

Instructions for Completing the Human Infection with 2019 Novel Coronavirus (COVID-19) Person Under Investigation (PUI) and Case Report Form

Purpose: This document describes the procedures for completing the 2019 Novel Coronavirus (COVID-19) Person Under Investigation (PUI) and Case Report Form (CRF) for persons under investigation who are being tested or have been tested for the virus that causes COVID-19.

- PUI: Any person who is currently under investigation for having the virus that causes COVID-19, or who was under investigation but tested negative for the virus.
- Laboratory-confirmed case of COVID-19: Individual who has tested positive for the virus that causes COVID-19 in at least one respiratory specimen (Note: effective 3/14/2020 there is no longer the designation of “presumptive positive”).

If a sample from a PUI tests positive for the virus that causes COVID-19, the form should be updated to indicate an individual’s change in status from a PUI to being a laboratory-confirmed case.

The form should be completed if a person has a positive laboratory result for the virus that causes COVID-19, even when not previously identified as a PUI.

General:

1. All dates should be formatted MM/DD/YYYY.
2. If completing the .pdf version of the form, use an “X” to mark boxes. Make sure to carefully mark boxes so that the “X” does not cross multiple boxes.

Header:

PATIENT IDENTIFIER INFORMATION IS NOT TRANSMITTED TO CDC AND IS FOR LOCAL-USE ONLY:

Patient first name: Enter case’s first (given) name.

Patient last name: Enter case’s last (family) name.

Date of birth (MM/DD/YYYY): Enter date of birth in MM/DD/YYYY format.

ID information:

Reporting jurisdiction: Enter the reporting jurisdiction where the PUI or case was identified. The reporting jurisdiction must be a state/city/territory authorized to submit data through NNDSS.

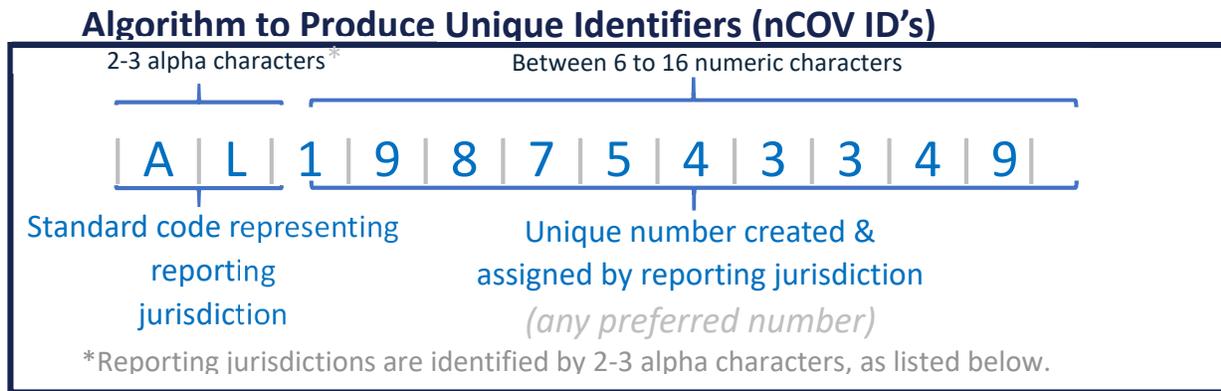
Reporting health department: Enter the name of the health department completing the PUI or case report.

Case state/local ID: Enter a local-use ID assigned by the state or local health department if desired for patient tracking or matching.

