

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT\_SELECTION

**Form Version:** 30-Jul-2020 21:29

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1139

**Site Name:** (1139) Duke University Medical Center

**Subject No:** 11391024

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

**Cohort Selection**

DO NOT USE THE OPTIONS STAGE 1 NONSENTINEL and STAGE 2 from this CRF. As per protocol amendment 5, STAGE 3 option is equivalent to PHASE 2/3.

|    |   |                 |
|----|---|-----------------|
| 1. | Select appropriate response - Protocol version                        | 30 JUN 2020     |
| 2. | Select appropriate response - What cohort does the subject belong to? | STAGE 3 COHORTS |

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1139

**Subject No:** 11391024

**Generated By:** (b) (4)

**Form:** MAIN INFORMED CONSENT

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1139) Duke University Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:44

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**Informed Consent**

|    |              |  |
|----|--------------|--|
| 1. | Consent Was: | OBTAINED<br>Date Written Consent Obtained<br>Jul/31/2020 |
|----|--------------|--|

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** DEMOGRAPHY

**Form Version:** 06-Jul-2020 21:55

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1139

**Site Name:** (1139) Duke University Medical Center

**Subject No:** 11391024

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

**Demography**

|    |                                 |  |
|----|---------------------------------|--|
| 1. | Subject ID                      | [11391024]                                     |
| 2. | Birth Date:                     | (b) (6)/1949                                   |
| 3. | Sex:                            | FEMALE   |
| 4. | Ethnicity:                      | NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN |
| 5. | Race: (Check X all that apply): | WHITE  |
| 6. | Racial Designation:             |  |

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1139

**Subject No:** 11391024

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1139) Duke University Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

**Date of Visit**

|    |                 |             |
|----|-----------------|-------------|
| 1. | Date of Visit   | Jul/31/2020 |
| 2. | Erroneous Visit |             |

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 30-Jul-2020 21:27**Site No:** 1139**Subject No:** 11391024**Generated By:** (b) (4)**Form:** INCLUSION/EXCLUSION CRITERIA**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1139) Duke University Medical Center**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:44[eCRF Audit Trail History](#)

Study eligibility requires subjects to meet all inclusion criteria (YES) and Not meet exclusion criteria (NO).

**Inclusion Criteria**

|     |                                     |  |
|-----|-------------------------------------|--|
| 1.a | Inclusion Number:                   | 1  |
|     | Criterion Description:              | Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage) |
|     | Criterion met?                      | YES  |
|     | Criterion ID: (For Pfizer use only) | IN01A00  |
| 1.b | Inclusion Number:                   | 2  |
|     | Criterion Description:              | Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures                  |
|     | Criterion met?                      | YES  |
|     | Criterion ID: (For Pfizer use only) | IN02A00  |
| 1.c | Inclusion Number:                   | 3  |
|     | Criterion Description:              | Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study                |
|     | Criterion met?                      | YES  |
|     | Criterion ID: (For Pfizer use only) | IN03A00  |
| 1.d | Inclusion Number:                   | 4  |
|     | Criterion Description:              | Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol                          |
|     | Criterion met?                      | YES  |
|     | Criterion ID: (For Pfizer use only) | IN04A00  |

**Exclusion Criteria**

|     |                        |   |
|-----|------------------------|---|
| 2.a | Exclusion Number:      | 1   |
|     | Criterion Description: | Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation |

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**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 30-Jul-2020 21:27

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**Form:** INCLUSION/EXCLUSION CRITERIA

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**Generated Time (GMT):** 29-Mar-2021 11:44

|     |                                     |  |
|-----|-------------------------------------|--|
|     | Criterion met?                      | NO   |
|     | Criterion ID: (For Pfizer use only) | EX01A00  |
| 2.b | Exclusion Number:                   | 2  |
|     | Criterion Description:              | Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)   |
|     | Criterion met?                      | NO   |
|     | Criterion ID: (For Pfizer use only) | EX02A00  |
| 2.c | Exclusion Number:                   | 3  |
|     | Criterion Description:              | History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s) |
|     | Criterion met?                      | NO   |
|     | Criterion ID: (For Pfizer use only) | EX03A00  |
| 2.d | Exclusion Number:                   | 4  |
|     | Criterion Description:              | Receipt of medications intended to prevent COVID-19  |
|     | Criterion met?                      | NO   |
|     | Criterion ID: (For Pfizer use only) | EX04A00  |
| 2.e | Exclusion Number:                   | 8  |
|     | Criterion Description:              | Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination                      |
|     | Criterion met?                      | NO   |
|     | Criterion ID: (For Pfizer use only) | EX08A00  |
| 2.f | Exclusion Number:                   | 10   |
|     | Criterion Description:              | Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection    |
|     | Criterion met?                      | NO   |
|     | Criterion ID: (For Pfizer use only) | EX10A00  |

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1139

**Subject No:** 11391024

**Generated By:** (b) (4)

**Form:** INCLUSION/EXCLUSION CRITERIA

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1139) Duke University Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:44

|     |                                     |   |
|-----|-------------------------------------|---|
| 2.g | Exclusion Number:                   | 11  |
|     | Criterion Description:              | Women who are pregnant or breastfeeding   |
|     | Criterion met?                      | NO  |
|     | Criterion ID: (For Pfizer use only) | EX11A00   |
| 2.h | Exclusion Number:                   | 12  |
|     | Criterion Description:              | Previous vaccination with any coronavirus vaccine   |
|     | Criterion met?                      | NO  |
|     | Criterion ID: (For Pfizer use only) | EX12A00   |
| 2.i | Exclusion Number:                   | 13  |
|     | Criterion Description:              | Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids  |
|     | Criterion met?                      | NO  |
|     | Criterion ID: (For Pfizer use only) | EX13A01   |
| 2.j | Exclusion Number:                   | 15  |
|     | Criterion Description:              | Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study |
|     | Criterion met?                      | NO  |
|     | Criterion ID: (For Pfizer use only) | EX14A01   |
| 2.k | Exclusion Number:                   | 16  |
|     | Criterion Description:              | Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation                 |
|     | Criterion met?                      | NO  |
|     | Criterion ID: (For Pfizer use only) | EX15A01   |
| 2.l | Exclusion Number:                   | 17  |
|     | Criterion Description:              | Previous participation in other studies involving study intervention containing lipid nanoparticles   |
|     | Criterion met?                      | NO  |
|     | Criterion ID: (For Pfizer use only) | EX16A01   |

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**Form Version:** 30-Jul-2020 21:27

**Site No:** 1139

**Subject No:** 11391024

**Generated By:** (b) (4)

**Form:** INCLUSION/EXCLUSION CRITERIA

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1139) Duke University Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:44

|     |                                     |   |
|-----|-------------------------------------|---|
| 2.m | Exclusion Number:                   | 22  |
|     | Criterion Description:              | Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members |
|     | Criterion met?                      | NO  |
|     | Criterion ID: (For Pfizer use only) | EX21A01   |



**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1139

**Subject No:** 11391024

**Generated By:** (b) (4)

**Form:** DISPOSITION - SCREENING

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1139) Duke University Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

**Disposition - Screening**

|    |   |             |
|----|---|-------------|
| 1. | Date of Completion/Discontinuation /Death | Jul/31/2020 |
| 2. | Phase of Disposition:                     | SCREENING   |
| 3. | Status:                                   | COMPLETED   |
| 4. | Specify Status:                           | [ ]         |

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Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1139

Subject No: 11391024

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Medical History Details

|     |  |                                |
|-----|--|--------------------------------|
| 1.a | Line/MH Number:  | [1]                            |
|     | Disease/Syndrome/Surgery<br>/Non-Drug Allergies/Drug<br>Allergies: | [Hypercholesterolemia]         |
|     | Start Date:  | Jun/30/2008                    |
|     | Ongoing:   | YES                            |
| 1.b | Line/MH Number:  | [2]                            |
|     | Disease/Syndrome/Surgery<br>/Non-Drug Allergies/Drug<br>Allergies: | [Hypertension]                 |
|     | Start Date:  | Jun/30/2015                    |
|     | Ongoing:   | YES                            |
| 1.c | Line/MH Number:  | [3]                            |
|     | Disease/Syndrome/Surgery<br>/Non-Drug Allergies/Drug<br>Allergies: | [Left knee replacement]        |
|     | Start Date:  | Dec/12/2012                    |
|     | Ongoing:   | NO<br>End Date:<br>Dec/12/2012 |
| 1.d | Line/MH Number:  | [4]                            |
|     | Disease/Syndrome/Surgery<br>/Non-Drug Allergies/Drug<br>Allergies: | [Left knee injury]             |
|     | Start Date:  | Jan/15/2008                    |
|     | Ongoing:   | NO<br>End Date:<br>Dec/12/2012 |

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1139

**Subject No:** 11391024

**Generated By:** (b) (4)

**Form:** GENERAL MEDICAL HISTORY

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1139) Duke University Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:44

|     |  |                                |
|-----|--|--------------------------------|
| 1.e | Line/MH Number:  | [5]                            |
|     | Disease/Syndrome/Surgery<br>/Non-Drug Allergies/Drug<br>Allergies: | [Right shoulder injury]        |
|     | Start Date:  | Jun/30/2014                    |
|     | Ongoing:   | NO<br>End Date:<br>Aug/15/2014 |
| 1.f | Line/MH Number:  | [6]                            |
|     | Disease/Syndrome/Surgery<br>/Non-Drug Allergies/Drug<br>Allergies: | [Right shoulder repair]        |
|     | Start Date:  | Aug/15/2014                    |
|     | Ongoing:   | NO<br>End Date:<br>Aug/15/2014 |

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 30-Jul-2020 21:28

**Site No:** 1139

**Subject No:** 11391024

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - BASELINE

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1139) Duke University Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

**Vital Signs**

|    |                  |             |
|----|------------------|-------------|
| 1. | Date:            | Jul/31/2020 |
| 2. | Weight:          | [207.8]     |
| 3. | Unit:            | LB          |
| 4. | Height:          | [62.0]      |
| 5. | Unit:            | in          |
| 6. | Body Mass Index: | [38.0]      |

**Vital Signs Details**

|     |                       |             |
|-----|-----------------------|-------------|
| 7.a | Record Identifier:    | 1           |
|     | Temperature:          | [98.3]      |
|     | Unit:                 | F           |
|     | Temperature Location: | ORAL CAVITY |

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1139

**Subject No:** 11391024

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1139) Duke University Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:44

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**Lab Urinalysis**

|    |                                       |              |
|----|---------------------------------------|--------------|
| 1. | Lab Panel:                            | URINALYSIS   |
| 2. | Lab Sub-Panel:                        | PREGNANCY    |
| 3. | Collection Date:                      | Jul/31/2020  |
| 4. | Laboratory Name and Address (Derived) | [STUDY SITE] |
| 5. | Specimen Type:                        | URINE        |

**Lab Result**

|     |             |                               |
|-----|-------------|-------------------------------|
| 6.a | Sponsor ID: | [113]                         |
|     | Test:       | Choriogonadotropin Beta_PX113 |
|     | Result:     |                               |
|     | Not Done:   | NOT DONE                      |

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1139

**Subject No:** 11391024

**Generated By:** (b) (4)

**Form:** RANDOMIZATION

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1139) Duke University Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

**Disposition**

|    |                       |             |
|----|-----------------------|-------------|
| 1. | Randomization Date :  | Jul/31/2020 |
| 2. | Randomization Number: | [220836]    |
| 3. | Randomization Group:  | [ ]         |

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1139

**Subject No:** 11391024

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1139) Duke University Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

|    |  |   |
|----|--|---|
| 1. | Data Origin  | SITE                                      |
| 2. | Sample Type  | SERUM                                     |
| 3. | Sample Collected?  | YES<br>Date of Collection:<br>Jul/31/2020 |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [ ]                                       |

**Aliquot**

Please enter barcode for each aliquot.

|     |           |          |
|-----|-----------|----------|
| 5.a | Sample ID | [BP6ZNP] |
| 5.b | Sample ID | [BP6ZNR] |
| 5.c | Sample ID | [BP6ZNS] |
| 5.d | Sample ID | [BPRBGL] |
| 5.e | Sample ID | [BPRBGM] |

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1139

**Subject No:** 11391024

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1139) Duke University Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

|    |  |   |
|----|--|---|
| 1. | Data Origin  | SITE                                      |
| 2. | Sample Type  | NASAL_SWAB                                |
| 3. | Sample Collected?  | YES<br>Date of Collection:<br>Jul/31/2020 |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [ ]                                       |

**Aliquot**

Please enter barcode for each aliquot.

|     |           |          |
|-----|-----------|----------|
| 5.a | Sample ID | [BP6ZNY] |
|-----|-----------|----------|

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1139

**Subject No:** 11391024

**Generated By:** (b) (4)

**Form:** VACCINATION

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1139) Duke University Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

**Vaccination**

|     |   |   |
|-----|---|---|
| 1.  | Was there a temporary delay of vaccination?   | NO  |
| 2.  | Treatment Name  | [BLINDED THERAPY]                         |
| 3.  | Formulation:  | INJECTION                                 |
| 4.  | Dose Date Time:   | Jul/31/2020 15:57                         |
| 5.  | Anatomical Location:  | DELTOID MUSCLE                            |
| 6.  | Body Side:  | LEFT                                      |
| 7.  | Route:  | INTRAMUSCULAR                             |
| 8.  | Actual Dose:  | [ ]                                       |
| 9.  | Unit:   |   |
| 10. | Timeframe Subject Was Observed  | THE PROTOCOL SPECIFIED OBSERVATION PERIOD |
| 11. | Was the subject observed for at least the protocol specified observation period after investigational product administration? | YES                                       |

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**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1139

**Subject No:** 11391024

**Generated By:** (b) (4)

**Form:** REACTOGENICITY DIARY

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1139) Duke University Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:44

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**Reactogenicity Diary**

|    |  |   |
|----|--|---|
| 1. | Select appropriate response -<br>Reactogenicity diary collection | YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT |
|----|--|---|

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1139

**Subject No:** 11391024

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1139) Duke University Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:44

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**Date of Visit**

|    |                 |             |
|----|-----------------|-------------|
| 1. | Date of Visit   | Aug/19/2020 |
| 2. | Erroneous Visit |             |

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 30-Jul-2020 21:30

**Site No:** 1139

**Subject No:** 11391024

**Generated By:** (b) (4)

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1139) Duke University Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

**Vaccination Symptoms Diary - Symptom Resolved Dates**

|     |   |          |
|-----|---|----------|
| 1.  | Were medications to treat fever/pain given on the last day the Subject Diary was completed? | NO       |
| 2.a | Symptom:  | FEVER    |
|     | Were fever or systemic symptoms present on the last day the Subject Diary was completed?    | NO       |
| 2.b | Symptom:  | FATIGUE  |
|     | Were fever or systemic symptoms present on the last day the Subject Diary was completed?    | NO       |
| 2.c | Symptom:  | HEADACHE |
|     | Were fever or systemic symptoms present on the last day the Subject Diary was completed?    | NO       |
| 2.d | Symptom:  | CHILLS   |
|     | Were fever or systemic symptoms present on the last day the Subject Diary was completed?    | NO       |
| 2.e | Symptom:  | VOMITING |
|     | Were fever or systemic symptoms present on the last day the Subject Diary was completed?    | NO       |
| 2.f | Symptom:  | DIARRHEA |
|     | Were fever or systemic symptoms present on the last day the Subject Diary was completed?    | NO       |

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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

**Form Version:** 30-Jul-2020 21:30

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1139

**Site Name:** (1139) Duke University Medical Center

**Subject No:** 11391024

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:44

|     |  |                               |
|-----|--|-------------------------------|
| 2.g | Symptom:   | NEW OR WORSENERED MUSCLE PAIN |
|     | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO                            |
| 2.h | Symptom:   | NEW OR WORSENERED JOINT PAIN  |
|     | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO                            |
| 3.  | Injection Site Location:   | DELTOID MUSCLE                |
| 4.  | Injection Site Body Side:  | LEFT                          |
| 5.a | Injection Site Reaction:   | REDNESS                       |
|     | Were injection site reactions present on the last day the Subject Diary was completed?   | NO                            |
| 5.b | Injection Site Reaction:   | SWELLING                      |
|     | Were injection site reactions present on the last day the Subject Diary was completed?   | NO                            |
| 5.c | Injection Site Reaction:   | PAIN AT INJECTION SITE        |
|     | Were injection site reactions present on the last day the Subject Diary was completed?   | NO                            |

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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 30-Jul-2020 21:28

**Site No:** 1139

**Subject No:** 11391024

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - TEMP

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1139) Duke University Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

**Vital Signs**

|    |       |             |
|----|-------|-------------|
| 1. | Date: | Aug/19/2020 |
|----|-------|-------------|

**Vital Signs Details**

|     |                       |             |
|-----|-----------------------|-------------|
| 2.a | Record Identifier:    | 1           |
|     | Temperature:          | [97.3]      |
|     | Unit:                 | F           |
|     | Temperature Location: | ORAL CAVITY |

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form Version:** 30-Jul-2020 21:27**Site No:** 1139**Subject No:** 11391024**Generated By:** (b) (4)**Form:** LAB URINALYSIS - PREGNANCY TEST**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1139) Duke University Medical Center**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:44

[Form Comments](#)  
[eCRF Audit Trail History](#)

**Lab Urinalysis**

|    |  |                                |                          |
|----|--|--------------------------------|--------------------------|
| 1. | Lab Panel:                               | Not Applicable<br>_____        | <a href="#">Comments</a> |
| 2. | Lab Sub-Panel:                           | Not Applicable<br>_____        | <a href="#">Comments</a> |
| 3. | Collection Date:                         | Not Applicable<br>_____<br>//  | <a href="#">Comments</a> |
| 4. | Laboratory Name and Address<br>(Derived) | Not Applicable<br>_____<br>[ ] | <a href="#">Comments</a> |
| 5. | Specimen Type:                           | Not Applicable<br>_____        | <a href="#">Comments</a> |

**Lab Result**

|     |             |  |                          |
|-----|-------------|--|--------------------------|
| 6.a | Sponsor ID: | Not Applicable<br>_____<br>[ ]                           | <a href="#">Comments</a> |
|     | Test:       | Not Applicable<br>_____<br>Choriogonadotropin Beta_PX113 |                          |
|     | Result:     | Not Applicable<br>_____                                  | <a href="#">Comments</a> |
|     | Not Done:   | Not Applicable<br>_____                                  | <a href="#">Comments</a> |

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1139

**Subject No:** 11391024

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1139) Duke University Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

|    |  |   |
|----|--|---|
| 1. | Data Origin  | SITE                                      |
| 2. | Sample Type  | NASAL_SWAB                                |
| 3. | Sample Collected?  | YES<br>Date of Collection:<br>Aug/19/2020 |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [ ]                                       |

**Aliquot**

Please enter barcode for each aliquot.

|     |           |          |
|-----|-----------|----------|
| 5.a | Sample ID | [BP6ZYX] |
|-----|-----------|----------|

