter the case-patient's grade level in school (in free text field).
   If child, does s/he attend day care?: If the case-patient is a child, mark if he/she attends day care.

Symptoms, clinical course, past medical history and social history:

6. **During this illness, did you experience any of the following symptoms?:** For this section, indicate the symptoms that the case-patient experienced to date. Please mark "yes," "no," or "unknown" for each symptom. Ask the case-patient or proxy person interviewed each symptom, even if he/she may have been asymptomatic. All symptoms should have a marked answer. If other symptoms were experienced, then describe the symptom in the space after "Other".
7. **Did you miss work or school for this illness?:** Mark appropriate response.
   If yes, how many days?: If case-patient missed work or school because of illness, indicate how many days were missed. Round to the nearest whole number.
8. **Do you feel back to normal?:** Mark appropriate response.
   If yes, when did you feel back to normal?: If case-patient indicates that he/she feels back to normal, record the date in MM/DD/YYYY format that the case-patient felt back to normal. If the case-patient has an approximate date, please record this in the approximate date field as a text response.
9. **Did you receive any medical care for the illness?:** Mark the appropriate response.
10. **If yes, where and on which dates did you seek care after this illness started?:** Indicate where the case-patient sought care during this illness and on which dates using MM/DD/YYYY format. Please enter the start date of each care-encounter; up to two dates (encounter 1, encounter 2) for each encounter type.

11. **Were you hospitalized for the illness?**: Mark the appropriate response.
    Purpose: Mark the appropriate response.

Past medical history:

12. **Do you have any pre-existing medical conditions?:** Mark the appropriate response based on whether the case-patient has any pre-existing medical conditions (currently or ever). If case-patient has no pre-existing medical conditions, mark "no." If not collected during interview and medical chart is missing, mark "unknown."
    Was the medical chart used to inform this section?: Indicate whether the case-patient's medical chart was used to fill out the pre-existing medical conditions section.
13. **Current height:** Identify if data were collected in inches or centimeters. Record data in field for correct measurement type; data should not be entered in both fields. Round to the nearest whole number.
14. **Current weight:** Identify if data were collected in pounds or kilograms. Record data in field for correct measurement type; data should not be entered in both fields. Round to the nearest whole number.
15. **If female, are you currently pregnant?:** Indicate the appropriate response. If case-patient is currently pregnant, provide how many weeks the case-patient was at illness onset. If the patient is very recently postpartum, but was pregnant at the time of illness onset (i.e., gave birth while ill with 2019-nCoV), mark "yes" for "if female, are you currently pregnant" and provide the gestational age at illness onset.
16. **If female, are you postpartum (12 months postpartum or less)?:** Indicate the appropriate response.
17. **If female, are you breastfeeding?** Indicate the appropriate response.
18. **If child, is he/she being breastfed?** Indicate the appropriate response.

Social history:

19. **Do you currently smoke cigarettes?:** Indicate the appropriate response.
    If yes, how many packs of cigarettes per day?: Enter the approximate number of packs of cigarettes per day the case-patient currently smokes. Please enter the mean if a range is given.
    For how many years?: Indicate how many years the case-patient has smoked cigarettes. Round to the nearest whole number.
20. **Have you ever smoked cigarettes?:** Indicate the appropriate response.
    If yes, how many packs of cigarettes per day?: Enter the approximate number of packs of cigarettes per day the case-patient used to smoke. Please enter the mean if a range is given.
    For how many years?: Indicate the cumulative number of years the case-patient used to smoke. Round to the nearest whole number.
    How long since you last smoked a cigarette? Enter months and/or years. Please round to the nearest whole number.
21. **Do you currently use e-cigarettes/vape-pen?:** Indicate the appropriate response. E-cigarettes are sometimes called "e-cigs," "vapes," "e-hookahs," "vape pens," and "electronic nicotine delivery systems (ENDS)." If the case-patient currently uses any of these, please mark "yes."
22. **In the past year, how often did you have a drink containing alcohol?**: Indicate the appropriate response.