CDC 2019-nCoV ID: Enter the CDC 2019-nCoV ID assigned to the PUI or case. If the case was already identified as a PUI in collaboration with CDC, or was part of a contact investigation in which CDC was collaborating with the state or local health department, this CDC 2019-nCoV ID should have already been assigned and the CDC 2019-nCoV ID that was already provided by CDC should be entered. The CDC 2019 nCoV ID should be a part of the

state or local health departments records; please check with the reporting jurisdiction. This may have previously been called a PUI ID. **Do not assign a new 2019-nCoV ID for these individuals.**

If this is a new PUI or case that was not previously under investigation or reported, the CDC 2019-nCoV ID should be assigned by the jurisdiction. CDC 2019-nCoV IDs should be assigned for all PUIs and laboratory-confirmed cases so that this person can be tracked at the jurisdictional and national level. The reporting jurisdiction should assign the CDC 2019-nCoV ID, and use this ID for all specimens and data transmitted to CDC for that person. The structure of the ID should be as follows:



!!! Important !!!

Do not add special characters, dashes, or white spaces to the nCoV ID. The alpha- and numeric-portions of the ID are seamless. The numeric portion of the ID cannot begin with zero ('0').

| State | Code | State | Code | State | Code | Territory/Jurisdiction | Code |
|-------------|------|----------------|------|----------------|------|--------------------------------|------|
| Alabama | AL | Louisiana | LA | Ohio | OH | American Samoa | AS |
| Alaska | AK | Maine | ME | Oklahoma | OK | District of Columbia | DC |
| Arizona | AZ | Maryland | MD | Oregon | OR | Guam | GU |
| Arkansas | AR | Massachusetts | MA | Pennsylvania | PA | New York City | NYC |
| California | CA | Michigan | MI | Rhode Island | RI | Northern Mariana Islands | MP |
| Colorado | CO | Minnesota | MN | South Carolina | SC | Puerto Rico | PR |
| Connecticut | CT | Mississippi | MS | South Dakota | SD | U.S. Virgin Islands | VI |
| Delaware | DE | Missouri | MO | Tennessee | TN | Federated States of Micronesia | FSM |
| Florida | FL | Montana | MT | Texas | TX | Republic of Marshall Islands | RMI |
| Georgia | GA | Nebraska | NE | Utah | UT | Republic of Palau | ROP |
| Hawaii | HI | Nevada | NV | Vermont | VT | | |
| Idaho | ID | New Hampshire | NH | Virginia | VA | | |
| Illinois | IL | New Jersey | NJ | Washington | WA | | |
| Indiana | IN | New Mexico | NM | West Virginia | WV | | |
| Iowa | IA | New York | NY | Wisconsin | WI | | |
| Kansas | KS | North Carolina | NC | Wyoming | WY | | |
| Kentucky | KY | North Dakota | ND | | | | |

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

Contact ID: Only fill out this field if a PUI or case-patient is a known contact to another confirmed case of COVID-19. Contact IDs are assigned using the original (source) case-patient's nCoV ID followed by a hyphen and a sequential number indicating the order in which the contact was identified (e.g., Confirmed case CA102034567 may have contacts CA102034567 -01 and CA102034567 -02). 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 have been assigned previously. This should be a part of the state or local health departments records; please check with the reporting jurisdiction.

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

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.

Basic case information

What is the current status of this person?

- Select "PUI, testing pending" if a PUI has been identified but the initial laboratory testing has not yet been completed.
- Select "PUI, tested negative" if a PUI was previously identified, but the laboratory testing for the virus that causes COVID-19 was negative.
- Select "laboratory-confirmed case" if a person has at least one respiratory specimen that tested positive for the virus that causes COVID-19 by a CDC laboratory, state or local public health laboratory, or commercial laboratory using FDA-validated COVID 19 NAA. (Note: effective 3/14/2020 there is no longer the designation of "presumptive positive").

Please update this field each time the individual's status changes.

Report date of PUI to CDC: Enter the date the person was initially reported to CDC as a PUI in MM/DD/YYYY format.

Report date of case to CDC: Enter the date the case-patient was initially reported to CDC as a case in MM/DD/YYYY format. That is, please report the date at which the person changed from not being a case to being either a laboratory-confirmed case.