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1139

**Subject No:** 11391024

**Generated By:** (b) (4)

**Form:** VACCINATION

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1139) Duke University Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

**Vaccination**

|     |   |   |
|-----|---|---|
| 1.  | Was there a temporary delay of vaccination?   | NO  |
| 2.  | Treatment Name  | [BLINDED THERAPY]                         |
| 3.  | Formulation:  | INJECTION                                 |
| 4.  | Dose Date Time:   | Aug/19/2020 15:13                         |
| 5.  | Anatomical Location:  | DELTOID MUSCLE                            |
| 6.  | Body Side:  | LEFT                                      |
| 7.  | Route:  | INTRAMUSCULAR                             |
| 8.  | Actual Dose:  | [ ]                                       |
| 9.  | Unit:   |   |
| 10. | Timeframe Subject Was Observed  | THE PROTOCOL SPECIFIED OBSERVATION PERIOD |
| 11. | Was the subject observed for at least the protocol specified observation period after investigational product administration? | YES                                       |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1139

**Subject No:** 11391024

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1139) Duke University Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

**Date of Visit**

|    |                 |             |
|----|-----------------|-------------|
| 1. | Date of Visit   | Sep/22/2020 |
| 2. | Erroneous Visit |             |

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

**Form Version:** 30-Jul-2020 21:30

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1139

**Site Name:** (1139) Duke University Medical Center

**Subject No:** 11391024

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

**Vaccination Symptoms Diary - Symptom Resolved Dates**

|     |   |          |
|-----|---|----------|
| 1.  | Were medications to treat fever/pain given on the last day the Subject Diary was completed? | NO       |
| 2.a | Symptom:  | FEVER    |
|     | Were fever or systemic symptoms present on the last day the Subject Diary was completed?    | NO       |
| 2.b | Symptom:  | FATIGUE  |
|     | Were fever or systemic symptoms present on the last day the Subject Diary was completed?    | NO       |
| 2.c | Symptom:  | HEADACHE |
|     | Were fever or systemic symptoms present on the last day the Subject Diary was completed?    | NO       |
| 2.d | Symptom:  | CHILLS   |
|     | Were fever or systemic symptoms present on the last day the Subject Diary was completed?    | NO       |
| 2.e | Symptom:  | VOMITING |
|     | Were fever or systemic symptoms present on the last day the Subject Diary was completed?    | NO       |
| 2.f | Symptom:  | DIARRHEA |
|     | Were fever or systemic symptoms present on the last day the Subject Diary was completed?    | NO       |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

**Form Version:** 30-Jul-2020 21:30

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1139

**Site Name:** (1139) Duke University Medical Center

**Subject No:** 11391024

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:44

|     |  |                               |
|-----|--|-------------------------------|
| 2.g | Symptom:   | NEW OR WORSENERED MUSCLE PAIN |
|     | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO                            |
| 2.h | Symptom:   | NEW OR WORSENERED JOINT PAIN  |
|     | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO                            |
| 3.  | Injection Site Location:   | DELTOID MUSCLE                |
| 4.  | Injection Site Body Side:  | LEFT                          |
| 5.a | Injection Site Reaction:   | REDNESS                       |
|     | Were injection site reactions present on the last day the Subject Diary was completed?   | NO                            |
| 5.b | Injection Site Reaction:   | SWELLING                      |
|     | Were injection site reactions present on the last day the Subject Diary was completed?   | NO                            |
| 5.c | Injection Site Reaction:   | PAIN AT INJECTION SITE        |
|     | Were injection site reactions present on the last day the Subject Diary was completed?   | NO                            |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1139

**Subject No:** 11391024

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1139) Duke University Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

|    |  |   |
|----|--|---|
| 1. | Data Origin  | SITE                                      |
| 2. | Sample Type  | SERUM                                     |
| 3. | Sample Collected?  | YES<br>Date of Collection:<br>Sep/22/2020 |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [ ]                                       |

**Aliquot**

Please enter barcode for each aliquot.

|     |           |          |
|-----|-----------|----------|
| 5.a | Sample ID | [BP706R] |
| 5.b | Sample ID | [BP706S] |
| 5.c | Sample ID | [BP706T] |
| 5.d | Sample ID | [BPRBTR] |
| 5.e | Sample ID | [BPRBTS] |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1139

**Subject No:** 11391024

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1139) Duke University Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

**Date of Visit**

|    |                 |             |
|----|-----------------|-------------|
| 1. | Date of Visit   | Jan/21/2021 |
| 2. | Erroneous Visit |             |

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1139

**Subject No:** 11391024

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1139) Duke University Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

|    |  |   |
|----|--|---|
| 1. | Data Origin  | SITE                                      |
| 2. | Sample Type  | SERUM                                     |
| 3. | Sample Collected?  | YES<br>Date of Collection:<br>Jan/21/2021 |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [ ]                                       |

**Aliquot**

Please enter barcode for each aliquot.

|     |           |          |
|-----|-----------|----------|
| 5.a | Sample ID | [BP8MM4] |
| 5.b | Sample ID | [BP8MM5] |
| 5.c | Sample ID | [BP8MM6] |
| 5.d | Sample ID | [BNWYH4] |
| 5.e | Sample ID | [BNWYH5] |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

**Header Text:** c4591001

**Visit:** V5\_MONTH12\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1139

**Subject No:** 11391024

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1139) Duke University Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:44

**Date of Visit**

|    |                 |    |
|----|-----------------|----|
| 1. | Date of Visit   | // |
| 2. | Erroneous Visit |    |



**Header Text:** c4591001

**Visit:** V5\_MONTH12\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1139

**Subject No:** 11391024

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1139) Duke University Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:44

**Electronic Sample Tracking**

|    |  |     |
|----|--|-----|
| 1. | Data Origin  |     |
| 2. | Sample Type  |     |
| 3. | Sample Collected?  |     |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [ ] |

**Aliquot**

Please enter barcode for each aliquot.

|    |           |     |
|----|-----------|-----|
| 5. | Sample ID | [ ] |
|----|-----------|-----|

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

**Header Text:** c4591001

**Visit:** V6\_MONTH24\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1139

**Subject No:** 11391024

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1139) Duke University Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:44

**Date of Visit**

|    |                 |    |
|----|-----------------|----|
| 1. | Date of Visit   | // |
| 2. | Erroneous Visit |    |

**Header Text:** c4591001

**Visit:** V6\_MONTH24\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1139

**Subject No:** 11391024

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1139) Duke University Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:44

**Electronic Sample Tracking**

|    |  |     |
|----|--|-----|
| 1. | Data Origin  |     |
| 2. | Sample Type  |     |
| 3. | Sample Collected?  |     |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [ ] |

**Aliquot**

Please enter barcode for each aliquot.

|    |           |     |
|----|-----------|-----|
| 5. | Sample ID | [ ] |
|----|-----------|-----|

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit

**Form:** DATE OF VISIT - ILLNESS ONSET

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1139

**Site Name:** (1139) Duke University Medical Center

**Subject No:** 11391024

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:44

**Date of Visit**

|    |                 |    |
|----|-----------------|----|
| 1. | Date of Visit   | // |
| 2. | Erroneous Visit |    |

**COVID-19 Illness Visit**

|    |                         |  |
|----|-------------------------|--|
| 3. | COVID-19 Illness Visit: |  |
|----|-------------------------|--|

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

**Form Version:** 20-Feb-2021 02:17

**Form Status:** Not Started

**Site No:** 1139

**Site Name:** (1139) Duke University Medical Center

**Subject No:** 11391024

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:44

**Signs and Symptoms**

|    |                                |    |
|----|--------------------------------|----|
| 1. | Date of Assessment:            | // |
| 2. | Date of First Symptom Started: | // |
| 3. | Symptoms Ongoing?              |    |

**Symptoms**

|    |                      |  |
|----|----------------------|--|
| 4. | Symptoms:            |  |
|    | Was symptom present? |  |

**Symptoms - Other**

|    |                        |     |
|----|------------------------|-----|
| 5. | Symptoms - Other Text: | [ ] |
|----|------------------------|-----|

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1139

**Site Name:** (1139) Duke University Medical Center

**Subject No:** 11391024

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:44

**Electronic Sample Tracking**

|    |  |     |
|----|--|-----|
| 1. | Data Origin  |     |
| 2. | Sample Type  |     |
| 3. | Sample Collected?  |     |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [ ] |

**Aliquot**

Please enter barcode for each aliquot.

|    |           |     |
|----|-----------|-----|
| 5. | Sample ID | [ ] |
|----|-----------|-----|

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1139

**Site Name:** (1139) Duke University Medical Center

**Subject No:** 11391024

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:44

**Electronic Sample Tracking**

|    |  |     |
|----|--|-----|
| 1. | Data Origin  |     |
| 2. | Sample Type  |     |
| 3. | Sample Collected?  |     |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [ ] |

**Aliquot**

Please enter barcode for each aliquot.

|    |           |     |
|----|-----------|-----|
| 5. | Sample ID | [ ] |
|----|-----------|-----|

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit

**Form:** HEALTH CARE UTILIZATION

**Form Version:** 20-Feb-2021 02:19

**Form Status:** Not Started

**Site No:** 1139

**Site Name:** (1139) Duke University Medical Center

**Subject No:** 11391024

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:44

**Health Care Utilization**

|    |                                       |  |
|----|---------------------------------------|--|
| 1. | Physician or Healthcare Professional: |  |
|    | Occurrence of Visits or Contacts:     |  |

**Health Care Utilization Other**

|    |                                     |     |
|----|-------------------------------------|-----|
| 2. | Other Type of Practitioner Specify: | [ ] |
|----|-------------------------------------|-----|

**Health Care Utilization**

|    |  |  |
|----|--|--|
| 3. | Has the subject been hospitalized due to potential COVID-19 illness? |  |
|----|--|--|



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit

**Form:** ILLNESS DETAILS

**Form Version:** 06-Jul-2020 21:52

**Form Status:** Not Started

**Site No:** 1139

**Site Name:** (1139) Duke University Medical Center

**Subject No:** 11391024

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:44

**Illness Details**

|    |  |  |
|----|--|--|
| 1. | Category of Clinical Event:                              |  |
| 2. | Was a diagnosis obtained for Potential COVID-19 Illness? |  |
| 3. | Toxicity Grade:  |  |

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA - New  
Unscheduled Visit

**Form:** DATE OF VISIT - ILLNESS CONVALESCENT

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Not Started

**Site No:** 1139

**Site Name:** (1139) Duke University Medical Center

**Subject No:** 11391024

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:44

**Date of Visit**

|    |                 |    |
|----|-----------------|----|
| 1. | Date of Visit   | // |
| 2. | Erroneous Visit |    |

**COVID-19 Illness Visit**

|    |                         |  |
|----|-------------------------|--|
| 3. | COVID-19 Illness Visit: |  |
|----|-------------------------|--|

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA - New  
Unscheduled Visit

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1139

**Site Name:** (1139) Duke University Medical Center

**Subject No:** 11391024

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:44

**Electronic Sample Tracking**

|    |  |     |
|----|--|-----|
| 1. | Data Origin  |     |
| 2. | Sample Type  |     |
| 3. | Sample Collected?  |     |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [ ] |

**Aliquot**

Please enter barcode for each aliquot.

|    |           |     |
|----|-----------|-----|
| 5. | Sample ID | [ ] |
|----|-----------|-----|

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned - New Unscheduled Visit

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Not Started

**Site No:** 1139

**Site Name:** (1139) Duke University Medical Center

**Subject No:** 11391024

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:44

**Date of Visit**

|    |                 |    |
|----|-----------------|----|
| 1. | Date of Visit   | // |
| 2. | Erroneous Visit |    |

**Header Text:** c4591001

**Visit:** Unplanned - New Unscheduled Visit

**Form:** UNPLANNED VISIT

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Not Started

**Site No:** 1139

**Site Name:** (1139) Duke University Medical Center

**Subject No:** 11391024

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:44

**Unplanned Assessments**

|    |             |  |
|----|-------------|--|
| 1. | Assessments |  |
|----|-------------|--|

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

**Form Version:** 15-Sep-2020 21:55

**Site No:** 1139

**Subject No:** 11391024

**Generated By:** (b) (4)

**Form:** DISPOSITION - TREATMENT

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1139) Duke University Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

**Disposition - Treatment**

|    |  |             |
|----|--|-------------|
| 1. | Date of Completion/Discontinuation<br>/Death : | Sep/22/2020 |
| 2. | Phase of Disposition:                          | VACCINATION |
| 3. | Status:  | COMPLETED   |
| 4. | Specify Status:                                | [ ]         |

**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

**Form Version:** 15-Sep-2020 21:53

**Site No:** 1139

**Subject No:** 11391024

**Generated By:** (b) (4)

**Form:** DISPOSITION - FOLLOW-UP

**Form Status:** Not Started

**Site Name:** (1139) Duke University Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:44

**Disposition - Follow-Up**

|    |   |     |
|----|---|-----|
| 1. | Date of Completion/Discontinuation /Death : | //  |
| 2. | Phase of Disposition:                       |     |
| 3. | Status:                                     |     |
| 4. | Specify Status:                             | [ ] |

**Header Text:** c4591001

**Visit:** POT\_COVID\_REPEAT\_SWAB - New  
Unscheduled Visit

**Form:** DATE OF VISIT - REPEAT SWAB

**Form Version:** 10-Oct-2020 15:57

**Form Status:** Not Started

**Site No:** 1139

**Site Name:** (1139) Duke University Medical Center

**Subject No:** 11391024

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:44

**Date of Visit**

|    |                 |    |
|----|-----------------|----|
| 1. | Date of Visit   | // |
| 2. | Erroneous Visit |    |

**COVID-19 Repeat Swab**

|    |                       |  |
|----|-----------------------|--|
| 3. | COVID-19 Repeat Swab: |  |
|----|-----------------------|--|



**Header Text:** c4591001

**Visit:** POT\_COVID\_REPEAT\_SWAB - New  
Unscheduled Visit

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

**Form Version:** 10-Oct-2020 15:57

**Form Status:** Not Started

**Site No:** 1139

**Site Name:** (1139) Duke University Medical Center

**Subject No:** 11391024

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:44

**Electronic Sample Tracking**

|    |  |     |
|----|--|-----|
| 1. | Data Origin  |     |
| 2. | Sample Type  |     |
| 3. | Sample Collected?  |     |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [ ] |

**Aliquot**

Please enter barcode for each aliquot.

|    |           |     |
|----|-----------|-----|
| 5. | Sample ID | [ ] |
|----|-----------|-----|

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** ADVERSE EVENT REPORT

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1139

**Site Name:** (1139) Duke University Medical Center

**Subject No:** 11391024

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:44

| #  | Category      | AE Identifier | Adverse Event  | Start Date       | Is the Adverse Event Still Ongoing | Form Instance                   |
|----|---------------|---------------|--|------------------|------------------------------------|---------------------------------|
| 1. | ADVERSE EVENT | 1             | Malignant neoplasm of upper-outer quadrant of right breast in female, estrogen receptor positive | Feb/2/2021 12:00 | YES                                | <a href="#">Repeating Pages</a> |

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1139

Subject No: 11391024

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

[Back to Form](#)  
[eCRF Audit Trail History](#)  
[Form Audit Trail](#)

**Adverse Event Report**

|    |   |   |
|----|---|---|
| 1. | Category:   | ADVERSE EVENT   |
| 2. | AE ID:  | [1]   |
| 3. | Adverse Event:<br>(If possible specify diagnosis, not individual symptoms)  | [Malignant neoplasm of upper-outer quadrant of right breast in female, estrogen receptor positive]  |
| 4. | Start Date Time:  | Feb/2/2021 12:00  |
| 5. | Is the adverse event still ongoing?   | YES   |
| 6. | Toxicity Grade:   | 3   |
| 7. | Is the adverse event serious?<br><br>If Yes, NOTIFY PFIZER IMMEDIATELY.<br><br>Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes). | YES<br><br>Is this serious event associated with congenital anomaly or birth defect?<br>NO<br><br>Did this serious event result in death?<br>NO<br><br>Did this serious event require or prolong hospitalization?<br>NO<br><br>Did this serious event result in persistent or significant disability/incapacity?<br>NO<br><br>Is this serious event life threatening?<br>NO<br><br>Other medically important serious event<br>YES |
| 8. | Is this adverse event the result of a study Medication Error?<br>If Yes, record the type of medication error on the Medication Error Log.   | NO  |
| 9. | Is this event related to study treatment:   | NOT RELATED<br><br>If Not Related to study treatment(s), this event is due to:<br>OTHER<br><br>If Other, specify:<br>[Breast Cancer]  |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1139

**Subject No:** 11391024

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete

**Site Name:** (1139) Duke University Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:44

|     |  |                            |
|-----|--|----------------------------|
| 10. | Latest Action Taken with Study Treatment:                                  | NOT APPLICABLE             |
| 11. | Was a Concomitant Medication given?  | NO                         |
| 12. | Was a Non-Drug Treatment given?  | NO                         |
| 13. | What was the outcome of this adverse event?:                               | NOT RECOVERED/NOT RESOLVED |
| 14. | Did the adverse event cause the subject to be discontinued from the study? | NO                         |
| 15. | Serious Adverse Event Number: For Pfizer Use Only                          | [2021218812]               |

**Header Text:** c4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

**Form Version:** 17-Jul-2020 21:54

**Site No:** 1139

**Site Name:** (1139) Duke University Medical Center

**Subject No:** 11391024

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:44

| #  | Category | Medication Error | Start Date | Is the medication error Still Ongoing | Study Medication Errors Action | Form Instance                   |
|----|----------|------------------|------------|---------------------------------------|--------------------------------|---------------------------------|
| 1. |          |                  |            |                                       |                                | <a href="#">Repeating Pages</a> |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 17-Jul-2020 21:54

**Site No:** 1139

**Subject No:** 11391024

**Generated By:** (b) (4)

**Form:** MEDICATION ERROR

**Form Status:** Not Started

**Site Name:** (1139) Duke University Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:44

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**Medication Error**

|     |   |     |
|-----|---|-----|
| 1.  | Category:   |     |
| 2.  | Medication Error (Type of Medication Error):                                  | [ ] |
| 3.  | Start Date:   | //  |
| 4.  | Is the medication error still ongoing?  |     |
| 5.  | Latest Action Taken with Study Treatment:                                     |     |
| 6.  | Was a Concomitant Medication given?   |     |
| 7.  | Was a Non-Drug Treatment given?   |     |
| 8.  | Did the Medication Error cause the subject to be discontinued from the study? |     |
| 9.  | Was this medication error associated with any adverse events?                 |     |
| 10. | Serious Adverse Event Number: For Pfizer Use Only                             | [ ] |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - NON STUDY  
VACCINATIONS

