COVID-19 Vaccine Breakthrough Case Investigation Form

Case Identification Numbers and Contacts

Vaccine breakthrough REDCap ID: _____

CDC case identification number: _____

State/local case identification number: _____

State health department contact name: _____

Email address: _____

Case-Patient Demographics

Age: _____

Sex:
- ○ Male
- ○ Female
- ○ Unknown

Race (Select all that apply):
- ☐ American Indian/Alaska Native
- ☐ Asian
- ☐ Black or African American
- ☐ Native Hawaiian/Other Pacific
- ☐ White

OR ☐ **Unknown**

Ethnicity:
- ○ Hispanic or Latino
- ○ Not Hispanic or Latino
- ○ Unknown

State of residence: _____

County of residence: _____

Type of residence [Select one]
- ○ House
- ○ Apartment
- ○ Hotel
- ○ Long-term care facility
- ○ Correctional facility
- ○ Mobile home
- ○ Group home
- ○ Shelter
- ○ Other
- ○ Unknown

COVID Laboratory Confirmation

Specimen Type :
- ○ Upper respiratory sample *(nasopharyngeal swab, nasal swab, nasal wash, oropharyngeal swab)*
- ○ Saliva
- ○ Sputum
- ○ Bronchoalveolar lavage fluid
- ○ Pleural fluid
- ○ Lung tissue

Date specimen was collected: _____

Location where testing performed:
- ○ Laboratory or medical facility
- ○ Home test only

Name of laboratory where testing was performed:

Test type:
- ○ RT-PCR or other NAAT
- ○ Antigen only

Test result:
- ○ Positive
- ○ Negative
- ○ Indeterminate

CT Value: _____

Available specimens from initial COVID-19 laboratory confirmation: (Select all that apply)
- ☐ SARS-CoV-2 sequence data
- ☐ Primary respiratory specimen
- ☐ None

SARS-CoV-2 sequencing performed: ○ Yes ○ No ○ Unknown

SARS-CoV-2 lineage: _____ **GISAID accession number:** _____ **GenBank accession number:** _____

COVID-19 Vaccination Information

DOSE # 1

Vaccine manufacturer and type: _____ ***or Other:*** _____

Date received: _____ **Vaccine lot number:** _____

Name of facility where vaccine was received: _____

City and state where vaccine was received: _____

DOSE # 2

Vaccine manufacturer and type: _____ ***or Other:*** _____

Date received: _____ **Vaccine lot number:** _____

Name of facility where vaccine was received: _____

City and state where vaccine was received: _____

Clinical Illness

Symptoms during the course of illness

- ○ Yes
- ○ No
- ○ Unknown

Clinical symptoms reported from 2 days before to 2 weeks after the positive test (Select any present):

- ☐ Fever
- ☐ Chills
- ☐ Rigors
- ☐ Myalgia
- ☐ Headache
- ☐ Sore throat
- ☐ Nausea or vomiting
- ☐ Diarrhea
- ☐ Fatigue
- ☐ Congestion or runny nose
- ☐ Cough
- ☐ Shortness of breath
- ☐ Difficulty breathing
- ☐ New olfactory disorder
- ☐ New taste disorder

OR ☐ **No COVID-19-like symptoms**

Underlying Medical Conditions

Underlying medical conditions: (Select all that apply)

- ☐ Pregnancy
- ☐ Diabetes mellitus
- ☐ Chronic kidney disease
- ☐ Chronic liver disease
- ☐ Autoimmune disease
- ☐ Immunocompromised
- ☐ HIV infection
- ☐ Active cancer
- ☐ Solid organ transplant
- ☐ Hematopoietic stem cell transplant
- ☐ Other immunosuppressive condition: *(specify)* _____

Systemic immunosuppressive therapy or medications (i.e., chemotherapy, corticosteroids, monoclonal antibodies, excludes topical agents and inhaled steroids)

- ○ Yes
- ○ No
- ○ Unknown

Clinical Course

Presented for outpatient medical care (e.g., telemedicine, clinic, urgent care, or emergency room) from 2 days before to 2 weeks after the positive test:

- ○ Yes
- ○ No
- ○ Unknown

Hospitalized for ≥1 night in an inpatient facility within 2 weeks after the positive test:

- ○ Yes
- ○ No
- ○ Unknown

If Yes

Admitted to an intensive care unit during the hospitalization:

- ○ Yes
- ○ No
- ○ Unknown

Required mechanical ventilation during the hospitalization:

- ○ Yes
- ○ No
- ○ Unknown

Hospitalization related to SARS-CoV-2 infection:

- ○ Yes
- ○ No
- ○ Unknown

Died:

- ○ Yes
- ○ No
- ○ Unknown

If Yes

Date died: _____

Death related to SARS-CoV-2 infection:

- ○ Yes
- ○ No
- ○ Unknown