County of Residence: Please enter the individual's county of residence. Residence is typically defined by CSTE as the place of 'usual residence' at the time an infection is acquired.

State of Residence: Please enter the individual's county of residence. Residence is typically defined by CSTE as the place of 'usual residence' at the time an infection is acquired. The state of residence and reporting jurisdiction may be two distinct places.

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

Sex: Select appropriate response.

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

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

Age: Enter the PUI or case-patient's age. Age may be entered in units of years, months, or days. Units will be specified later.

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

Date of first positive specimen collection: Enter the date of this person's first positive respiratory specimen collection, regardless of specimen type, in MM/DD/YYYY format. If the person tested positive, but the date is unknown, select "Unknown." If the person is a PUI and tested negative or is awaiting initial test results, select "N/A."

Did the patient develop pneumonia?: Select the appropriate response. Refer to the clinical discharge summary in the patient's medical chart. This should not be from ICD codes. Select 'unknown' if missing chart.

Did the patient have acute respiratory distress syndrome?: Select appropriate response. Refer to the clinical discharge summary in the patient's medical chart. This should not be from ICD codes. Select "unknown" if missing chart.

Did the patient have another diagnosis/etiology for their illness?: Select appropriate response. Refer to the clinical discharge summary in the patient's medical chart. This should not be from ICD codes. Select "unknown" if missing chart.

Did the patient have an abnormal chest X-ray?: Select appropriate response. Select "unknown" if missing chart. Select 'yes' if—at any time—the person had an abnormal chest X-ray as part of this illness.

Symptoms present during course of illness?: This question refers to the PUI or case-patient's symptom status related to the entire duration of illness. If the PUI or case-patient was ever symptomatic as part of this illness with COVID-19, select "symptomatic." If the PUI or case-patient was asymptomatic (never experienced symptoms as part of this illness), please select "asymptomatic." If symptom status is unknown, select "unknown."

- If symptomatic, record symptom onset date in MM/DD/YYYY format or mark "unknown."
- If the PUI or case-patient was previously symptomatic and symptoms are currently resolved at the time of completing or updating this form, 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 date field. If still symptomatic at time of interview, mark "Still symptomatic." If the PUI or case-patient had symptoms, and the symptoms are resolved, but there is 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."

Was the patient hospitalized? Select the appropriate response. If yes, provide dates of first hospital admission and first hospital discharge in MM/DD/YYYY format. If the patient is currently hospitalized, please leave the discharge date blank. This field can be revised at a later time.

Was the patient admitted to an intensive care unit (ICU)? Select the appropriate response. Select "unknown" if the medical chart is not available or ICU admission is not known.

Did the patient receive mechanical ventilation (MV)/intubation? Select “Yes” if the patient was mechanically ventilated during hospitalization via intubation or tracheostomy. If yes, count the total number of days with mechanical ventilation. Round up to whole number. Select “unknown” if the medical chart is not available.

Did the patient receive extracorporeal membrane oxygenation (ECMO)?: Select the appropriate response. Select “unknown” if the medical chart is not available.

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, please select “Unknown date of death.” (In DCIPHER, this is phrased as “Check if date of death unknown.”)

Is the patient a health care worker in the United States?: Select the appropriate response. HCP are defined as all paid and unpaid persons working in health-care settings who have the potential for exposure to patients and/or to infectious materials, including body substances, contaminated medical supplies and equipment, contaminated environmental surfaces, or contaminated air. HCP might include (but are not limited to) physicians, nurses, nursing assistants, therapists, technicians, emergency medical service personnel, dental personnel, pharmacists, laboratory personnel, autopsy personnel, students and trainees, contractual staff not employed by the health-care facility, and persons (e.g., clerical, dietary, housekeeping, laundry, security, maintenance, administrative, billing, and volunteers) not directly involved in patient care but potentially exposed to infectious agents that can be transmitted to and from HCP and patients.