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1139

**Site Name:** (1139) Duke University Medical Center

**Subject No:** 11391024

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:44

| #  | Sponsor-Defined Identifier | Category for Medication | Concomitant Medications Pre-specified | Name of Medication | Start Date | Form Instance                   |
|----|----------------------------|-------------------------|---------------------------------------|--------------------|------------|---------------------------------|
| 1. |                            |                         |                                       |                    |            | <a href="#">Repeating Pages</a> |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - NON STUDY  
VACCINATIONS

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1139

**Site Name:** (1139) Duke University Medical Center

**Subject No:** 11391024

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:44

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**Concomitant Medications**

|    |   |     |
|----|---|-----|
| 1. | What is the medication identifier?  | [ ] |
| 2. | Category:   |     |
| 3. | Concomitant Medications<br>Pre-specified:   |     |
| 4. | Medication:<br><br>Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation). | [ ] |
| 5. | Date:   | //  |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)



**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1139

**Site Name:** (1139) Duke University Medical Center

**Subject No:** 11391024

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:44

| #  | Sponsor-Defined Identifier | Category for Medication | Concomitant Medications Pre-specified | Name of Medication | Dose Description | Form Instance                   |
|----|----------------------------|-------------------------|---------------------------------------|--------------------|------------------|---------------------------------|
| 1. |                            |                         |                                       |                    |                  | <a href="#">Repeating Pages</a> |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1139

**Subject No:** 11391024

**Generated By:** (b) (4)

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Status:** Not Started

**Site Name:** (1139) Duke University Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:44

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**Concomitant Medications**

|     |   |     |
|-----|---|-----|
| 1.  | What is the medication identifier?  | [ ] |
| 2.  | Category:   |     |
| 3.  | Concomitant Medications<br>Pre-specified:   |     |
| 4.  | Medication:<br><br>Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation). | [ ] |
| 5.  | Dose:   | [ ] |
| 6.  | Dose Unit:  |     |
| 7.  | Dose Frequency:   |     |
| 8.  | Route:  |     |
| 9.  | Start Date:   | //  |
| 10. | Ongoing?  |     |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1139

**Site Name:** (1139) Duke University Medical Center

**Subject No:** 11391024

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:44

| #  | Category | Treatment Identifier | Con Non-Drug Treatments Pre-specified | Treatment | Start Date | Form Instance                   |
|----|----------|----------------------|---------------------------------------|-----------|------------|---------------------------------|
| 1. |          |                      |                                       |           |            | <a href="#">Repeating Pages</a> |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1139

**Subject No:** 11391024

**Generated By:** (b) (4)

**Form:** RADIATION TREATMENT

**Form Status:** Not Started

**Site Name:** (1139) Duke University Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:44

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**Radiation Treatment**

|    |  |     |
|----|--|-----|
| 1. | Category:  |     |
| 2. | What is the treatment Identifier?                | [ ] |
| 3. | Concomitant Non-drug Treatment<br>Pre-specified: |     |
| 4. | Treatment:                                       | [ ] |
| 5. | Start Date:                                      | //  |
| 6. | Ongoing?   |     |

**Header Text:** c4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1139

**Site Name:** (1139) Duke University Medical Center

**Subject No:** 11391024

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:44

| #  | Transfusion Type | Date of Transfusion | Form Instance                   |
|----|------------------|---------------------|---------------------------------|
| 1. |                  |                     | <a href="#">Repeating Pages</a> |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1139

**Subject No:** 11391024

**Generated By:** (b) (4)

**Form:** TRANSFUSIONS

**Form Status:** Not Started

**Site Name:** (1139) Duke University Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:44

[Back to Form](#)

|    |                      |    |
|----|----------------------|----|
| 1. | Transfusion Type:    |    |
| 2. | Date of Transfusion: | // |

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Not Started

**Site No:** 1139

**Site Name:** (1139) Duke University Medical Center

**Subject No:** 11391024

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:44

**Date of Visit**

|    |                 |    |
|----|-----------------|----|
| 1. | Date of Visit   | // |
| 2. | Erroneous Visit |    |

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** VITAL SIGNS - TEMP

**Form Version:** 20-Feb-2021 02:16

**Form Status:** Not Started

**Site No:** 1139

**Site Name:** (1139) Duke University Medical Center

**Subject No:** 11391024

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:44

**Vital Signs**

|    |       |    |
|----|-------|----|
| 1. | Date: | // |
|----|-------|----|

**Vital Signs Details**

|    |                       |     |
|----|-----------------------|-----|
| 2. | Record Identifier:    |     |
|    | Temperature:          | [ ] |
|    | Unit:                 |     |
|    | Temperature Location: |     |



**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Version:** 20-Feb-2021 02:14

**Form Status:** Not Started

**Site No:** 1139

**Site Name:** (1139) Duke University Medical Center

**Subject No:** 11391024

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:44

**Lab Urinalysis**

|    |                                       |     |
|----|---------------------------------------|-----|
| 1. | Lab Panel:                            |     |
| 2. | Lab Sub-Panel:                        |     |
| 3. | Collection Date:                      | //  |
| 4. | Laboratory Name and Address (Derived) | [ ] |
| 5. | Specimen Type:                        |     |

**Lab Result**

|    |             |     |
|----|-------------|-----|
| 6. | Sponsor ID: | [ ] |
|    | Test:       |     |
|    | Result:     |     |
|    | Not Done:   |     |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** VACCINATION

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Not Started

**Site No:** 1139

**Site Name:** (1139) Duke University Medical Center

**Subject No:** 11391024

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:44

**Vaccination**

|     |   |     |
|-----|---|-----|
| 1.  | Was there a temporary delay of vaccination?   |     |
| 2.  | Treatment Name  | [ ] |
| 3.  | Formulation:  |     |
| 4.  | Dose Date Time:   | //  |
| 5.  | Anatomical Location:  |     |
| 6.  | Body Side:  |     |
| 7.  | Route:  |     |
| 8.  | Actual Dose:  | [ ] |
| 9.  | Unit:   |     |
| 10. | Timeframe Subject Was Observed  |     |
| 11. | Was the subject observed for at least the protocol specified observation period after investigational product administration? |     |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** CONTACT OUTCOME - MONTH 1

**Form Version:** 10-Oct-2020 15:57

**Form Status:** Not Started

**Site No:** 1139

**Site Name:** (1139) Duke University Medical Center

**Subject No:** 11391024

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:44

**Contact Outcome**

|    |                   |     |
|----|-------------------|-----|
| 1. | Contact Type:     |     |
| 2. | Was contact made? |     |
| 3. | Comments:         | [ ] |

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** CONTACT OUTCOME - MONTH 6

**Form Version:** 10-Oct-2020 16:01

**Form Status:** Not Started

**Site No:** 1139

**Site Name:** (1139) Duke University Medical Center

**Subject No:** 11391024

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:44

**Contact Outcome**

|    |                   |     |
|----|-------------------|-----|
| 1. | Contact Type:     |     |
| 2. | Was contact made? |     |
| 3. | Comments:         | [ ] |

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Not Started

**Site No:** 1139

**Site Name:** (1139) Duke University Medical Center

**Subject No:** 11391024

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:44

**Date of Visit**

|    |                 |    |
|----|-----------------|----|
| 1. | Date of Visit   | // |
| 2. | Erroneous Visit |    |

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**Form:** INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE

**Form Version:** 14-Jan-2021 02:29

**Form Status:** Not Started

**Site No:** 1139

**Site Name:** (1139) Duke University Medical Center

**Subject No:** 11391024

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:44

**Informed Consent - Asymptomatic Surveillance**

|    |              |  |
|----|--------------|--|
| 1. | Consent Was: |  |
|----|--------------|--|

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1139

**Site Name:** (1139) Duke University Medical Center

**Subject No:** 11391024

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:44

**Electronic Sample Tracking**

|    |  |     |
|----|--|-----|
| 1. | Data Origin  |     |
| 2. | Sample Type  |     |
| 3. | Sample Collected?  |     |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [ ] |

**Aliquot**

Please enter barcode for each aliquot.

|    |           |     |
|----|-----------|-----|
| 5. | Sample ID | [ ] |
|----|-----------|-----|

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1139

**Site Name:** (1139) Duke University Medical Center

**Subject No:** 11391024

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:44

**Electronic Sample Tracking**

|    |  |     |
|----|--|-----|
| 1. | Data Origin  |     |
| 2. | Sample Type  |     |
| 3. | Sample Collected?  |     |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [ ] |

**Aliquot**

Please enter barcode for each aliquot.

|    |           |     |
|----|-----------|-----|
| 5. | Sample ID | [ ] |
|----|-----------|-----|



**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1139

**Site Name:** (1139) Duke University Medical Center

**Subject No:** 11391024

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

**Date of Visit**

|    |                 |             |
|----|-----------------|-------------|
| 1. | Date of Visit   | Jan/15/2021 |
| 2. | Erroneous Visit |             |

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form:** FURTHER VACCINATION CONFIRMATION

**Form Version:** 10-Dec-2020 02:25

**Form Status:** Data Complete, Frozen

**Site No:** 1139

**Site Name:** (1139) Duke University Medical Center

**Subject No:** 11391024

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

**Further Vaccination Confirmation**

|    |   |  |
|----|---|--|
| 1. | Select appropriate response - Is participant willing to return for Vaccination 3? | Participant is willing to return for Vaccination 3<br>Participant is:<br>eligible and NOT confirmed to have received only placebo at Vaccination 1/2 |
|----|---|--|

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1139

**Subject No:** 11391024

**Generated By:** (b) (4)

**Form:** TREATMENT UNBLINDED

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1139) Duke University Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

**Treatment Unblinded**

|    |                                |   |
|----|--------------------------------|---|
| 1. | Date Treatment Unblinded :     | Jan/15/2021                                   |
| 2. | Primary Reason for Unblinding: | ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION |

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1139

**Subject No:** 11391024

**Generated By:** (b) (4)

**Form:** WITHDRAWAL OF CONSENT

**Form Status:** Not Started

**Site Name:** (1139) Duke University Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:44

**Withdrawal Of Consent**

|    |                              |    |
|----|------------------------------|----|
| 1. | Withdrawal of Consent Date : | // |
|----|------------------------------|----|

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** DEATH DETAILS CODED

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1139

**Site Name:** (1139) Duke University Medical Center

**Subject No:** 11391024

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:44

**Death Details**

|    |   |    |
|----|---|----|
| 1. | Date of Collection / Notification of Death: | // |
|----|---|----|

**Cause of Death**

|    |                        |     |
|----|------------------------|-----|
| 2. | Cause of Death Status: |     |
|    | Cause of Death:        | [ ] |

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form:** SUBJECT STATUS

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Verified

**Site No:** 1139

**Site Name:** (1139) Duke University Medical Center

**Subject No:** 11391024

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

**Subject Status**

|    |                     |             |
|----|---------------------|-------------|
| 1. | Subject Status      | FOLLOW-UP   |
| 2. | Subject Status Date | Sep/22/2020 |

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Signed, Verified

**Site No:** 1139

**Site Name:** (1139) Duke University Medical Center

**Subject No:** 11391024

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

**Casebook Signature Form**

|    |                    |                                      |
|----|--------------------|--------------------------------------|
| 1. | Casebook Signature | <a href="#">Click Here to Enable</a> |
|----|--------------------|--------------------------------------|

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Signed, Verified

**Site No:** 1139

**Site Name:** (1139) Duke University Medical Center

**Subject No:** 11391024

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:44

[Audit Trail](#)

This form requires signing by a member of each of the following signature groups:

- CRF\_Sign

| Name            | Signature Meaning | Date  | Type | Action |
|-----------------|-------------------|---|------|--------|
| Emmanuel Walter | Approved          | Mar-05-2021 09:51:37 (UTC-05:00) Eastern Time (US & Canada) | BOOK | Signed |

**Affidavit:**

By my dated signature below, I, EmmanuelWalter, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1139

**Subject No:** 11391024

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1139) Duke University Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:44

[Back to Form](#)

| Item | Date  | User                                 | Comment        |
|------|---|--------------------------------------|----------------|
| Form | Aug-20-2020 09:06:07 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6)<br>(b) (4), (b) (6) | Not Applicable |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1139

**Subject No:** 11391024

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1139) Duke University Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:44

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| Item | Date  | User                                 | Comment        |
|------|---|--------------------------------------|----------------|
| 1    | Aug-20-2020 09:06:07 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6)<br>(b) (4), (b) (6) | Not Applicable |

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1139

**Subject No:** 11391024

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1139) Duke University Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:44

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| Item | Date  | User                                 | Comment        |
|------|---|--------------------------------------|----------------|
| 2    | Aug-20-2020 09:06:07 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6)<br>(b) (4), (b) (6) | Not Applicable |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1139

**Subject No:** 11391024

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1139) Duke University Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:44

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| Item | Date  | User                                 | Comment        |
|------|---|--------------------------------------|----------------|
| 3    | Aug-20-2020 09:06:07 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6)<br>(b) (4), (b) (6) | Not Applicable |

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1139

**Subject No:** 11391024

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1139) Duke University Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:44

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| Item | Date  | User                                 | Comment        |
|------|---|--------------------------------------|----------------|
| 4    | Aug-20-2020 09:06:07 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6)<br>(b) (4), (b) (6) | Not Applicable |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1139

**Subject No:** 11391024

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1139) Duke University Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:44

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| Item | Date  | User                                 | Comment        |
|------|---|--------------------------------------|----------------|
| 5    | Aug-20-2020 09:06:07 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6)<br>(b) (4), (b) (6) | Not Applicable |

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1139

**Subject No:** 11391024

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1139) Duke University Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:44

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| Item | Date  | User                                 | Comment        |
|------|---|--------------------------------------|----------------|
| 6.a  | Aug-20-2020 09:06:07 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6)<br>(b) (4), (b) (6) | Not Applicable |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1139

**Subject No:** 11391024

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1139) Duke University Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:44

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| Item | Date  | User                                 | Comment        |
|------|---|--------------------------------------|----------------|
| 6.a  | Aug-20-2020 09:06:07 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6)<br>(b) (4), (b) (6) | Not Applicable |



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1139

**Subject No:** 11391024

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1139) Duke University Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:44

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| Item | Date  | User                                 | Comment        |
|------|---|--------------------------------------|----------------|
| 6.a  | Aug-20-2020 09:06:07 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6)<br>(b) (4), (b) (6) | Not Applicable |

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Signed, Verified

**Site No:** 1139

**Site Name:** (1139) Duke University Medical Center

**Subject No:** 11391024

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:44

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This form requires signing by a member of each of the following signature groups:

- CRF\_Sign

| Name            | Signature Meaning | Date  | Type | Action |
|-----------------|-------------------|---|------|--------|
| Emmanuel Walter | Approved          | Mar-05-2021 09:51:37 (UTC-05:00) Eastern Time (US & Canada) | BOOK | Signed |

**Affidavit:**

By my dated signature below, I, EmmanuelWalter, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

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To this I do attest by supplying my user name and password and clicking the button marked Submit below.

|                    |     |   |  |                                   |
|--------------------|-----|---|--|-----------------------------------|
| (b) (6)<br>(b) (6) | N/A | Mar-01-2021 11:15:55 (UTC-05:00) Eastern Time (US & Canada) |  | Edit - All signatures invalidated |
|--------------------|-----|---|--|-----------------------------------|

**Affidavit:**

N/A

|                 |          |   |      |        |
|-----------------|----------|---|------|--------|
| Emmanuel Walter | Approved | Feb-18-2021 12:24:52 (UTC-05:00) Eastern Time (US & Canada) | BOOK | Signed |
|-----------------|----------|---|------|--------|

**Affidavit:**

By my dated signature below, I, EmmanuelWalter, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

|         |     |   |  |                                   |
|---------|-----|---|--|-----------------------------------|
| (b) (6) | N/A | Feb-16-2021 12:57:12 (UTC-05:00) Eastern Time (US & Canada) |  | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

**Affidavit:**

N/A

|                 |          |   |      |        |
|-----------------|----------|---|------|--------|
| Emmanuel Walter | Approved | Jan-27-2021 22:59:18 (UTC-05:00) Eastern Time (US & Canada) | BOOK | Signed |
|-----------------|----------|---|------|--------|

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391024

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

**Affidavit:**

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To this I do attest by supplying my user name and password and clicking the button marked Submit below.

|         |     |   |  |                                   |
|---------|-----|---|--|-----------------------------------|
| (b) (6) | N/A | Jan-25-2021 11:24:50 (UTC-05:00) Eastern Time (US & Canada) |  | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

**Affidavit:**

N/A

|                 |          |   |      |        |
|-----------------|----------|---|------|--------|
| Emmanuel Walter | Approved | Jan-22-2021 15:07:04 (UTC-05:00) Eastern Time (US & Canada) | BOOK | Signed |
|-----------------|----------|---|------|--------|

**Affidavit:**

By my dated signature below, I, EmmanuelWalter, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

|                    |     |   |  |                                   |
|--------------------|-----|---|--|-----------------------------------|
| (b) (6)<br>(b) (6) | N/A | Jan-21-2021 13:59:20 (UTC-05:00) Eastern Time (US & Canada) |  | Edit - All signatures invalidated |
|--------------------|-----|---|--|-----------------------------------|

**Affidavit:**

N/A

|                 |          |   |      |        |
|-----------------|----------|---|------|--------|
| Emmanuel Walter | Approved | Sep-30-2020 12:04:07 (UTC-05:00) Eastern Time (US & Canada) | BOOK | Signed |
|-----------------|----------|---|------|--------|

**Affidavit:**

By my dated signature below, I, EmmanuelWalter, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Signed, Verified

**Site No:** 1139

**Site Name:** (1139) Duke University Medical Center

**Subject No:** 11391024

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:44

|         |     |   |  |                                   |
|---------|-----|---|--|-----------------------------------|
| (b) (6) | N/A | Sep-22-2020 10:13:37 (UTC-05:00) Eastern Time (US & Canada) |  | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

**Affidavit:**

N/A

|                 |          |   |      |        |
|-----------------|----------|---|------|--------|
| Emmanuel Walter | Approved | Sep-04-2020 09:37:33 (UTC-05:00) Eastern Time (US & Canada) | BOOK | Signed |
|-----------------|----------|---|------|--------|

**Affidavit:**

By my dated signature below, I, EmmanuelWalter, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 30-Jul-2020 21:29

**Site No:** 1139

**Subject No:** 11391024

**Generated By:** (b) (4)

**Form:** COHORT\_SELECTION - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1139) Duke University Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:44

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**1. Select appropriate response - Protocol version**

| Date  | Location        | User                                 | Value                             | Reason        |
|---|-----------------|--------------------------------------|-----------------------------------|---------------|
| Jul-31-2020 20:45:54<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>30 JUN 2020 | Initial Entry |

**2. Select appropriate response - What cohort does the subject belong to?**

| Date  | Location        | User                                 | Value                                 | Reason        |
|---|-----------------|--------------------------------------|---------------------------------------|---------------|
| Jul-31-2020 20:45:54<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>STAGE 3 COHORTS | Initial Entry |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1139