Travel history:

23. **In the 14 days prior to illness onset, were you traveling away from your home (domestic and international)?:** Indicate the appropriate response. If response is "no" or "unknown", skip to Q25.
24. **Where did you travel 14 days prior to illness onset (list <u>ALL</u> locations, including overnight transits and layovers)?:** In the 14 days prior to illness onset, document any travel by the case-patient outside their

city/town of current residence, if known. For each place traveled, list the departure date in MM/DD/YYY, departure city, state/province/country, arrival date MM/DD/YYY, and arrival city, state/province/country. Include any overnight transits and layovers. If exact dates are not known, but approximate dates for each instance of travel are known, provide this in the text field for approximate dates.

Exposure history:

25. **In the 14 DAYS prior to illness, did you have close contact with another lab-confirmed 2019-nCoV case-patient?**: Indicate the appropriate response.
    If YES, please fill out the "Household/Close Contact Investigation Form."
26. **Relationship to 2019-nCoV Source Case:** Select all that apply. Specify if other; but do not provide PII.
27. **Exposure setting to the 2019-nCoV source case:** Select all that apply. Specify if other; but do not provide PII.
28. **In the 14 days prior to illness onset, did you…?** Indicate the appropriate response per question. All exposures should have a marked answer. For each exposure that occurred, indicate start and end date in MM/DD/YYYY format; if exact date is unknown, provide an approximate date in text field.
29. **During 14 days prior to illness onset, did you have any direct contact with any type of animals including livestock, pets, or wildlife, whether at home or away from home? (list ALL animal exposures including livestock, pets, and wildlife):** Indicate the appropriate response. If YES, fill out the accompanying table:
    a. **City/Country contact occurred:** Enter the city and country where the contact with the animal occurred.
    b. **Type of animal(s) contacted (one type of animal per row):** Enter the type of animal, with one animal per row.
    c. **Date(s) contact occurred:** Enter the date(s) in MM/DD/YYYY when the contact with the animal occurred.
    d. **Contact setting(s) (check all that apply):** Indicate the type of contact setting where the exposure to the animal occurred. Check all settings that apply. If other, specify, but do not provide PII.
30. **In the 14 days prior to illness onset, did you…:** For each exposure in the table, indicate the appropriate response. For any exposures marked as "Y", indicate the facility type and the start and end dates that the exposure occurred. If exact dates are not known, please specify approximate dates in text field.

Outpatient chart abstraction

31. **Did the patient seek medical care in an outpatient setting?** If the patient sought medical care in an outpatient setting, then mark the appropriate response. If patient was hospitalized or was evaluated in the Emergency Department (ED), this should be marked "No."
    If yes, did the patient receive the following medications or were they prescribed? Please mark the appropriate response. Specify the medication in free text.
    - Examples of antivirals: Oseltamivir (Tamiflu), ribavirin
    - Examples of antibiotics: ceftriaxone, azithromycin, levofloxacin, vancomycin, Augmentin
    - Examples of bronchodilators: albuterol, ipratropium, Proventil HFA, ProAir, Ventolin HFA, Xopenex HFA, Combivent, Duoneb
    - Examples of IV/IM steroids: Methylprednisolone (SoluMedrol), prednisone, dexamethasone. Do not record if patient took steroids by mouth.
    - Examples of inhaled steroids: Mometasone (Asmanex), ciclesonidde (Alvesco), budenoside (Pulmicort)

Hospital chart abstraction

32. **If hospitalized more than once, please enter the second hospitalization's admission and discharge dates:** Record the Admission Date and Discharge Dates of the second hospitalization in MM/DD/YYYY format, if applicable.

33. **First recorded vital signs:** Record the first vital signs that are recorded in the medical chart. This can also include vital signs recorded by Emergency Medical Services (EMS)/ambulance and/or in the Emergency Department. Do not record vital signs from an outpatient setting.
    - Temp (F): temperature in Fahrenheit
    - Blood pressure (BP): usually notated "X/Y" (for example, 120/80)
    - Heart rate (HR)
    - Respiratory rate (RR)

34. **Did the patient receive supplemental oxygen during hospitalization?** Answer yes if indications of nasal cannula, face mask, or hi-flow nasal cannula (HFNC) are recorded any time during the hospitalization. Answer unknown if medical chart is not available, or information is not known.

35. **Was the patient admitted to an intensive care unit (ICU)?** Select appropriate answer. Answer unknown if medical chart is not available, or ICU admission is not known. If yes, then record the ICU admission date and the ICU Discharge date in MM/DD/YYYY. There is space to record two ICU stays during a hospitalization on the CRF. If more space is needed, use the additional comments or notes section.