Does the patient have a history of being in a healthcare facility (as a patient, worker, or visitor) in China?: Select the appropriate response.

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 COVID-19 case-patient, check if the PUI or 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 COVID-19 case-patient.

If the PUI or case-patient traveled to a non-US country that was not China, select all of the countries that the person traveled to within the past 14 days by selecting all relevant response options from the drop-down menu. If the country that the PUI or case-patient traveled to in the past 14 days is not listed, you may write the appropriate country in the text field. **If the PUI or case-patient had traveled on a cruise, had exposure to large social gatherings (e.g. conference, concert), or had work-related exposures to large groups (e.g. airport screeners, port workers), please include details in the free text field.**

If the patient had contact with another COVID-19 case, was this person a U.S. case?: Select the appropriate response. If yes, please provide the nCoV ID of the source case. If the patient did not have contact with another case, please select “N/A.”

Under what process was the PUI or case first identified? Please check all that apply. If identified by the EpiX notification of travelers, please provide the DGMQID. If other, please specify.

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

Collected from (check all that apply): Please select “patient interview” or “medical record review.” If both sources were used to collect information on symptoms, clinical course, past medical history, and social history, please select both response options.

During this illness, did you experience any of the following symptoms? Please select “Yes,” “No,” or “Unknown” for each specific symptom. Please indicate the symptoms that the PUI or case-patient has experienced to date, even if he/she is no longer experiencing these symptoms. All symptoms should have an answer. If other symptoms were experienced, then describe the symptom in the space after “Other”.

Pre-existing medical conditions?: Mark the appropriate response based on whether the PUI or case-patient has *any* pre-existing medical conditions prior to investigation or confirmation of COVID-19. If PUI or case-patient has no pre-existing medical conditions, mark “No.” If not collected during interview and medical chart is missing, mark “Unknown.” After answering the initial (summary) question, please provide a response for *each* pre-existing condition. All questions—other than pregnancy—pertain to a *current* or *past* history of the condition. If “Yes” to neurologic/neurodevelopment/intellectual disability or Other Chronic Diseases, please specify. The pregnancy question should be marked “Yes” if the PUI or case-patient is female and currently or recently pregnant (i.e., gave birth while ill with COVID-19).

Current smoker: Select the appropriate response.

Former smoker: Select the appropriate response.

Respiratory diagnostic testing: For each pathogen, indicate whether the test was positive, negative, pending, or not done. If the PUI or case-patient had a test performed for another pathogen, please check the appropriate test result and specify the name of the pathogen next to “Other, Specify.” (In DCIPHER, please specify additional tests/pathogens only if they are positive.) If multiple tests for the same pathogen were completed, mark “Positive” if any of the tests for that pathogen were positive during the course of the illness suspected to be COVID-19.

Specimens for COVID-19 testing: For each specimen tested for the virus that causes COVID-19, record if the specimen was from a nasopharyngeal swab (NP), oropharyngeal swab (OP), sputum, or other specimen (specify type). If combined NP/OP swabs are collected, record results in the field for NP swabs. Jurisdictions can provide up to three results for each type of specimen; if additional specimens are collected, please provide information about these specimens in the “additional state/local specimen ID” fields below this question. If there are still additional specimens, please use the notes field following the specimen collection information to provide specimen IDs. Provide the local, state, or jurisdictional specimen ID associated with each specimen, as well as the date the specimen was collected in MM/DD/YYYY format. For specimens tested at a local or state public health laboratory or at a commercial laboratory, select “State Lab Tested.” For specimens tested at CDC, select “Sent to CDC.” For each test performed, indicate the result: positive, negative, pending, not done, or indeterminate.

Please update these test results as they become available.

Additional state/local Specimen IDs: Provide additional specimen IDs from state/local laboratories for specimens tested for the virus that causes COVID-19. If needed, prioritize listing those specimens testing positive for the virus that causes COVID-19, regardless of specimen type.