**Subject No:** 11391024

**Generated By:** (b) (4)

**Form:** MAIN INFORMED CONSENT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1139) Duke University Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:44

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**I. Consent Was:**

| Date  | Location        | User                                 | Value  | Reason        |
|---|-----------------|--------------------------------------|--|---------------|
| Jul-31-2020 20:46:06<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>OBTAINED<br>Date Written Consent Obtained<br><br>Jul/31/2020 | Initial Entry |

Header Text: c4591001

Visit: COHORT\_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1139

Subject No: 11391024

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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**1. Subject ID**

| Date   | Location        | User                    | Value                          | Reason                         |
|--|-----------------|-------------------------|--------------------------------|--------------------------------|
| Jul-31-2020 20:45:43<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>11391024 | Item copied from previous form |

**2. Birth Date:**

| Date   | Location        | User                    | Value                              | Reason           |
|--|-----------------|-------------------------|------------------------------------|------------------|
| Jul-31-2020 20:45:37<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>(b) (6)/1949 | Enrollment Entry |

**3. Sex:**

| Date   | Location        | User                                 | Value                        | Reason        |
|--|-----------------|--------------------------------------|------------------------------|---------------|
| Jul-31-2020 20:46:19<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>FEMALE | Initial Entry |

**4. Ethnicity:**

| Date   | Location        | User                                 | Value   | Reason        |
|--|-----------------|--------------------------------------|---|---------------|
| Jul-31-2020 20:46:19<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>NOT HISPANIC OR LATINO(A)<br>OR OF SPANISH ORIGIN | Initial Entry |

**5. Race: (Check X all that apply):**

| Date   | Location        | User                                 | Value                       | Reason        |
|--|-----------------|--------------------------------------|-----------------------------|---------------|
| Jul-31-2020 20:46:19<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>WHITE | Initial Entry |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1139

**Subject No:** 11391024

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1139) Duke University Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:44

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*I. Date of Visit*

| Date  | Location        | User                                 | Value                             | Reason        |
|---|-----------------|--------------------------------------|-----------------------------------|---------------|
| Jul-31-2020 20:46:33<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Jul/31/2020 | Initial Entry |



**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:27**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1139**Site Name:** (1139) Duke University Medical Center**Subject No:** 11391024**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:44[Back to Form](#)**I.a**

| Date  | Location        | User                                 | Value   | Reason        |
|---|-----------------|--------------------------------------|---|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br><b>Inclusion Number:</b><br><b>Criterion Description:</b> Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage)<br><b>Criterion Met?:</b><br><b>Criterion ID:</b> IN01A00<br><b>Use only:</b> (For Pfizer use only): | Initial Entry |

**I.a Inclusion Number:**

| Date  | Location        | User                                 | Value                   | Reason        |
|---|-----------------|--------------------------------------|-------------------------|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>1 | Initial Entry |

**I.a Criterion Description:**

| Date  | Location        | User                                 | Value  | Reason        |
|---|-----------------|--------------------------------------|--|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at ra | Initial Entry |

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391024

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

|  |  |  |  |  |
|--|--|--|--|--|
|  |  |  | ndomization (dependent upon study stage) |  |
|--|--|--|--|--|

**1.a Criterion met?**

| Date   | Location        | User                                 | Value                     | Reason        |
|--|-----------------|--------------------------------------|---------------------------|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

**1.a Criterion ID: (For Pfizer use only)**

| Date   | Location        | User                                 | Value                         | Reason        |
|--|-----------------|--------------------------------------|-------------------------------|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>IN01A00 | Initial Entry |

**1.b**

| Date   | Location        | User                                 | Value  | Reason        |
|--|-----------------|--------------------------------------|--|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br><b>Inclusion Number:</b><br><b>Criteria</b> Participants who are will<br><b>on Design</b> ing and able to comply w<br><b>cription</b> ith all scheduled visits, v<br><b>n:</b> accination plan, laborator<br>y tests, lifestyle consider<br>ations, and other study pr<br>ocedures<br><br><b>Criteria YES</b><br><b>on met</b><br><b>?:</b><br><b>Criteria IN02A00</b><br><b>on ID:</b><br><b>(For Pfizer use only)</b><br><b>):</b> | Initial Entry |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391024

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

**1.b Inclusion Number:**

| Date   | Location        | User                                 | Value                   | Reason        |
|--|-----------------|--------------------------------------|-------------------------|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>2 | Initial Entry |

**1.b Criterion Description:**

| Date   | Location        | User                                 | Value   | Reason        |
|--|-----------------|--------------------------------------|---|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures | Initial Entry |

**1.b Criterion met?**

| Date   | Location        | User                                 | Value                     | Reason        |
|--|-----------------|--------------------------------------|---------------------------|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

**1.b Criterion ID: (For Pfizer use only)**

| Date   | Location        | User                                 | Value                         | Reason        |
|--|-----------------|--------------------------------------|-------------------------------|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>IN02A00 | Initial Entry |

**1.c**

| Date   | Location        | User                                 | Value                                   | Reason        |
|--|-----------------|--------------------------------------|---|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Inclusion Number: | Initial Entry |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1139

**Subject No:** 11391024

**Generated By:** (b) (4)

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1139) Duke University Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:44

|  |  |  |   |  |
|--|--|--|---|--|
|  |  |  | <p><b>Criterion Description:</b> Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study</p> <p><b>Criterion ID:</b> IN03A00</p> <p><b>Criterion Name:</b> (For Pfizer use only):</p> |  |
|--|--|--|---|--|

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391024

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

**I.c Inclusion Number:**

| Date   | Location        | User                                 | Value                   | Reason        |
|--|-----------------|--------------------------------------|-------------------------|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>3 | Initial Entry |

**I.c Criterion Description:**

| Date   | Location        | User                                 | Value   | Reason        |
|--|-----------------|--------------------------------------|---|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study | Initial Entry |

**I.c Criterion met?**

| Date   | Location        | User                                 | Value                     | Reason        |
|--|-----------------|--------------------------------------|---------------------------|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

**I.c Criterion ID: (For Pfizer use only)**

| Date   | Location        | User                                 | Value                         | Reason        |
|--|-----------------|--------------------------------------|-------------------------------|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>IN03A00 | Initial Entry |

**I.d**

| Date   | Location        | User                                 | Value                                   | Reason        |
|--|-----------------|--------------------------------------|---|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Inclusion Number: | Initial Entry |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1139

**Subject No:** 11391024

**Generated By:** (b) (4)

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1139) Duke University Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:44

|  |  |  |   |  |
|--|--|--|---|--|
|  |  |  | <p><b>Criteria Description:</b> Capable of giving person oral signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol</p> <p><b>Criteria Met:</b> YES</p> <p><b>Criteria ID:</b> IN04A00 (For Pfizer use only)</p> |  |
|--|--|--|---|--|

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391024

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

**1.d Inclusion Number:**

| Date   | Location        | User                                 | Value                   | Reason        |
|--|-----------------|--------------------------------------|-------------------------|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>4 | Initial Entry |

**1.d Criterion Description:**

| Date   | Location        | User                                 | Value  | Reason        |
|--|-----------------|--------------------------------------|--|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD a nd in this protocol | Initial Entry |

**1.d Criterion met?**

| Date   | Location        | User                                 | Value                     | Reason        |
|--|-----------------|--------------------------------------|---------------------------|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

**1.d Criterion ID: (For Pfizer use only)**

| Date   | Location        | User                                 | Value                         | Reason        |
|--|-----------------|--------------------------------------|-------------------------------|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>IN04A00 | Initial Entry |

**2.a**

| Date   | Location        | User                                 | Value   | Reason        |
|--|-----------------|--------------------------------------|---|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Exclus 1<br>ion N<br>umber<br>: | Initial Entry |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391024

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

|  |  |  |  |  |
|--|--|--|--|--|
|  |  |  | <p><b>Criterion Description:</b> Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation</p> <p><b>Criterion met?:</b> NO</p> <p><b>Criterion ID:</b> EX01A00<br/>(For Pfizer use only):</p> |  |
|--|--|--|--|--|

2.a Exclusion Number:

| Date   | Location        | User                                 | Value                   | Reason        |
|--|-----------------|--------------------------------------|-------------------------|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>1 | Initial Entry |

2.a Criterion Description:

| Date   | Location        | User                                 | Value   | Reason        |
|--|-----------------|--------------------------------------|---|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation | Initial Entry |

2.a Criterion met?

| Date   | Location        | User                                 | Value                    | Reason        |
|--|-----------------|--------------------------------------|--------------------------|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

2.a Criterion ID: (For Pfizer use only)

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391024

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

|   |                 |                                      |                               |               |
|---|-----------------|--------------------------------------|-------------------------------|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>EX01A00 | Initial Entry |
|---|-----------------|--------------------------------------|-------------------------------|---------------|

2.b

| Date  | Location        | User                                 | Value  | Reason        |
|---|-----------------|--------------------------------------|--|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br><b>Exclusio 2</b><br><b>n Numb</b><br><b>er:</b><br><b>Criteria</b> Known infection with h<br><b>n Descri</b> uman immunodeficienc<br><b>ption:</b> y virus (HIV), hepatitis<br>C virus (HCV), or hepa<br>titis B virus (HBV)<br><br><b>Criteria</b> NO<br><b>n met?:</b><br><b>Criteria</b> EX02A00<br><b>n ID: (F</b><br><b>or Pfize</b><br><b>r use on</b><br><b>ly):</b> | Initial Entry |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391024

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

2.b Exclusion Number:

| Date   | Location        | User                                 | Value                   | Reason        |
|--|-----------------|--------------------------------------|-------------------------|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>2 | Initial Entry |

2.b Criterion Description:

| Date   | Location        | User                                 | Value  | Reason        |
|--|-----------------|--------------------------------------|--|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV) | Initial Entry |

2.b Criterion met?

| Date   | Location        | User                                 | Value                    | Reason        |
|--|-----------------|--------------------------------------|--------------------------|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

2.b Criterion ID: (For Pfizer use only)

| Date   | Location        | User                                 | Value                         | Reason        |
|--|-----------------|--------------------------------------|-------------------------------|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>EX02A00 | Initial Entry |

2.c

| Date   | Location        | User                                 | Value   | Reason        |
|--|-----------------|--------------------------------------|---|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Exclus 3<br>ion Number: | Initial Entry |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1139

**Subject No:** 11391024

**Generated By:** (b) (4)

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1139) Duke University Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:44

|  |  |  |  |  |
|--|--|--|--|--|
|  |  |  | <p><b>Criteria</b> History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)</p> <p><b>Criteria</b> NO</p> <p><b>Criteria</b> EX03A00</p> <p><b>Criteria</b> ID:<br/>(For Pfizer use only):</p> |  |
|--|--|--|--|--|

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391024

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

2.c Exclusion Number:

| Date   | Location        | User                                 | Value                   | Reason        |
|--|-----------------|--------------------------------------|-------------------------|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>3 | Initial Entry |

2.c Criterion Description:

| Date   | Location        | User                                 | Value  | Reason        |
|--|-----------------|--------------------------------------|--|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s) | Initial Entry |

2.c Criterion met?

| Date   | Location        | User                                 | Value                    | Reason        |
|--|-----------------|--------------------------------------|--------------------------|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

2.c Criterion ID: (For Pfizer use only)

| Date   | Location        | User                                 | Value                         | Reason        |
|--|-----------------|--------------------------------------|-------------------------------|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>EX03A00 | Initial Entry |

2.d

| Date   | Location        | User                                 | Value  | Reason        |
|--|-----------------|--------------------------------------|--|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br><b>Exclusion Number:</b> 4<br><b>Criterion Description:</b> Receipt of medications intended to prevent COVID-19<br><b>Criterion met?:</b> NO | Initial Entry |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391024

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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|--|--|--|--|--|
|  |  |  | <b>Criterion ID</b> EX04A00<br><b>: (For Pfizer use only):</b> |  |
|--|--|--|--|--|

2.d Exclusion Number:

| Date   | Location        | User                                 | Value                   | Reason        |
|--|-----------------|--------------------------------------|-------------------------|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>4 | Initial Entry |

2.d Criterion Description:

| Date   | Location        | User                                 | Value   | Reason        |
|--|-----------------|--------------------------------------|---|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Receipt of medications intended to prevent COVID-19 | Initial Entry |

2.d Criterion met?

| Date   | Location        | User                                 | Value                    | Reason        |
|--|-----------------|--------------------------------------|--------------------------|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

2.d Criterion ID: (For Pfizer use only)

| Date   | Location        | User                                 | Value                         | Reason        |
|--|-----------------|--------------------------------------|-------------------------------|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>EX04A00 | Initial Entry |

2.e

| Date   | Location        | User                                 | Value                                   | Reason        |
|--|-----------------|--------------------------------------|---|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Exclusion Number: | Initial Entry |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1139

**Subject No:** 11391024

**Generated By:** (b) (4)

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1139) Duke University Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:44

|  |  |  |  |  |
|--|--|--|--|--|
|  |  |  | <p><b>Criteria on Descriptio n:</b> Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination</p> <p><b>Criteria on met?:</b> NO</p> <p><b>Criteria on ID:</b> EX08A00<br/>(For Pfizer use only)<br/>:</p> |  |
|--|--|--|--|--|

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391024

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

2.e Exclusion Number:

| Date   | Location        | User                                 | Value                   | Reason        |
|--|-----------------|--------------------------------------|-------------------------|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>8 | Initial Entry |

2.e Criterion Description:

| Date   | Location        | User                                 | Value  | Reason        |
|--|-----------------|--------------------------------------|--|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Immunocompromised individuals with known or suspected immuno deficiency, as determined by history and/or laboratory/physical examination | Initial Entry |

2.e Criterion met?

| Date   | Location        | User                                 | Value                    | Reason        |
|--|-----------------|--------------------------------------|--------------------------|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

2.e Criterion ID: (For Pfizer use only)

| Date   | Location        | User                                 | Value                         | Reason        |
|--|-----------------|--------------------------------------|-------------------------------|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>EX08A00 | Initial Entry |

2.f

| Date   | Location        | User                                 | Value  | Reason        |
|--|-----------------|--------------------------------------|--|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Exclus 10<br>ion Nu<br>mber: | Initial Entry |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1139

**Subject No:** 11391024

**Generated By:** (b) (4)

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1139) Duke University Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:44

|  |  |  |   |  |
|--|--|--|---|--|
|  |  |  | <p><b>Criteria Description:</b> Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection</p> <p><b>Criteria Met:</b> NO</p> <p><b>Criteria ID:</b> EX10A00 (For Pfizer use only)</p> |  |
|--|--|--|---|--|

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391024

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

2.f Exclusion Number:

| Date   | Location        | User                                 | Value                    | Reason        |
|--|-----------------|--------------------------------------|--------------------------|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>10 | Initial Entry |

2.f Criterion Description:

| Date   | Location        | User                                 | Value  | Reason        |
|--|-----------------|--------------------------------------|--|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Bleeding diathesis or condition as associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection | Initial Entry |

2.f Criterion met?

| Date   | Location        | User                                 | Value                    | Reason        |
|--|-----------------|--------------------------------------|--------------------------|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

2.f Criterion ID: (For Pfizer use only)

| Date   | Location        | User                                 | Value                         | Reason        |
|--|-----------------|--------------------------------------|-------------------------------|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>EX10A00 | Initial Entry |

2.g

| Date   | Location        | User                                 | Value   | Reason        |
|--|-----------------|--------------------------------------|---|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br><b>Exclusion Number:</b> 11<br><b>Criterion Description:</b> Women who are pregnant or breastfeeding<br><b>Criterion met?:</b> NO | Initial Entry |

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Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391024

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

|  |  |  |   |  |
|--|--|--|---|--|
|  |  |  | <b>Criterion ID:</b> EX11A00<br><b>(For Pfizer use only):</b> |  |
|--|--|--|---|--|

**2.g Exclusion Number:**

| Date   | Location        | User                                 | Value                    | Reason        |
|--|-----------------|--------------------------------------|--------------------------|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>11 | Initial Entry |

**2.g Criterion Description:**

| Date   | Location        | User                                 | Value   | Reason        |
|--|-----------------|--------------------------------------|---|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Women who are pregnant or breastfeeding | Initial Entry |

**2.g Criterion met?**

| Date   | Location        | User                                 | Value                    | Reason        |
|--|-----------------|--------------------------------------|--------------------------|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**2.g Criterion ID: (For Pfizer use only)**

| Date   | Location        | User                                 | Value                         | Reason        |
|--|-----------------|--------------------------------------|-------------------------------|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>EX11A00 | Initial Entry |

**2.h**

| Date   | Location        | User                                 | Value   | Reason        |
|--|-----------------|--------------------------------------|---|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br><b>Exclusion Number:</b><br><b>Criterion Description:</b> Previous vaccination with any coronavirus vaccine | Initial Entry |

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Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391024

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

|  |  |  |   |  |
|--|--|--|---|--|
|  |  |  | <b>Criterion met?:</b><br><b>Criterion ID: EX12A00</b><br><b>(For Pfizer use only):</b> |  |
|--|--|--|---|--|

**2.h Exclusion Number:**

| Date   | Location        | User                                 | Value                    | Reason        |
|--|-----------------|--------------------------------------|--------------------------|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>12 | Initial Entry |

**2.h Criterion Description:**

| Date   | Location        | User                                 | Value   | Reason        |
|--|-----------------|--------------------------------------|---|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Previous vaccination with any coronavirus vaccine | Initial Entry |

**2.h Criterion met?**

| Date   | Location        | User                                 | Value                    | Reason        |
|--|-----------------|--------------------------------------|--------------------------|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**2.h Criterion ID: (For Pfizer use only)**

| Date   | Location        | User                                 | Value                         | Reason        |
|--|-----------------|--------------------------------------|-------------------------------|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>EX12A00 | Initial Entry |

**2.i**

| Date   | Location        | User                                 | Value                                   | Reason        |
|--|-----------------|--------------------------------------|---|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Exclusion Number: | Initial Entry |

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Site Name: (1139) Duke University Medical Center

Subject No: 11391024

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

|  |  |  |  |  |
|--|--|--|--|--|
|  |  |  | <b>Criterion Description:</b> Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids<br><br><b>Criterion met?:</b> NO<br><br><b>Criterion ID: (For Pfizer use only):</b> EX13A01 |  |
|--|--|--|--|--|

2.i Exclusion Number:

| Date  | Location        | User                                 | Value                    | Reason        |
|---|-----------------|--------------------------------------|--------------------------|---------------|
| Jul-31-2020 20:47:26 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>13 | Initial Entry |

2.i Criterion Description:

| Date  | Location        | User                                 | Value  | Reason        |
|---|-----------------|--------------------------------------|--|---------------|
| Jul-31-2020 20:47:26 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids | Initial Entry |

2.i Criterion met?

| Date  | Location        | User                                 | Value                    | Reason        |
|---|-----------------|--------------------------------------|--------------------------|---------------|
| Jul-31-2020 20:47:26 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