36. **Was the patient placed on non-invasive ventilation (BiPAP/CPAP)?** Select if BiPAP or CPAP was used during a hospitalization.

37. **Did the patient receive mechanical ventilation (MV)/intubation?** Select if patient was intubated or was mechanically ventilated during a hospitalization.
    If yes, record first date of mechanical ventilation/intubation: MM/DD/YYYY format
    If yes, record total days with mechanical ventilation: Count number of days on MV. If partial day, then round up to next whole number.
    If yes, then record date last extubated: Record the date of extubation associated with the last intubation during the hospitalization in MM/DD/YYYY format.

38. **Did the patient have ECMO?** Select if patient had ECMO (extracorporeal membrane oxygenation) during a hospitalization.
    If yes, record the start date of ECMO: MM/DD/YYYY format
    If yes, record the length of ECMO: Record total number of days on ECMO. Round up to whole number.

39. **Did the patient have a new abnormality on chest x-ray or CT scan?** Respond appropriately. Select unknown if missing.

40. **Did the patient receive a discharge diagnosis of pneumonia?** Refer to the clinical discharge summary. This should not be from ICD codes. Select unknown if missing chart.
    If yes, was the determination?: Select "clinical" if documentation is in medical chart and not supported by radiology (i.e. CXR, CT). Select "radiographic" if radiology supported pneumonia diagnosis.

41. **Did the patient receive a discharge diagnosis of acute respiratory distress syndrome (ARDS)?** Refer to the clinical discharge summary. This should not be from ICD codes. Select unknown if missing chart.

42. **Clinical Discharge Diagnoses and ICD10 Discharge Diagnoses:** Under Discharge Diagnoses, use the clinical discharge summary to record the first 10 discharge diagnoses. Under ICD-10-CM Codes, record the first 10 ICD-10-CM discharge codes.

43. **Did the patient receive the following medications during hospitalization for this illness?**
Please mark the appropriate response. Specify the medication in free text.
    - Examples of antivirals: Oseltamivir (Tamiflu), ribavirin
    - Examples of antibiotics: ceftriaxone, azithromycin, levofloxacin, vancomycin, Augmentin
    - Examples of bronchodilators: albuterol, ipratropium, Proventil HFA, ProAir, Ventolin HFA, Xopenex HFA, Combivent, Duoneb
    - Examples of IV/IM steroids: Methylprednisolone (SoluMedrol), prednisone, dexamethasone. Do not record if patient took steroids by mouth.

- Examples of inhaled steroids: Mometasone (Asmanex), ciclesonidde (Alvesco), budenoside (Pulmicort)

44. **Did the patient die as a result of this illness?** If yes, then record date of death in MM/DD/ YYYY.
Contribution of 2019-novel coronavirus to death: Record appropriate answer using death certificate or death note in hospital record.
Was autopsy performed? Record appropriate answer using death certificate or death note in hospital record.
Primary cause of death: record this from death certificate/coroner using free text.

45. **To where was the patient discharged?** Record appropriate answer.

Laboratory testing

46. **For the following section, please complete for ANY specimen tested for a respiratory pathogen:**
Specimen collection date: Record in MM/DD/YYYYY format. Do not record specimen result/report date.
Specimen type: Record if nasopharyngeal swab (NP), nasopharyngeal aspirate (NPA), nasal aspirate, nasal swab, mid-turbinate swab, sputum, oropharyngeal swab (OP), endotracheal aspirate, chest tube fluid, bronchoalveolar lavage (BAL), serum, stool, urine, other (specify), and unknown.
Test type: Record if reverse transcriptase-polymerase chain reaction (RT-PCR), viral/bacterial culture, rapid antigen test, fluorescent antibody test, other (specify), and unknown.
Pathogen: Record the pathogen that was tested for (e.g, influenza, adenovirus, HMPV, etc.)
Result: Record if positive, negative, pending, or indeterminate.
Sent to CDC: check if sent to CDC
If sent to CDC, specimen ID#: Record specimen ID# given by the state or local laboratory.

47. **Any additional comments or notes?** Record any additional notes.