2.i Criterion ID: (For Pfizer use only)

| Date  | Location        | User                                 | Value                         | Reason        |
|---|-----------------|--------------------------------------|-------------------------------|---------------|
| Jul-31-2020 20:47:26 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>EX13A01 | Initial Entry |

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**Visit:** V1\_DAY1\_VAX1\_L

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1139

**Site Name:** (1139) Duke University Medical Center

**Subject No:** 11391024

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:44

2.j

| Date  | Location        | User                                 | Value   | Reason        |
|---|-----------------|--------------------------------------|---|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br><b>Exclusion Number:</b> 15<br><b>Criterion Description:</b> Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study<br><b>Criterion met?:</b> NO<br><b>Criterion ID:</b> EX14A01<br><b>(For Pfizer use only):</b><br>: | Initial Entry |

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Site Name: (1139) Duke University Medical Center

Subject No: 11391024

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

2.j Exclusion Number:

| Date   | Location        | User                                 | Value                    | Reason        |
|--|-----------------|--------------------------------------|--------------------------|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>15 | Initial Entry |

2.j Criterion Description:

| Date   | Location        | User                                 | Value   | Reason        |
|--|-----------------|--------------------------------------|---|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study | Initial Entry |

2.j Criterion met?

| Date   | Location        | User                                 | Value                    | Reason        |
|--|-----------------|--------------------------------------|--------------------------|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

2.j Criterion ID: (For Pfizer use only)

| Date   | Location        | User                                 | Value                         | Reason        |
|--|-----------------|--------------------------------------|-------------------------------|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>EX14A01 | Initial Entry |

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Header Text: c4591001

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Site Name: (1139) Duke University Medical Center

Subject No: 11391024

Subject Initials: ---

Generated By: (b) (4)

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| 2.k   |                 |                                      |  |               |
|---|-----------------|--------------------------------------|--|---------------|
| Date  | Location        | User                                 | Value  | Reason        |
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br><b>Exclusion Number:</b> 16<br><b>Criterion Description:</b> Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation<br><b>Criterion met?:</b> NO<br><b>Criterion ID: (For Pfizer use only):</b> EX15A01 | Initial Entry |

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Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391024

Subject Initials: ---

Generated By: (b) (4)

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2.k Exclusion Number:

| Date   | Location        | User                                 | Value                    | Reason        |
|--|-----------------|--------------------------------------|--------------------------|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>16 | Initial Entry |

2.k Criterion Description:

| Date   | Location        | User                                 | Value   | Reason        |
|--|-----------------|--------------------------------------|---|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation | Initial Entry |

2.k Criterion met?

| Date   | Location        | User                                 | Value                    | Reason        |
|--|-----------------|--------------------------------------|--------------------------|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

2.k Criterion ID: (For Pfizer use only)

| Date   | Location        | User                                 | Value                         | Reason        |
|--|-----------------|--------------------------------------|-------------------------------|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>EX15A01 | Initial Entry |

2.l

| Date   | Location        | User                                 | Value  | Reason        |
|--|-----------------|--------------------------------------|--|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br><b>Exclusion Number:</b> 17<br><b>Criterion Description:</b> Previous participation in other studies involving study intervention containing lipid nanoparticles | Initial Entry |

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Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391024

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

|  |  |  |  |
|--|--|--|--|
|  |  |  | <b>Criterion met?:</b><br><b>Criterion ID: (For Pfizer use only):</b><br>NO<br>EX16A01 |
|--|--|--|--|

**2.1 Exclusion Number:**

| Date   | Location        | User                                 | Value                    | Reason        |
|--|-----------------|--------------------------------------|--------------------------|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>17 | Initial Entry |

**2.1 Criterion Description:**

| Date   | Location        | User                                 | Value   | Reason        |
|--|-----------------|--------------------------------------|---|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Previous participation in other studies involving study intervention containing lipid nanoparticles | Initial Entry |

**2.1 Criterion met?:**

| Date   | Location        | User                                 | Value                    | Reason        |
|--|-----------------|--------------------------------------|--------------------------|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**2.1 Criterion ID: (For Pfizer use only)**

| Date   | Location        | User                                 | Value                         | Reason        |
|--|-----------------|--------------------------------------|-------------------------------|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>EX16A01 | Initial Entry |

**2.m**

| Date  | Location        | User                                 | Value                          | Reason        |
|---|-----------------|--------------------------------------|--------------------------------|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Exclu 22 | Initial Entry |

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1139

**Subject No:** 11391024

**Generated By:** (b) (4)

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1139) Duke University Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:44

|                    |  |  |  |  |
|--------------------|--|--|--|--|
| Time (US & Canada) |  |  | <p><b>ion N<br/>umbe<br/>r:</b><br/><b>Criterion De<br/>scripti<br/>on:</b> Investigator site staff or<br/>Pfizer employees directly<br/>involved in the conduct o<br/>f the study, site staff othe<br/>rwise supervised by the i<br/>nvestigator, and their res<br/>pective family members</p> <p><b>Criterion m<br/>et?:</b><br/><b>Criterion ID<br/>: (For<br/>Pfizer<br/>use on<br/>ly):</b></p> |  |
|--------------------|--|--|--|--|

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Header Text: c4591001

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Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391024

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

**2.m Exclusion Number:**

| Date   | Location        | User                                 | Value                    | Reason        |
|--|-----------------|--------------------------------------|--------------------------|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>22 | Initial Entry |

**2.m Criterion Description:**

| Date   | Location        | User                                 | Value   | Reason        |
|--|-----------------|--------------------------------------|---|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members | Initial Entry |

**2.m Criterion met?**

| Date   | Location        | User                                 | Value                    | Reason        |
|--|-----------------|--------------------------------------|--------------------------|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**2.m Criterion ID: (For Pfizer use only)**

| Date   | Location        | User                                 | Value                         | Reason        |
|--|-----------------|--------------------------------------|-------------------------------|---------------|
| Jul-31-2020 20:47:26<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>EX21A01 | Initial Entry |

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1139

**Subject No:** 11391024

**Generated By:** (b) (4)

**Form:** DISPOSITION - SCREENING - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1139) Duke University Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:44

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**1. Date of Completion/Discontinuation/Death**

| Date  | Location        | User                                 | Value                             | Reason        |
|---|-----------------|--------------------------------------|-----------------------------------|---------------|
| Jul-31-2020 20:47:50<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Jul/31/2020 | Initial Entry |

**2. Phase of Disposition:**

| Date  | Location        | User                    | Value                           | Reason        |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Jul-31-2020 20:47:50<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SCREENING | Initial Entry |

**3. Status:**

| Date  | Location        | User                                 | Value                           | Reason        |
|---|-----------------|--------------------------------------|---------------------------------|---------------|
| Jul-31-2020 20:47:50<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>COMPLETED | Initial Entry |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1139

Subject No: 11391024

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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*1.a*

| Date  | Location        | User                    | Value   | Reason        |
|---|-----------------|-------------------------|---|---------------|
| Aug-04-2020 10:54:32<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>Line/MH Numbe 1<br><b>r:</b><br><b>Medical History</b> Hypercholester<br><b>Term:</b> olemia<br><b>Start Date:</b> Jun/30/2008<br><b>Ongoing:</b> YES | Initial Entry |

*1.a Line/MH Number:*

| Date  | Location        | User                    | Value                   | Reason        |
|---|-----------------|-------------------------|-------------------------|---------------|
| Aug-04-2020 10:54:32<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>1 | Initial Entry |

*1.a Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:*

| Date  | Location        | User                                 | Value                                      | Reason        |
|---|-----------------|--------------------------------------|--|---------------|
| Aug-04-2020 10:54:32<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Hypercholesterolemia | Initial Entry |

*1.a Start Date:*

| Date  | Location        | User                                 | Value                             | Reason        |
|---|-----------------|--------------------------------------|-----------------------------------|---------------|
| Aug-04-2020 10:54:32<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Jun/30/2008 | Initial Entry |

*1.a Ongoing:*

| Date  | Location        | User                                 | Value                     | Reason        |
|---|-----------------|--------------------------------------|---------------------------|---------------|
| Aug-04-2020 10:54:32<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

*1.b*

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1139

Subject No: 11391024

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

| Date  | Location        | User                    | Value  | Reason        |
|---|-----------------|-------------------------|--|---------------|
| Aug-04-2020 10:54:56<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Line/MH Number:</b> 2<br><b>Medical History Term:</b> Hypertension<br><b>Start Date:</b> Jun/30/2015<br><b>Ongoing:</b> YES | Initial Entry |

**1.b Line/MH Number:**

| Date  | Location        | User                    | Value                   | Reason        |
|---|-----------------|-------------------------|-------------------------|---------------|
| Aug-04-2020 10:54:56<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>2 | Initial Entry |

**1.b Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

| Date  | Location        | User                                 | Value                              | Reason        |
|---|-----------------|--------------------------------------|------------------------------------|---------------|
| Aug-04-2020 10:54:56<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Hypertension | Initial Entry |

**1.b Start Date:**

| Date  | Location        | User                                 | Value                             | Reason        |
|---|-----------------|--------------------------------------|-----------------------------------|---------------|
| Aug-04-2020 10:54:56<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Jun/30/2015 | Initial Entry |

**1.b Ongoing:**

| Date  | Location        | User                                 | Value                     | Reason        |
|---|-----------------|--------------------------------------|---------------------------|---------------|
| Aug-04-2020 10:54:56<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

**1.c**

| Date  | Location        | User                    | Value  | Reason        |
|---|-----------------|-------------------------|--|---------------|
| Aug-04-2020 10:55:38<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Line/MH Number:</b> 3 | Initial Entry |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1139

Subject No: 11391024

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

|  |  |  |  |  |
|--|--|--|--|--|
|  |  |  | <b>Medical History Term:</b> Left knee replacement<br><b>Start Date:</b> Dec/12/2012<br><b>Ongoing:</b> NO<br>End Date:<br>Dec/12/2012 |  |
|--|--|--|--|--|

**I.c Line/MH Number:**

| Date   | Location        | User                    | Value                   | Reason        |
|--|-----------------|-------------------------|-------------------------|---------------|
| Aug-04-2020 10:55:38<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>3 | Initial Entry |

**I.c Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

| Date   | Location        | User                                 | Value                                       | Reason        |
|--|-----------------|--------------------------------------|---|---------------|
| Aug-04-2020 10:55:38<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Left knee replacement | Initial Entry |

**I.c Start Date:**

| Date   | Location        | User                                 | Value                             | Reason        |
|--|-----------------|--------------------------------------|-----------------------------------|---------------|
| Aug-04-2020 10:55:38<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Dec/12/2012 | Initial Entry |

**I.c Ongoing:**

| Date   | Location        | User                                 | Value  | Reason        |
|--|-----------------|--------------------------------------|--|---------------|
| Aug-04-2020 10:55:38<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>NO<br>End Date:<br>Dec/12/2012 | Initial Entry |

**I.d**

| Date  | Location        | User                    | Value  | Reason        |
|---|-----------------|-------------------------|--|---------------|
| Aug-04-2020 10:56:34<br>(UTC-05:00) Eastern | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Line/MH Number:</b> 4 | Initial Entry |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1139

Subject No: 11391024

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

|                    |  |  |   |
|--------------------|--|--|---|
| Time (US & Canada) |  |  | <b>Medical History Te</b> Left knee inju<br><b>rm:</b> ry<br><b>Start Date:</b> Jan/15/2008<br><b>Ongoing:</b> NO<br>End Date:<br>Dec/12/20<br>12 |
|--------------------|--|--|---|

**1.d Line/MH Number:**

| Date  | Location        | User                    | Value                   | Reason        |
|---|-----------------|-------------------------|-------------------------|---------------|
| Aug-04-2020 10:56:34<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>4 | Initial Entry |

**1.d Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

| Date  | Location        | User                                 | Value                                  | Reason        |
|---|-----------------|--------------------------------------|--|---------------|
| Aug-04-2020 10:56:34<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Left knee injury | Initial Entry |

**1.d Start Date:**

| Date  | Location        | User                                 | Value                             | Reason        |
|---|-----------------|--------------------------------------|-----------------------------------|---------------|
| Aug-04-2020 10:56:34<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Jan/15/2008 | Initial Entry |

**1.d Ongoing:**

| Date  | Location        | User                                 | Value  | Reason        |
|---|-----------------|--------------------------------------|--|---------------|
| Aug-04-2020 10:56:34<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>NO<br>End Date:<br>Dec/12/2012 | Initial Entry |

**1.e**

| Date                 | Location        | User      | Value              | Reason        |
|----------------------|-----------------|-----------|--------------------|---------------|
| Aug-04-2020 10:57:34 | ACV0PFEINFP6000 | auto calc | <b>Data Entry:</b> | Initial Entry |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1139

Subject No: 11391024

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

|  |  |            |  |
|--|--|------------|--|
| (UTC-05:00) Eastern Time (US & Canada) |  | (autocalc) | <b>Line/MH Number:</b><br><b>Medical History</b> Right shoulder injury<br><b>Term:</b> njury<br><b>Start Date:</b> Jun/30/2014<br><b>Ongoing:</b> NO<br>End Date:<br>Aug/15/2014 |
|--|--|------------|--|

*I.e Line/MH Number:*

| Date  | Location        | User                 | Value                | Reason        |
|---|-----------------|----------------------|----------------------|---------------|
| Aug-04-2020 10:57:34 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <b>Data Entry:</b> 5 | Initial Entry |

*I.e Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:*

| Date  | Location        | User                                 | Value                                    | Reason        |
|---|-----------------|--------------------------------------|--|---------------|
| Aug-04-2020 10:57:34 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b> Right shoulder injury | Initial Entry |

*I.e Start Date:*

| Date  | Location        | User                                 | Value                          | Reason        |
|---|-----------------|--------------------------------------|--------------------------------|---------------|
| Aug-04-2020 10:57:34 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b> Jun/30/2014 | Initial Entry |

*I.e Ongoing:*

| Date  | Location        | User                                 | Value   | Reason        |
|---|-----------------|--------------------------------------|---|---------------|
| Aug-04-2020 10:57:34 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b> NO<br>End Date:<br>Aug/15/2014 | Initial Entry |

*I.f*

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1139

Subject No: 11391024

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

|   |                 |                         |   |               |
|---|-----------------|-------------------------|---|---------------|
| Aug-04-2020 10:58:09<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Line/MH Number:</b><br>6<br><b>Medical History Term:</b> Right shoulder repair<br><b>Start Date:</b> Aug/15/2014<br><b>Ongoing:</b> NO<br>End Date:<br>Aug/15/2014 | Initial Entry |
|---|-----------------|-------------------------|---|---------------|

*1.f Line/MH Number:*

| Date  | Location        | User                    | Value                   | Reason        |
|---|-----------------|-------------------------|-------------------------|---------------|
| Aug-04-2020 10:58:09<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>6 | Initial Entry |

*1.f Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:*

| Date  | Location        | User                                 | Value                                       | Reason        |
|---|-----------------|--------------------------------------|---|---------------|
| Aug-04-2020 10:58:09<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Right shoulder repair | Initial Entry |

*1.f Start Date:*

| Date  | Location        | User                                 | Value                             | Reason        |
|---|-----------------|--------------------------------------|-----------------------------------|---------------|
| Aug-04-2020 10:58:09<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Aug/15/2014 | Initial Entry |

*1.f Ongoing:*

| Date  | Location        | User                                 | Value  | Reason        |
|---|-----------------|--------------------------------------|--|---------------|
| Aug-04-2020 10:58:09<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>NO<br>End Date:<br>Aug/15/2014 | Initial Entry |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 30-Jul-2020 21:28

Site No: 1139

Subject No: 11391024

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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**1. Date:**

| Date  | Location        | User                                 | Value                             | Reason        |
|---|-----------------|--------------------------------------|-----------------------------------|---------------|
| Jul-31-2020 20:53:43<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Jul/31/2020 | Initial Entry |

**2. Weight:**

| Date  | Location        | User                                 | Value                       | Reason        |
|---|-----------------|--------------------------------------|-----------------------------|---------------|
| Jul-31-2020 20:53:43<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>207.8 | Initial Entry |

**3. Unit:**

| Date  | Location        | User                                 | Value                    | Reason        |
|---|-----------------|--------------------------------------|--------------------------|---------------|
| Jul-31-2020 20:53:43<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>LB | Initial Entry |

**4. Height:**

| Date  | Location        | User                                 | Value                      | Reason        |
|---|-----------------|--------------------------------------|----------------------------|---------------|
| Jul-31-2020 20:53:43<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>62.0 | Initial Entry |

**5. Unit:**

| Date  | Location        | User                                 | Value                    | Reason        |
|---|-----------------|--------------------------------------|--------------------------|---------------|
| Jul-31-2020 20:53:43<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>in | Initial Entry |

**6. Body Mass Index:**

| Date  | Location        | User                    | Value                      | Reason        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Jul-31-2020 20:53:43<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>38.0 | Initial Entry |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 30-Jul-2020 21:28

Site No: 1139

Subject No: 11391024

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

7.a

| Date  | Location        | User                                 | Value   | Reason        |
|---|-----------------|--------------------------------------|---|---------------|
| Jul-31-2020 20:53:43<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br><b>Record Identifier:</b> 1<br>:<br><b>Temperature:</b> 98.3<br><b>Temperature Unit</b> F<br>:<br><b>Temperature Loca</b> ORAL CAV<br><b>tion::</b> ITY | Initial Entry |

7.a Record Identifier:

| Date  | Location        | User                                 | Value                   | Reason        |
|---|-----------------|--------------------------------------|-------------------------|---------------|
| Jul-31-2020 20:53:43<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>1 | Initial Entry |

7.a Temperature:

| Date  | Location        | User                                 | Value                      | Reason        |
|---|-----------------|--------------------------------------|----------------------------|---------------|
| Jul-31-2020 20:53:43<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>98.3 | Initial Entry |

7.a Unit:

| Date  | Location        | User                                 | Value                   | Reason        |
|---|-----------------|--------------------------------------|-------------------------|---------------|
| Jul-31-2020 20:53:43<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>F | Initial Entry |

7.a Temperature Location:

| Date  | Location        | User                                 | Value                             | Reason        |
|---|-----------------|--------------------------------------|-----------------------------------|---------------|
| Jul-31-2020 20:53:43<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>ORAL CAVITY | Initial Entry |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391024

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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**1. Lab Panel:**

| Date  | Location        | User                    | Value                            | Reason        |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Jul-31-2020 20:51:36<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>URINALYSIS | Initial Entry |

**2. Lab Sub-Panel:**

| Date  | Location        | User                    | Value                           | Reason        |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Jul-31-2020 20:51:36<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>PREGNANCY | Initial Entry |

**3. Collection Date:**

| Date  | Location        | User                                 | Value                             | Reason        |
|---|-----------------|--------------------------------------|-----------------------------------|---------------|
| Jul-31-2020 20:51:36<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Jul/31/2020 | Initial Entry |

**4. Laboratory Name and Address (Derived)**

| Date  | Location        | User                    | Value                            | Reason        |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Jul-31-2020 20:51:36<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>STUDY SITE | Initial Entry |

**5. Specimen Type:**

| Date  | Location        | User                    | Value                       | Reason        |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Jul-31-2020 20:51:36<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>URINE | Initial Entry |

**6.a**

| Date  | Location        | User                    | Value              | Reason        |
|---|-----------------|-------------------------|--------------------|---------------|
| Jul-31-2020 20:51:19<br>(UTC-05:00) Eastern | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b> | Initial Entry |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391024

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

|                    |  |  |  |
|--------------------|--|--|--|
| Time (US & Canada) |  |  | <b>Sponsor-Defined Identifier:</b> 113<br><b>Test::</b> Choriogonadotropin Beta_PX113<br><b>Result::</b><br><b>Not Done::</b> NOT DONE |
|--------------------|--|--|--|

6.a Sponsor ID:

| Date  | Location        | User                 | Value                  | Reason        |
|---|-----------------|----------------------|------------------------|---------------|
| Jul-31-2020 20:51:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <b>Data Entry:</b> 113 | Initial Entry |

6.a Test:

| Date  | Location        | User                                 | Value  | Reason        |
|---|-----------------|--------------------------------------|--|---------------|
| Jul-31-2020 20:51:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b> Choriogonadotropin Beta_PX113 | Initial Entry |

6.a Not Done:

| Date  | Location        | User                                 | Value                       | Reason        |
|---|-----------------|--------------------------------------|-----------------------------|---------------|
| Jul-31-2020 20:51:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b> NOT DONE | Initial Entry |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1139

**Subject No:** 11391024

**Generated By:** (b) (4)

**Form:** RANDOMIZATION - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1139) Duke University Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:44

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**1. Randomization Date :**

| Date  | Location        | User                                 | Value                             | Reason        |
|---|-----------------|--------------------------------------|-----------------------------------|---------------|
| Jul-31-2020 20:49:30<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Jul/31/2020 | Initial Entry |

**2. Randomization Number:**

| Date  | Location        | User                                 | Value                        | Reason        |
|---|-----------------|--------------------------------------|------------------------------|---------------|
| Jul-31-2020 20:49:30<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>220836 | Initial Entry |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391024

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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**1. Data Origin**

| Date  | Location        | User                    | Value                      | Reason        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Jul-31-2020 20:49:39<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date  | Location        | User                    | Value                       | Reason        |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Jul-31-2020 20:49:39<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SERUM | Initial Entry |

**3. Sample Collected?**

| Date  | Location        | User                                 | Value                     | Reason  |
|---|-----------------|--------------------------------------|---------------------------|---|
| Aug-05-2020 14:16:36<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)            | Query 1: Closed           | Close Auto Query  |
| Aug-04-2020 04:40:16<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | Query 1: Opened           | DQ: Please review the 'Sample Collected?' is reported as Yes however no any barcodes are entered. Kindly review and correct the data as appropriate. Thank you. |
| Jul-31-2020 20:49:39<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)            | Query 1: Candidate        | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.  |
| Jul-31-2020 20:49:39<br>(UTC-05:00) Eastern                       | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>YES | Initial Entry   |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391024

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

|                    |  |  |                     |  |
|--------------------|--|--|---------------------|--|
| Time (US & Canada) |  |  | Date of Collection: |  |
|                    |  |  | Jul/31/2020         |  |

5.a

| Date  | Location        | User                                 | Value  | Reason        |
|---|-----------------|--------------------------------------|--|---------------|
| Aug-05-2020 14:16:36<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br><b>Sample ID: BP6ZNP</b> | Initial Entry |

5.a Sample ID

| Date  | Location        | User                                 | Value                        | Reason        |
|---|-----------------|--------------------------------------|------------------------------|---------------|
| Aug-05-2020 14:16:36<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>BP6ZNP | Initial Entry |

5.b

| Date  | Location        | User                                 | Value  | Reason        |
|---|-----------------|--------------------------------------|--|---------------|
| Aug-05-2020 14:17:01<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br><b>Sample ID: BP6ZNR</b> | Initial Entry |

5.b Sample ID

| Date  | Location        | User                                 | Value                        | Reason        |
|---|-----------------|--------------------------------------|------------------------------|---------------|
| Aug-05-2020 14:17:01<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>BP6ZNR | Initial Entry |

5.c

| Date  | Location        | User                                 | Value  | Reason        |
|---|-----------------|--------------------------------------|--|---------------|
| Aug-05-2020 14:17:26<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br><b>Sample ID: BP6ZNS</b> | Initial Entry |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391024

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

5.c Sample ID

| Date  | Location        | User                                 | Value                        | Reason        |
|---|-----------------|--------------------------------------|------------------------------|---------------|
| Aug-05-2020 14:17:26<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>BP6ZNS | Initial Entry |

5.d

| Date  | Location        | User                                 | Value  | Reason        |
|---|-----------------|--------------------------------------|--|---------------|
| Aug-07-2020 15:45:13<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br><b>Sample ID: BPRBGL</b> | Initial Entry |

5.d Sample ID

| Date  | Location        | User                                 | Value                        | Reason        |
|---|-----------------|--------------------------------------|------------------------------|---------------|
| Aug-07-2020 15:45:13<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>BPRBGL | Initial Entry |

5.e

| Date  | Location        | User                                 | Value  | Reason        |
|---|-----------------|--------------------------------------|--|---------------|
| Aug-07-2020 15:45:27<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br><b>Sample ID: BPRBGM</b> | Initial Entry |

5.e Sample ID

| Date  | Location        | User                                 | Value                        | Reason        |
|---|-----------------|--------------------------------------|------------------------------|---------------|
| Aug-07-2020 15:45:27<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>BPRBGM | Initial Entry |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391024

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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**1. Data Origin**

| Date  | Location        | User                    | Value                      | Reason        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Jul-31-2020 20:49:54<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date  | Location        | User                    | Value                            | Reason        |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Jul-31-2020 20:49:54<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>NASAL_SWAB | Initial Entry |

**3. Sample Collected?**

| Date  | Location        | User                                 | Value                     | Reason  |
|---|-----------------|--------------------------------------|---------------------------|---|
| Aug-07-2020 14:52:32<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)            | Query 1: Closed           | Close Auto Query  |
| Aug-04-2020 04:40:16<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | Query 1: Opened           | DQ: Please review the 'Sample Collected?' is reported as Yes however no any barcodes are entered. Kindly review and correct the data as appropriate. Thank you. |
| Jul-31-2020 20:49:54<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)            | Query 1: Candidate        | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.  |
| Jul-31-2020 20:49:54<br>(UTC-05:00) Eastern                       | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>YES | Initial Entry   |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1139

**Site Name:** (1139) Duke University Medical Center

**Subject No:** 11391024

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:44

|                    |  |  |                     |  |
|--------------------|--|--|---------------------|--|
| Time (US & Canada) |  |  | Date of Collection: |  |
|                    |  |  | Jul/31/2020         |  |

**5.a**

| Date  | Location        | User                                 | Value  | Reason        |
|---|-----------------|--------------------------------------|--|---------------|
| Aug-07-2020 14:52:32<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br><b>Sample ID:</b> BP6ZNY | Initial Entry |

**5.a Sample ID**

| Date  | Location        | User                                 | Value                        | Reason        |
|---|-----------------|--------------------------------------|------------------------------|---------------|
| Aug-07-2020 14:52:32<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>BP6ZNY | Initial Entry |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1139

Subject No: 11391024

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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**1. Was there a temporary delay of vaccination?**

| Date  | Location        | User                                 | Value                    | Reason        |
|---|-----------------|--------------------------------------|--------------------------|---------------|
| Jul-31-2020 20:50:33<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**2. Treatment Name**

| Date  | Location        | User                    | Value                                 | Reason        |
|---|-----------------|-------------------------|---------------------------------------|---------------|
| Jul-31-2020 20:50:33<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>BLINDED THERAPY | Initial Entry |

**3. Formulation:**

| Date  | Location        | User                    | Value                           | Reason        |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Jul-31-2020 20:50:33<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>INJECTION | Initial Entry |

**4. Dose Date Time:**

| Date  | Location        | User                                 | Value                                   | Reason        |
|---|-----------------|--------------------------------------|---|---------------|
| Jul-31-2020 20:50:33<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Jul/31/2020 15:57 | Initial Entry |

**5. Anatomical Location:**

| Date  | Location        | User                    | Value                                | Reason        |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Jul-31-2020 20:50:33<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>DELTOID MUSCLE | Initial Entry |

**6. Body Side:**

| Date  | Location        | User                                 | Value                      | Reason        |
|---|-----------------|--------------------------------------|----------------------------|---------------|
| Aug-05-2020 11:08:11<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>LEFT | Initial Entry |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1139

Subject No: 11391024

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

7. Route:

| Date  | Location        | User                    | Value                               | Reason        |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Jul-31-2020 20:50:33<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>INTRAMUSCULAR | Initial Entry |

10. Timeframe Subject Was Observed

| Date  | Location        | User                    | Value   | Reason        |
|---|-----------------|-------------------------|---|---------------|
| Jul-31-2020 20:50:33<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>THE PROTOCOL SPECIFIED OB<br>SERVATION PERIOD | Initial Entry |

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

| Date  | Location        | User                                 | Value                     | Reason        |
|---|-----------------|--------------------------------------|---------------------------|---------------|
| Jul-31-2020 20:50:33<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1139

**Subject No:** 11391024

**Generated By:** (b) (4)

**Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1139) Duke University Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:44

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*1. Select appropriate response - Reactogenicity diary collection*

| Date  | Location        | User                                 | Value   | Reason        |
|---|-----------------|--------------------------------------|---|---------------|
| Aug-03-2020 09:51:41<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>YES - REACTOGENICITY E-<br>DIARY COLLECTED FOR TH<br>IS SUBJECT | Initial Entry |

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1139

**Subject No:** 11391024

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1139) Duke University Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:44

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*1. Date of Visit*

| Date  | Location        | User                                 | Value                             | Reason        |
|---|-----------------|--------------------------------------|-----------------------------------|---------------|
| Aug-20-2020 08:58:12<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Aug/19/2020 | Initial Entry |



**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:30**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1139**Site Name:** (1139) Duke University Medical Center**Subject No:** 11391024**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:44[Back to Form](#)**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

| Date  | Location        | User                                 | Value                    | Reason        |
|---|-----------------|--------------------------------------|--------------------------|---------------|
| Aug-20-2020 09:01:04<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**2.a**

| Date  | Location        | User                                 | Value  | Reason        |
|---|-----------------|--------------------------------------|--|---------------|
| Aug-20-2020 09:01:04<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br><b>Symptom::</b> FE<br>VE<br>R<br><b>Were fever or systemic sy</b> N<br><b>mptoms present on the la</b> O<br><b>st day the Subject Diary</b><br><b>was completed?:</b> | Initial Entry |

**2.a Symptom:**

| Date  | Location        | User                                 | Value                       | Reason        |
|---|-----------------|--------------------------------------|-----------------------------|---------------|
| Aug-20-2020 09:01:04<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>FEVER | Initial Entry |

**2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

| Date  | Location        | User                                 | Value                    | Reason        |
|---|-----------------|--------------------------------------|--------------------------|---------------|
| Aug-20-2020 09:01:04<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**2.b**

| Date  | Location        | User                                 | Value   | Reason        |
|---|-----------------|--------------------------------------|---|---------------|
| Aug-20-2020 09:01:04<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br><b>Symptom::</b> FA<br>TI<br>GU | Initial Entry |

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391024

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

|  |  |  |   |  |
|--|--|--|---|--|
|  |  |  | E |  |
| <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> |  |  |   |  |

**2.b Symptom:**

| Date  | Location        | User                                 | Value                         | Reason        |
|---|-----------------|--------------------------------------|-------------------------------|---------------|
| Aug-20-2020 09:01:04<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>FATIGUE | Initial Entry |

**2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

| Date  | Location        | User                                 | Value                    | Reason        |
|---|-----------------|--------------------------------------|--------------------------|---------------|
| Aug-20-2020 09:01:04<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**2.c**

| Date  | Location        | User                                 | Value  | Reason        |
|---|-----------------|--------------------------------------|--|---------------|
| Aug-20-2020 09:01:04<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br><br>Symptom:: HE<br>AD<br>AC<br>HE<br><br><b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> | Initial Entry |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391024

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

2.c Symptom:

| Date  | Location        | User                                 | Value                          | Reason        |
|---|-----------------|--------------------------------------|--------------------------------|---------------|
| Aug-20-2020 09:01:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>HEADACHE | Initial Entry |

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date  | Location        | User                                 | Value                    | Reason        |
|---|-----------------|--------------------------------------|--------------------------|---------------|
| Aug-20-2020 09:01:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

2.d

| Date  | Location        | User                                 | Value  | Reason        |
|---|-----------------|--------------------------------------|--|---------------|
| Aug-20-2020 09:01:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br><b>Symptom::</b> CH<br>IL<br>LS<br><b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO | Initial Entry |

2.d Symptom:

| Date  | Location        | User                                 | Value                        | Reason        |
|---|-----------------|--------------------------------------|------------------------------|---------------|
| Aug-20-2020 09:01:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>CHILLS | Initial Entry |

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date  | Location        | User                                 | Value                    | Reason        |
|---|-----------------|--------------------------------------|--------------------------|---------------|
| Aug-20-2020 09:01:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

2.e

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391024

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

|   |                 |                                      |   |               |
|---|-----------------|--------------------------------------|---|---------------|
| Aug-20-2020 09:01:04<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br><b>Symptom::</b> VO<br>MIT<br>ING<br><br><b>Were fever or systemic s<br/>ymptoms present on the<br/>last day the Subject Diar<br/>y was completed?:</b> | Initial Entry |
|---|-----------------|--------------------------------------|---|---------------|

2.e Symptom:

| Date  | Location        | User                                 | Value                          | Reason        |
|---|-----------------|--------------------------------------|--------------------------------|---------------|
| Aug-20-2020 09:01:04<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>VOMITING | Initial Entry |

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date  | Location        | User                                 | Value                    | Reason        |
|---|-----------------|--------------------------------------|--------------------------|---------------|
| Aug-20-2020 09:01:04<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

2.f

| Date  | Location        | User                                 | Value   | Reason        |
|---|-----------------|--------------------------------------|---|---------------|
| Aug-20-2020 09:01:04<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br><b>Symptom::</b> DIA<br>RR<br>HE<br>A<br><br><b>Were fever or systemic s<br/>ymptoms present on the<br/>last day the Subject Diar<br/>y was completed?:</b> | Initial Entry |

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Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391024

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

2.f Symptom:

| Date  | Location        | User                                 | Value                          | Reason        |
|---|-----------------|--------------------------------------|--------------------------------|---------------|
| Aug-20-2020 09:01:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>DIARRHEA | Initial Entry |

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date  | Location        | User                                 | Value                    | Reason        |
|---|-----------------|--------------------------------------|--------------------------|---------------|
| Aug-20-2020 09:01:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

2.g

| Date  | Location        | User                                 | Value  | Reason        |
|---|-----------------|--------------------------------------|--|---------------|
| Aug-20-2020 09:01:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br><b>Symptom::</b> NEW OR WORSE NED MU SCLE PA IN<br><b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO | Initial Entry |

2.g Symptom:

| Date  | Location        | User                                 | Value  | Reason        |
|---|-----------------|--------------------------------------|--|---------------|
| Aug-20-2020 09:01:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>NEW OR WORSE NED MUSCLE PAIN | Initial Entry |

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date  | Location        | User                                 | Value                    | Reason        |
|---|-----------------|--------------------------------------|--------------------------|---------------|
| Aug-20-2020 09:01:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391024

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

2.h

| Date  | Location        | User                                 | Value   | Reason        |
|---|-----------------|--------------------------------------|---|---------------|
| Aug-20-2020 09:01:04<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br><b>Symptom::</b> NEW OR WORSE<br>ENED JOINT PAIN<br><br><b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO | Initial Entry |

2.h Symptom:

| Date  | Location        | User                                 | Value   | Reason        |
|---|-----------------|--------------------------------------|---|---------------|
| Aug-20-2020 09:01:04<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>NEW OR WORSE<br>ENED JOINT PAIN | Initial Entry |

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date  | Location        | User                                 | Value                    | Reason        |
|---|-----------------|--------------------------------------|--------------------------|---------------|
| Aug-20-2020 09:01:04<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

3. Injection Site Location:

| Date  | Location        | User                    | Value                                | Reason        |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Aug-20-2020 09:01:04<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>DELTOID MUSCLE | Initial Entry |

4. Injection Site Body Side:

| Date  | Location        | User                                 | Value                      | Reason        |
|---|-----------------|--------------------------------------|----------------------------|---------------|
| Aug-20-2020 09:05:42<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>LEFT | Initial Entry |

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Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391024

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

5.a

| Date  | Location        | User                                 | Value   | Reason        |
|---|-----------------|--------------------------------------|---|---------------|
| Aug-20-2020 09:05:42<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br><b>Injection Site Reaction::</b> RE<br>DN<br>ESS<br><br><b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO | Initial Entry |
| Aug-20-2020 09:01:04<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br><b>Injection Site Reaction::</b> RE<br>DN<br>ESS<br><br><b>Were injection site reactions present on the last day the Subject Diary was completed?:</b>    | Initial Entry |

5.a Injection Site Reaction:

| Date  | Location        | User                                 | Value                         | Reason        |
|---|-----------------|--------------------------------------|-------------------------------|---------------|
| Aug-20-2020 09:01:04<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>REDNESS | Initial Entry |

5.a Were injection site reactions present on the last day the Subject Diary was completed?

| Date  | Location        | User                                 | Value                    | Reason        |
|---|-----------------|--------------------------------------|--------------------------|---------------|
| Aug-20-2020 09:05:42<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

5.b

| Date  | Location        | User                                 | Value   | Reason        |
|---|-----------------|--------------------------------------|---|---------------|
| Aug-20-2020 09:05:42<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br><b>Injection Site Reaction::</b> SW<br>ELL<br>ING | Initial Entry |

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Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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Site Name: (1139) Duke University Medical Center

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Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

|   |                 |                                      |  |               |
|---|-----------------|--------------------------------------|--|---------------|
|   |                 |                                      | Were injection site reactions present on the last day the Subject Diary was completed?:  |               |
| Aug-20-2020 09:01:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Injection Site Reaction: SWELLING<br><br>Were injection site reactions present on the last day the Subject Diary was completed?: | Initial Entry |

5.b Injection Site Reaction:

| Date  | Location        | User                                 | Value                          | Reason        |
|---|-----------------|--------------------------------------|--------------------------------|---------------|
| Aug-20-2020 09:01:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>SWELLING | Initial Entry |

5.b Were injection site reactions present on the last day the Subject Diary was completed?

| Date  | Location        | User                                 | Value                    | Reason        |
|---|-----------------|--------------------------------------|--------------------------|---------------|
| Aug-20-2020 09:05:42 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

5.c

| Date  | Location        | User                                 | Value  | Reason        |
|---|-----------------|--------------------------------------|--|---------------|
| Aug-20-2020 09:05:42 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Injection Site Reaction: PAIN AT INJECTION SITE<br><br>Were injection site reactions present on the last day the Subject Diary was completed?: | Initial Entry |
| Aug-20-2020 09:01:04  | ACV0PFEINFP6000 | (b) (4), (b) (6)                     | <b>Data Entry:</b>   | Initial Entry |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)



Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

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Subject Initials: ---

Generated By: (b) (4)

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|  |  |                  |   |
|--|--|------------------|---|
| (UTC-05:00) Eastern Time (US & Canada) |  | (b) (4), (b) (6) | <b>Injection Site Reaction:</b><br>PAIN AT INJECTION SITE<br><br><b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> |
|--|--|------------------|---|

**5.c Injection Site Reaction:**

| Date  | Location        | User                                 | Value  | Reason        |
|---|-----------------|--------------------------------------|--|---------------|
| Aug-20-2020 09:01:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>PAIN AT INJECTION SITE | Initial Entry |

**5.c Were injection site reactions present on the last day the Subject Diary was completed?**

| Date  | Location        | User                                 | Value                    | Reason        |
|---|-----------------|--------------------------------------|--------------------------|---------------|
| Aug-20-2020 09:05:42 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

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Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 30-Jul-2020 21:28

Site No: 1139

Subject No: 11391024

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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**1. Date:**

| Date  | Location        | User                                 | Value                             | Reason        |
|---|-----------------|--------------------------------------|-----------------------------------|---------------|
| Aug-20-2020 09:01:31<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Aug/19/2020 | Initial Entry |

**2.a**

| Date  | Location        | User                                 | Value  | Reason        |
|---|-----------------|--------------------------------------|--|---------------|
| Aug-20-2020 09:01:31<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Record Identifier 1<br>::<br>Temperature: 97.3<br>Temperature Unit:<br>Temperature Location: ORAL CAVITY | Initial Entry |

**2.a Record Identifier:**

| Date  | Location        | User                                 | Value                   | Reason        |
|---|-----------------|--------------------------------------|-------------------------|---------------|
| Aug-20-2020 09:01:31<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>1 | Initial Entry |

**2.a Temperature:**

| Date  | Location        | User                                 | Value                      | Reason        |
|---|-----------------|--------------------------------------|----------------------------|---------------|
| Aug-20-2020 09:01:31<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>97.3 | Initial Entry |

**2.a Unit:**

| Date  | Location        | User                                 | Value                   | Reason        |
|---|-----------------|--------------------------------------|-------------------------|---------------|
| Aug-20-2020 09:01:31<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>F | Initial Entry |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 30-Jul-2020 21:28

**Site No:** 1139

**Subject No:** 11391024

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1139) Duke University Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:44

**2.a Temperature Location:**

| <b>Date</b>   | <b>Location</b> | <b>User</b>                          | <b>Value</b>                      | <b>Reason</b> |
|---|-----------------|--------------------------------------|-----------------------------------|---------------|
| Aug-20-2020 09:01:31<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>ORAL CAVITY | Initial Entry |

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391024

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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**1. Lab Panel:**

| Date  | Location        | User                                 | Value                                | Reason        |
|---|-----------------|--------------------------------------|--------------------------------------|---------------|
| Aug-20-2020 09:06:07<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Not Applicable | Initial Entry |

**2. Lab Sub-Panel:**

| Date  | Location        | User                                 | Value                                | Reason        |
|---|-----------------|--------------------------------------|--------------------------------------|---------------|
| Aug-20-2020 09:06:07<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Not Applicable | Initial Entry |

**3. Collection Date:**

| Date  | Location        | User                                 | Value                                | Reason        |
|---|-----------------|--------------------------------------|--------------------------------------|---------------|
| Aug-20-2020 09:06:07<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Not Applicable | Initial Entry |

**4. Laboratory Name and Address (Derived)**

| Date  | Location        | User                                 | Value                                | Reason        |
|---|-----------------|--------------------------------------|--------------------------------------|---------------|
| Aug-20-2020 09:06:07<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Not Applicable | Initial Entry |

**5. Specimen Type:**

| Date  | Location        | User                                 | Value                                | Reason        |
|---|-----------------|--------------------------------------|--------------------------------------|---------------|
| Aug-20-2020 09:06:07<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Not Applicable | Initial Entry |

**6.a**

| Date  | Location        | User                                 | Value              | Reason        |
|---|-----------------|--------------------------------------|--------------------|---------------|
| Aug-20-2020 09:06:07<br>(UTC-05:00) Eastern | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b> | Initial Entry |

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Header Text: c4591001

Visit: V2\_VAX2\_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391024

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

|                    |  |  |   |
|--------------------|--|--|---|
| Time (US & Canada) |  |  | <b>Sponsor-Defined Identifier:</b> Not Applicable<br><b>Test::</b> Not Applicable<br><b>Result::</b> Not Applicable<br><b>Not Done::</b> Not Applicable |
|--------------------|--|--|---|

6.a Sponsor ID:

| Date  | Location        | User                                 | Value                                | Reason        |
|---|-----------------|--------------------------------------|--------------------------------------|---------------|
| Aug-20-2020 09:06:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Not Applicable | Initial Entry |

6.a Test:

| Date  | Location        | User                                 | Value                                | Reason        |
|---|-----------------|--------------------------------------|--------------------------------------|---------------|
| Aug-20-2020 09:06:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Not Applicable | Initial Entry |

6.a Result:

| Date  | Location        | User                                 | Value                                | Reason        |
|---|-----------------|--------------------------------------|--------------------------------------|---------------|
| Aug-20-2020 09:06:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Not Applicable | Initial Entry |

6.a Not Done:

| Date  | Location        | User                                 | Value                                | Reason        |
|---|-----------------|--------------------------------------|--------------------------------------|---------------|
| Aug-20-2020 09:06:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Not Applicable | Initial Entry |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391024

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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**1. Data Origin**

| Date  | Location        | User                    | Value                      | Reason        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Aug-20-2020 09:01:56<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date  | Location        | User                    | Value                            | Reason        |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Aug-20-2020 09:01:56<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>NASAL_SWAB | Initial Entry |

**3. Sample Collected?**

| Date  | Location        | User                                 | Value   | Reason  |
|---|-----------------|--------------------------------------|---|---|
| Aug-20-2020 09:56:11<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)            | Query 1: Deleted  | Close Auto Query  |
| Aug-20-2020 09:01:56<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)            | Query 1: Candidate  | 'Sample Collected?'<br>is Yes, however no<br>barcodes are<br>entered. Please<br>review and correct<br>as appropriate. |
| Aug-20-2020 09:01:56<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>YES<br>Date of Collection:<br><br>Aug/19/2020 | Initial Entry   |

**5.a**

| Date  | Location        | User                                 | Value                                   | Reason        |
|---|-----------------|--------------------------------------|---|---------------|
| Aug-20-2020 09:56:11<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Sample ID: BP6ZYX | Initial Entry |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1139

**Site Name:** (1139) Duke University Medical Center

**Subject No:** 11391024

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:44

**5.a Sample ID**

| Date  | Location        | User                                 | Value                        | Reason        |
|---|-----------------|--------------------------------------|------------------------------|---------------|
| Aug-20-2020 09:56:11<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>BP6ZYX | Initial Entry |

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1139

Subject No: 11391024

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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**1. Was there a temporary delay of vaccination?**

| Date  | Location        | User                                 | Value                    | Reason        |
|---|-----------------|--------------------------------------|--------------------------|---------------|
| Aug-20-2020 09:04:54<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**2. Treatment Name**

| Date  | Location        | User                    | Value                                 | Reason        |
|---|-----------------|-------------------------|---------------------------------------|---------------|
| Aug-20-2020 09:04:54<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>BLINDED THERAPY | Initial Entry |

**3. Formulation:**

| Date  | Location        | User                    | Value                           | Reason        |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Aug-20-2020 09:04:54<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>INJECTION | Initial Entry |

**4. Dose Date Time:**

| Date  | Location        | User                                 | Value                                   | Reason        |
|---|-----------------|--------------------------------------|---|---------------|
| Aug-20-2020 09:04:54<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Aug/19/2020 15:13 | Initial Entry |

**5. Anatomical Location:**

| Date  | Location        | User                    | Value                                | Reason        |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Aug-20-2020 09:04:54<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>DELTOID MUSCLE | Initial Entry |

**6. Body Side:**

| Date  | Location        | User                                 | Value                      | Reason        |
|---|-----------------|--------------------------------------|----------------------------|---------------|
| Aug-20-2020 09:05:18<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>LEFT | Initial Entry |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)



Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1139

Subject No: 11391024

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

7. Route:

| Date  | Location        | User                    | Value                               | Reason        |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Aug-20-2020 09:04:54<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>INTRAMUSCULAR | Initial Entry |

10. Timeframe Subject Was Observed

| Date  | Location        | User                    | Value   | Reason        |
|---|-----------------|-------------------------|---|---------------|
| Aug-20-2020 09:04:54<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>THE PROTOCOL SPECIFIED OB<br>SERVATION PERIOD | Initial Entry |

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

| Date  | Location        | User                                 | Value                     | Reason        |
|---|-----------------|--------------------------------------|---------------------------|---------------|
| Aug-20-2020 09:04:54<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1139

**Subject No:** 11391024

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1139) Duke University Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:44

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*1. Date of Visit*

| Date  | Location        | User                                 | Value                             | Reason        |
|---|-----------------|--------------------------------------|-----------------------------------|---------------|
| Sep-22-2020 10:13:37<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Sep/22/2020 | Initial Entry |

**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:30**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1139**Site Name:** (1139) Duke University Medical Center**Subject No:** 11391024**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:44[Back to Form](#)**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

| Date  | Location        | User                                 | Value                    | Reason        |
|---|-----------------|--------------------------------------|--------------------------|---------------|
| Sep-22-2020 10:14:13<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**2.a**

| Date  | Location        | User                                 | Value  | Reason        |
|---|-----------------|--------------------------------------|--|---------------|
| Sep-22-2020 10:14:13<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br><b>Symptom::</b> FE<br>VE<br>R<br><b>Were fever or systemic sy</b> N<br><b>mptoms present on the la</b> O<br><b>st day the Subject Diary</b><br><b>was completed?:</b> | Initial Entry |

**2.a Symptom:**

| Date  | Location        | User                                 | Value                       | Reason        |
|---|-----------------|--------------------------------------|-----------------------------|---------------|
| Sep-22-2020 10:14:13<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>FEVER | Initial Entry |

**2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

| Date  | Location        | User                                 | Value                    | Reason        |
|---|-----------------|--------------------------------------|--------------------------|---------------|
| Sep-22-2020 10:14:13<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**2.b**

| Date  | Location        | User                                 | Value   | Reason        |
|---|-----------------|--------------------------------------|---|---------------|
| Sep-22-2020 10:14:13<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br><b>Symptom::</b> FA<br>TI<br>GU | Initial Entry |

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391024

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

|   |  |  |   |  |
|---|--|--|---|--|
|   |  |  | E |  |
| Were fever or systemic symptoms present on the last day the Subject Diary was completed?: |  |  |   |  |

2.b Symptom:

| Date   | Location        | User                                 | Value                         | Reason        |
|--|-----------------|--------------------------------------|-------------------------------|---------------|
| Sep-22-2020 10:14:13<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <u>Data Entry:</u><br>FATIGUE | Initial Entry |

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date   | Location        | User                                 | Value                    | Reason        |
|--|-----------------|--------------------------------------|--------------------------|---------------|
| Sep-22-2020 10:14:13<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <u>Data Entry:</u><br>NO | Initial Entry |

2.c

| Date   | Location        | User                                 | Value  | Reason        |
|--|-----------------|--------------------------------------|--|---------------|
| Sep-22-2020 10:14:13<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <u>Data Entry:</u><br>Symptom:: HE<br>AD<br>AC<br>HE<br>Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO | Initial Entry |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391024

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

2.c Symptom:

| Date  | Location        | User                                 | Value                          | Reason        |
|---|-----------------|--------------------------------------|--------------------------------|---------------|
| Sep-22-2020 10:14:13<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>HEADACHE | Initial Entry |

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date  | Location        | User                                 | Value                    | Reason        |
|---|-----------------|--------------------------------------|--------------------------|---------------|
| Sep-22-2020 10:14:13<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

2.d

| Date  | Location        | User                                 | Value  | Reason        |
|---|-----------------|--------------------------------------|--|---------------|
| Sep-22-2020 10:14:13<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br><b>Symptom::</b> CH<br>IL<br>LS<br><b>Were fever or systemic sy</b> NO<br><b>mptoms present on the la</b><br><b>st day the Subject Diary</b><br><b>was completed?:</b> | Initial Entry |

2.d Symptom:

| Date  | Location        | User                                 | Value                        | Reason        |
|---|-----------------|--------------------------------------|------------------------------|---------------|
| Sep-22-2020 10:14:13<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>CHILLS | Initial Entry |

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date  | Location        | User                                 | Value                    | Reason        |
|---|-----------------|--------------------------------------|--------------------------|---------------|
| Sep-22-2020 10:14:13<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

2.e

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391024

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

|   |                 |                                      |  |               |
|---|-----------------|--------------------------------------|--|---------------|
| Sep-22-2020 10:14:13<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br><b>Symptom::</b> VO<br>MIT<br>ING<br><br><b>Were fever or systemic s<br/>ymptoms present on the<br/>last day the Subject Diar<br/>y was completed?:</b> NO | Initial Entry |
|---|-----------------|--------------------------------------|--|---------------|

2.e Symptom:

| Date  | Location        | User                                 | Value                          | Reason        |
|---|-----------------|--------------------------------------|--------------------------------|---------------|
| Sep-22-2020 10:14:13<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>VOMITING | Initial Entry |

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date  | Location        | User                                 | Value                    | Reason        |
|---|-----------------|--------------------------------------|--------------------------|---------------|
| Sep-22-2020 10:14:13<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

2.f

| Date  | Location        | User                                 | Value  | Reason        |
|---|-----------------|--------------------------------------|--|---------------|
| Sep-22-2020 10:14:13<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br><b>Symptom::</b> DIA<br>RR<br>HE<br>A<br><br><b>Were fever or systemic s<br/>ymptoms present on the<br/>last day the Subject Diar<br/>y was completed?:</b> NO | Initial Entry |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391024

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

2.f Symptom:

| Date  | Location        | User                                 | Value                          | Reason        |
|---|-----------------|--------------------------------------|--------------------------------|---------------|
| Sep-22-2020 10:14:13 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>DIARRHEA | Initial Entry |

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date  | Location        | User                                 | Value                    | Reason        |
|---|-----------------|--------------------------------------|--------------------------|---------------|
| Sep-22-2020 10:14:13 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

2.g

| Date  | Location        | User                                 | Value  | Reason        |
|---|-----------------|--------------------------------------|--|---------------|
| Sep-22-2020 10:14:13 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br><b>Symptom::</b> NEW OR WORSE NED MU SCLE PA IN<br><b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO | Initial Entry |

2.g Symptom:

| Date  | Location        | User                                 | Value  | Reason        |
|---|-----------------|--------------------------------------|--|---------------|
| Sep-22-2020 10:14:13 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>NEW OR WORSENERD MUSCLE PAIN | Initial Entry |

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date  | Location        | User                                 | Value                    | Reason        |
|---|-----------------|--------------------------------------|--------------------------|---------------|
| Sep-22-2020 10:14:13 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391024

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

2.h

| Date  | Location        | User                                 | Value   | Reason        |
|---|-----------------|--------------------------------------|---|---------------|
| Sep-22-2020 10:14:13<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br><b>Symptom::</b> NEW OR WORSE<br>ENED JOINT PAIN<br><br><b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO | Initial Entry |

2.h Symptom:

| Date  | Location        | User                                 | Value   | Reason        |
|---|-----------------|--------------------------------------|---|---------------|
| Sep-22-2020 10:14:13<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>NEW OR WORSE<br>ENED JOINT PAIN | Initial Entry |

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date  | Location        | User                                 | Value                    | Reason        |
|---|-----------------|--------------------------------------|--------------------------|---------------|
| Sep-22-2020 10:14:13<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

3. Injection Site Location:

| Date  | Location        | User                    | Value                                | Reason        |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Sep-22-2020 10:14:13<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>DELTOID MUSCLE | Initial Entry |

4. Injection Site Body Side:

| Date  | Location        | User                                 | Value                      | Reason        |
|---|-----------------|--------------------------------------|----------------------------|---------------|
| Sep-22-2020 10:14:13<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>LEFT | Initial Entry |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)



Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391024

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

5.a

| Date  | Location        | User                                 | Value   | Reason        |
|---|-----------------|--------------------------------------|---|---------------|
| Sep-22-2020 10:14:13<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br><b>Injection Site Reaction::</b> RE<br>DN<br>ESS<br><br><b>Were injection site reacti</b> NO<br><b>ons present on the last d</b><br><b>ay the Subject Diary was</b><br><b>completed?:</b> | Initial Entry |

5.a Injection Site Reaction:

| Date  | Location        | User                                 | Value                         | Reason        |
|---|-----------------|--------------------------------------|-------------------------------|---------------|
| Sep-22-2020 10:14:13<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>REDNESS | Initial Entry |

5.a Were injection site reactions present on the last day the Subject Diary was completed?

| Date  | Location        | User                                 | Value                    | Reason        |
|---|-----------------|--------------------------------------|--------------------------|---------------|
| Sep-22-2020 10:14:13<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

5.b

| Date  | Location        | User                                 | Value  | Reason        |
|---|-----------------|--------------------------------------|--|---------------|
| Sep-22-2020 10:14:13<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br><b>Injection Site Reaction::</b> SW<br>ELL<br>ING<br><br><b>Were injection site react</b> NO<br><b>ions present on the last</b><br><b>day the Subject Diary w</b><br><b>as completed?:</b> | Initial Entry |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391024

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

5.b Injection Site Reaction:

| Date  | Location        | User                                 | Value                          | Reason        |
|---|-----------------|--------------------------------------|--------------------------------|---------------|
| Sep-22-2020 10:14:13<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>SWELLING | Initial Entry |

5.b Were injection site reactions present on the last day the Subject Diary was completed?

| Date  | Location        | User                                 | Value                    | Reason        |
|---|-----------------|--------------------------------------|--------------------------|---------------|
| Sep-22-2020 10:14:13<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

5.c

| Date  | Location        | User                                 | Value   | Reason        |
|---|-----------------|--------------------------------------|---|---------------|
| Sep-22-2020 10:14:13<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Injection Site Reaction: PAIN AT INJECTION SITE<br><br>Were injection site reactions present on the last day the Subject Diary was completed?: NO | Initial Entry |

5.c Injection Site Reaction:

| Date  | Location        | User                                 | Value  | Reason        |
|---|-----------------|--------------------------------------|--|---------------|
| Sep-22-2020 10:14:13<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>PAIN AT INJECTION SITE | Initial Entry |

5.c Were injection site reactions present on the last day the Subject Diary was completed?

| Date  | Location        | User                                 | Value                    | Reason        |
|---|-----------------|--------------------------------------|--------------------------|---------------|
| Sep-22-2020 10:14:13<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391024

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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**1. Data Origin**

| Date  | Location        | User                    | Value                      | Reason        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Sep-22-2020 10:14:23<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date  | Location        | User                    | Value                       | Reason        |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Sep-22-2020 10:14:23<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SERUM | Initial Entry |

**3. Sample Collected?**

| Date  | Location        | User                                 | Value   | Reason  |
|---|-----------------|--------------------------------------|---|---|
| Sep-23-2020 10:35:42<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)            | Query 1: Closed   | Close Auto Query  |
| Sep-23-2020 06:15:35<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | Query 1: Opened   | 'Sample Collected?'<br>is Yes, however no<br>barcodes are<br>entered. Please<br>review and correct<br>as appropriate. |
| Sep-22-2020 10:14:23<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)            | Query 1: Candidate  | 'Sample Collected?'<br>is Yes, however no<br>barcodes are<br>entered. Please<br>review and correct<br>as appropriate. |
| Sep-22-2020 10:14:23<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>YES<br>Date of Collection:<br><br>Sep/22/2020 | Initial Entry   |

5.a

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391024

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| Date   | Location        | User             | Value  | Reason        |
|--|-----------------|------------------|--|---------------|
| Sep-23-2020 10:35:42<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Sample ID: BP706R</b> | Initial Entry |

5.a Sample ID

| Date   | Location        | User             | Value                        | Reason        |
|--|-----------------|------------------|------------------------------|---------------|
| Sep-23-2020 10:35:42<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>BP706R | Initial Entry |

5.b

| Date   | Location        | User             | Value  | Reason        |
|--|-----------------|------------------|--|---------------|
| Sep-23-2020 10:36:01<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Sample ID: BP706S</b> | Initial Entry |

5.b Sample ID

| Date   | Location        | User             | Value                        | Reason        |
|--|-----------------|------------------|------------------------------|---------------|
| Sep-23-2020 10:36:01<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>BP706S | Initial Entry |

5.c

| Date   | Location        | User             | Value  | Reason        |
|--|-----------------|------------------|--|---------------|
| Sep-23-2020 10:36:10<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Sample ID: BP706T</b> | Initial Entry |

5.c Sample ID

| Date   | Location        | User             | Value                        | Reason        |
|--|-----------------|------------------|------------------------------|---------------|
| Sep-23-2020 10:36:10<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>BP706T | Initial Entry |

5.d

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391024

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Sep-23-2020 10:36:38<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sample ID: BPRBTR</b> | Initial Entry |

5.d Sample ID

| Date  | Location        | User                | Value                        | Reason        |
|---|-----------------|---------------------|------------------------------|---------------|
| Sep-23-2020 10:36:38<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>BPRBTR | Initial Entry |

5.e

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Sep-23-2020 10:36:46<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sample ID: BPRBTS</b> | Initial Entry |

5.e Sample ID

| Date  | Location        | User                | Value                        | Reason        |
|---|-----------------|---------------------|------------------------------|---------------|
| Sep-23-2020 10:36:46<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>BPRBTS | Initial Entry |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1139

**Subject No:** 11391024

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1139) Duke University Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:44

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**I. Date of Visit**

| Date  | Location                                  | User                    | Value                             | Reason  |
|---|---|-------------------------|-----------------------------------|---|
| Feb-01-2021<br>03:46:04<br>(UTC-05:00)<br>Eastern Time<br>(US & Canada) | ACV0PFEINFP6000                           | (b) (4), (b) (6)        | Query 1:<br>Closed                | Per site confirmation_PD tracker updated  |
| Jan-31-2021<br>17:10:14<br>(UTC-05:00)<br>Eastern Time<br>(US & Canada) | ACV0PFEINFP6000                           | (b) (4), (b) (6)        | Query 1:<br>Answered              | Original value is correct   |
| Jan-28-2021<br>09:28:23<br>(UTC-05:00)<br>Eastern Time<br>(US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFE SDQ PROD<br>(b) (4) | Query 1:<br>Opened                | PDQ: Date of visit at V4_MONTH6_L is out of window for 20 days from V2_VAX2_L DOV or V2 Vaccination date. Please verify and update. Else, confirm in query response appropriately.<br>(b) (4) |
| Jan-21-2021<br>13:59:20<br>(UTC-05:00)<br>Eastern Time<br>(US & Canada) | ACV0PFEINFP6000                           | (b) (4), (b) (6)        | <b>Data Entry:</b><br>Jan/21/2021 | Initial Entry   |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V4\_MONTH6\_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391024

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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**1. Data Origin**

| Date  | Location        | User                    | Value                      | Reason        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Jan-21-2021 13:59:27<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date  | Location        | User                    | Value                       | Reason        |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Jan-21-2021 13:59:27<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SERUM | Initial Entry |

**3. Sample Collected?**

| Date  | Location        | User                                 | Value   | Reason  |
|---|-----------------|--------------------------------------|---|---|
| Jan-25-2021 11:24:50<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)            | Query 1: Closed   | Close Auto Query  |
| Jan-22-2021 05:32:04<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | Query 1: Opened   | 'Sample Collected?'<br>is Yes, however no<br>barcodes are<br>entered. Please<br>review and correct<br>as appropriate. |
| Jan-21-2021 13:59:27<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)            | Query 1: Candidate  | 'Sample Collected?'<br>is Yes, however no<br>barcodes are<br>entered. Please<br>review and correct<br>as appropriate. |
| Jan-21-2021 13:59:27<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b)<br>(6)                  | <b>Data Entry:</b><br>YES<br>Date of Collection:<br><br>Jan/21/2021 | Initial Entry   |

5.a

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V4\_MONTH6\_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391024

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| Date   | Location        | User             | Value                                   | Reason        |
|--|-----------------|------------------|---|---------------|
| Jan-25-2021 11:24:50<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Sample ID: BP8MM4 | Initial Entry |

5.a Sample ID

| Date   | Location        | User             | Value                        | Reason        |
|--|-----------------|------------------|------------------------------|---------------|
| Jan-25-2021 11:24:50<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>BP8MM4 | Initial Entry |

5.b

| Date   | Location        | User             | Value                                   | Reason        |
|--|-----------------|------------------|---|---------------|
| Jan-25-2021 11:25:03<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Sample ID: BP8MM5 | Initial Entry |

5.b Sample ID

| Date   | Location        | User             | Value                        | Reason        |
|--|-----------------|------------------|------------------------------|---------------|
| Jan-25-2021 11:25:03<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>BP8MM5 | Initial Entry |

5.c

| Date   | Location        | User             | Value                                   | Reason        |
|--|-----------------|------------------|---|---------------|
| Jan-25-2021 11:25:14<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Sample ID: BP8MM6 | Initial Entry |

5.c Sample ID

| Date   | Location        | User             | Value                        | Reason        |
|--|-----------------|------------------|------------------------------|---------------|
| Jan-25-2021 11:25:14<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>BP8MM6 | Initial Entry |

5.d

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)



Header Text: c4591001

Visit: V4\_MONTH6\_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1139

Site Name: (1139) Duke University Medical Center

Subject No: 11391024

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| Date  | Location        | User                   | Value  | Reason        |
|---|-----------------|------------------------|--|---------------|
| Jan-25-2021 12:25:44<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b)<br>(4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sample ID: BNWYH4</b> | Initial Entry |

5.d Sample ID

| Date  | Location        | User                   | Value                        | Reason        |
|---|-----------------|------------------------|------------------------------|---------------|
| Jan-25-2021 12:25:44<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b)<br>(4),<br>(b) (6) | <b>Data Entry:</b><br>BNWYH4 | Initial Entry |

5.e

| Date  | Location        | User                   | Value  | Reason        |
|---|-----------------|------------------------|--|---------------|
| Jan-25-2021 12:25:57<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b)<br>(4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sample ID: BNWYH5</b> | Initial Entry |

5.e Sample ID

| Date  | Location        | User                   | Value                        | Reason        |
|---|-----------------|------------------------|------------------------------|---------------|
| Jan-25-2021 12:25:57<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b)<br>(4),<br>(b) (6) | <b>Data Entry:</b><br>BNWYH5 | Initial Entry |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

**Form Version:** 15-Sep-2020 21:55

**Site No:** 1139

**Subject No:** 11391024

**Generated By:** (b) (4)

**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1139) Duke University Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:44

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**1. Date of Completion/Discontinuation/Death :**

| Date  | Location        | User                                 | Value                             | Reason        |
|---|-----------------|--------------------------------------|-----------------------------------|---------------|
| Sep-22-2020 10:14:38<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>Sep/22/2020 | Initial Entry |

**2. Phase of Disposition:**

| Date  | Location        | User                    | Value                             | Reason        |
|---|-----------------|-------------------------|-----------------------------------|---------------|
| Sep-22-2020 10:14:38<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>VACCINATION | Initial Entry |

**3. Status:**

| Date  | Location        | User                                 | Value                           | Reason        |
|---|-----------------|--------------------------------------|---------------------------------|---------------|
| Sep-22-2020 10:14:38<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>(b) (4), (b) (6) | <b>Data Entry:</b><br>COMPLETED | Initial Entry |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1139

**Subject No:** 11391024

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1139) Duke University Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:44

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| Date  | Location        | User                | Value        | Reason |
|---|-----------------|---------------------|--------------|--------|
| Mar-02-2021 10:00:18<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | Form Created |        |

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1139

Subject No: 11391024

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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**1. Category:**

| Date  | Location        | User                    | Value                               | Reason        |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Mar-02-2021 10:00:18<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>ADVERSE EVENT | Initial Entry |

**2. AE ID:**

| Date  | Location        | User                    | Value                   | Reason        |
|---|-----------------|-------------------------|-------------------------|---------------|
| Mar-02-2021 10:00:18<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>1 | Initial Entry |

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Mar-02-2021 10:00:18<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Malignant neoplasm of upper-out<br>er quadrant of right breast in female<br>, estrogen receptor positive | Initial Entry |

**4. Start Date Time:**

| Date  | Location        | User                | Value                                  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Mar-02-2021 10:00:18<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Feb/2/2021 12:00 | Initial Entry |

**5. Is the adverse event still ongoing?**

| Date  | Location        | User                | Value                     | Reason        |
|---|-----------------|---------------------|---------------------------|---------------|
| Mar-02-2021 10:00:18<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>YES | Initial Entry |

**6. Toxicity Grade:**

| Date  | Location        | User             | Value                   | Reason        |
|---|-----------------|------------------|-------------------------|---------------|
| Mar-02-2021 10:00:18<br>(UTC-05:00) Eastern | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>3 | Initial Entry |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1139

Subject No: 11391024

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

Time (US & Canada)

(b) (4), (b) (6)

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

| Date  | Location        | User                      | Value  | Reason  |
|---|-----------------|---------------------------|--|---|
| Mar-03-2021 06:18:17<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Deleted   | Close Auto Query  |
| Mar-02-2021 10:00:18<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate   | For AE Malignant neoplasm of upper-outer quadrant of right breast in female, estrogen receptor positive : Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank. |
| Mar-02-2021 10:00:18<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)          | <p><b>Data Entry:</b></p> <p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>NO</p> <p>Did this serious event result in p</p> | Initial Entry   |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1139

Subject No: 11391024

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

|  |  |  |  |  |
|--|--|--|--|--|
|  |  |  | <p>ersistent or significant disability/<br/>incapacity?</p> <p>NO</p> <p>Is this serious event life threaten<br/>ing?</p> <p>NO</p> <p>Other medically important serio<br/>us event</p> <p>YES</p> |  |
|--|--|--|--|--|

**8. Is this adverse event the result of a study Medication Error?**

*If Yes, record the type of medication error on the Medication Error Log.*

| Date  | Location        | User                | Value                    | Reason        |
|---|-----------------|---------------------|--------------------------|---------------|
| Mar-02-2021 10:00:18<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>NO | Initial Entry |

**9. Is this event related to study treatment:**

| Date  | Location        | User                | Value   | Reason        |
|---|-----------------|---------------------|---|---------------|
| Mar-02-2021 10:00:18<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>NOT RELATED<br>If Not Related to study treatment<br>(s), this event is due to:<br><br>OTHER<br><br><i>If Other, specify:</i><br><br>Breast Cancer | Initial Entry |

**10. Latest Action Taken with Study Treatment:**

| Date  | Location        | User                | Value                                | Reason        |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Mar-02-2021 10:00:18<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>NOT APPLICABLE | Initial Entry |

**11. Was a Concomitant Medication given?**

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1139

Subject No: 11391024

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

| Date  | Location        | User                | Value                    | Reason        |
|---|-----------------|---------------------|--------------------------|---------------|
| Mar-02-2021 10:00:18<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>NO | Initial Entry |

**12. Was a Non-Drug Treatment given?**

| Date  | Location        | User                | Value                    | Reason        |
|---|-----------------|---------------------|--------------------------|---------------|
| Mar-02-2021 10:00:18<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>NO | Initial Entry |

**13. What was the outcome of this adverse event?:**

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Mar-02-2021 10:00:18<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>NOT RECOVERED/NOT RESOL<br>VED | Initial Entry |

**14. Did the adverse event cause the subject to be discontinued from the study?**

| Date  | Location        | User                | Value                    | Reason        |
|---|-----------------|---------------------|--------------------------|---------------|
| Mar-02-2021 10:00:18<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>NO | Initial Entry |

**15. Serious Adverse Event Number: For Pfizer Use Only**

| Date  | Location        | User                | Value                            | Reason        |
|---|-----------------|---------------------|----------------------------------|---------------|
| Mar-03-2021 06:18:17<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>2021218812 | Initial Entry |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1139

**Site Name:** (1139) Duke University Medical Center

**Subject No:** 11391024

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:44

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*I. Date of Visit*

| Date  | Location        | User             | Value                             | Reason        |
|---|-----------------|------------------|-----------------------------------|---------------|
| Feb-16-2021 12:57:25<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Jan/15/2021 | Initial Entry |



**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form Version:** 10-Dec-2020 02:25

**Site No:** 1139

**Subject No:** 11391024

**Generated By:** (b) (4)

**Form:** FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail  
History

**Form Status:** Data Complete, Frozen

**Site Name:** (1139) Duke University Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:44

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**1. Select appropriate response - Is participant willing to return for Vaccination 3?**

| Date  | Location        | User                | Value   | Reason              |
|---|-----------------|---------------------|---|---------------------|
| Mar-01-2021 11:15:55<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Participant is willing to return for<br>Vaccination 3<br>Participant is:<br><br>eligible and NOT confirmed to<br>have received only placebo at<br>Vaccination 1/2 | Transcription Error |
| Feb-16-2021 12:57:34<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)    | <b>Data Entry:</b><br>Participant is NOT willing to return for<br>Vaccination 3 OR otherwise<br>not eligible  | Initial Entry       |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1139

Subject No: 11391024

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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**1. Date Treatment Unblinded :**

| Date   | Location        | User             | Value                             | Reason        |
|--|-----------------|------------------|-----------------------------------|---------------|
| Feb-16-2021 12:57:12<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Jan/15/2021 | Initial Entry |

**2. Primary Reason for Unblinding:**

| Date   | Location                                  | User                 | Value                           | Reason  |
|--|---|----------------------|---------------------------------|---|
| Mar-01-2021 23:29:10<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000                           | (b) (4), (b) (6)     | Query 1: Closed                 | Response satisfies query  |
| Mar-01-2021 11:16:38<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000                           | (b) (4), (b) (6)     | Query 1: Answered               | Changed data per query  |
| Feb-22-2021 15:35:23<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | DMW QUERY<br>(b) (4) | Query 1: Opened                 | DMW7350330;Primary Reason for Unblinding is "ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION", but "Participant is willing to return for Vaccination 3" is not selected in the Further Vaccination Confirmation CRF. Please review and update as appropriate. |
| Feb-16-2021 12:57:12<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000                           | (b) (4), (b) (6)     | <b>Data Entry:</b><br>ASSESS EL | Initial Entry   |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1139

**Subject No:** 11391024

**Generated By:** (b) (4)

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1139) Duke University Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:44

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Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1139

Subject No: 11391024

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1139) Duke University Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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**I. Subject Status**

| Date  | Location        | User                    | Value                                     | Reason        |
|---|-----------------|-------------------------|---|---------------|
| Sep-22-2020 10:14:38<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>FOLLOW-UP           | Initial Entry |
| Jul-31-2020 20:49:30<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>ENROLLED/RANDOMIZED | Initial Entry |
| Jul-31-2020 20:47:50<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SCREENED            | Initial Entry |

**2. Subject Status Date**

| Date  | Location        | User                    | Value                             | Reason  |
|---|-----------------|-------------------------|-----------------------------------|---|
| Mar-03-2021 06:18:55<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b)<br>(6)     | Query 1: Closed                   | Response satisfies query  |
| Mar-02-2021 13:38:26<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b)<br>(6)     | Query 1: Answered                 | Changed data per query  |
| Mar-02-2021 05:17:42<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b)<br>(6)     | Query 1: Opened                   | SAE<br>RECON:AER#2021218812<br>malignant neoplasm of<br>upper-outer quadrant of<br>right breast in female,<br>estrogen receptor positive<br>was reported as serious in<br>Safety database but missing<br>in AE CRF. Please confirm.<br>If safety update is required,<br>submit a ffup form. |
| Sep-22-2020 10:14:38<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>Sep/22/2020 | Initial Entry   |
| Jul-31-2020 20:49:30<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>Jul/31/2020 | Initial Entry   |

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1139

**Subject No:** 11391024

**Generated By:** (b) (4)

**Form:** SUBJECT STATUS - eCRF Audit Trail History

**Form Status:** Data Complete, Verified

**Site Name:** (1139) Duke University Medical Center

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:44

|   |                 |                         |                                   |               |
|---|-----------------|-------------------------|-----------------------------------|---------------|
| Jul-31-2020 20:47:50<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>Jul/31/2020 | Initial Entry |
|---|-----------------|-------------------------|-----------------------------------|---------------|

090177e196ae3d88\Final\Final On: 01-Apr-2021 04:37 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Signed, Verified

**Site No:** 1139

**Site Name:** (1139) Duke University Medical Center

**Subject No:** 11391024

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:44

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*1. Casebook Signature*

| Date  | Location        | User                | Value                                      | Reason        |
|---|-----------------|---------------------|--|---------------|
| Sep-04-2020 08:55:36<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Click Here to Enable | Initial Entry |