

**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:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

[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	24 JUL 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

**Form:** MAIN INFORMED CONSENT

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

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

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

[eCRF Audit Trail History](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/9/2020
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**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

**Form:** DEMOGRAPHY

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

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

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[12041078]
2.	Birth Date:	(b) (6) 1976
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1204

**Subject No:** 12041078

**Generated By:**

(b) (4)

**Form:** DATE OF VISIT

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

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Sep/9/2020
2.	Erroneous Visit	

**Header Text:** C4591001

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

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

**Site No:** 1204

**Subject No:** 12041078

**Generated By:**

(b) (4)

**Form:** INCLUSION/EXCLUSION CRITERIA

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

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

**Form Comments**

**Inclusion Criteria Not Met**

1.	Description of Inclusion Criterion Not Met	Not Applicable _____
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**Exclusion Criteria Met**

2.	Description of Exclusion Criterion Met	Not Applicable _____
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090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1204

**Subject No:** 12041078

**Generated By:**

(b) (4)

**Form:** DISPOSITION - SCREENING

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

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

**Disposition - Screening**

1.	Date of Completion/Discontinuation /Death	Sep/9/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1204

**Subject No:** 12041078

**Generated By:**

(b) (4)

**Form:** GENERAL MEDICAL HISTORY

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

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Herniated Disc]
	Start Date:	Oct/1/2019
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Vasectomy]
	Start Date:	UNK/UNK/2014
	Ongoing:	NO End Date: UNK/UNK/2014

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001

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

**Form:** VITAL SIGNS - BASELINE

**Form Version:** 21-Aug-2020 02:51

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

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Sep/9/2020
2.	Weight:	[170.0]
3.	Unit:	LB
4.	Height:	[66.0]
5.	Unit:	in
6.	Body Mass Index:	[27.4]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[99.4]
	Unit:	F
	Temperature Location:	ORAL CAVITY



**Header Text:** C4591001

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

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

**Site No:** 1204

**Subject No:** 12041078

**Generated By:**

(b) (4)

**Form:** RANDOMIZATION

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

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Sep/9/2020
2.	Randomization Number:	[85740]
3.	Randomization Group:	[ ]

**Header Text:** C4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1204**Site Name:** (1204) Icahn School of Medicine at Mount Sinai**Subject No:** 12041078**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Sep/9/2020
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	[BNWL3W]
5.b	Sample ID	[BNWL3X]
5.c	Sample ID	[BPYM3R]
5.d	Sample ID	[BNWL3M]

**Header Text:** C4591001

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

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

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

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

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/9/2020
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	[BPYM3K]
-----	-----------	----------

**Header Text:** C4591001

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

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

**Site No:** 1204

**Subject No:** 12041078

**Generated By:**

(b) (4)

**Form:** VACCINATION

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

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

[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:	Sep/9/2020 17:20
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

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1204

**Subject No:** 12041078

**Generated By:**

(b) (4)

**Form:** REACTOGENICITY DIARY

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

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

**Reactogenicity Diary**

1.	Select appropriate response - Reactogenicity diary collection	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT
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**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1204

**Subject No:** 12041078

**Generated By:**

(b) (4)

**Form:** DATE OF VISIT

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

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Sep/30/2020
2.	Erroneous Visit	

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 15-Sep-2020 21:54

**Site No:** 1204

**Subject No:** 12041078

**Generated By:**

(b) (4)

**Form:** VITAL SIGNS - TEMP

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

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Sep/30/2020
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**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[98.3]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/30/2020
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	[BPYN3P]
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**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1204

**Subject No:** 12041078

**Generated By:**

(b) (4)

**Form:** VACCINATION

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

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

[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:	Sep/30/2020 16:09
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

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1204 **Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Oct/28/2020
2.	Erroneous Visit	

**Header Text:** C4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1204**Site Name:** (1204) Icahn School of Medicine at Mount Sinai**Subject No:** 12041078**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/28/2020
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	[BRC016]
5.b	Sample ID	[BSMGW7]
5.c	Sample ID	[BSMGW4]
5.d	Sample ID	[BSMGW3]

**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:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

3.	COVID-19 Illness Visit:	
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**Header Text:** C4591001

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

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

**Site No:** 1204

**Subject No:** 12041078

**Generated By:**

(b) (4)

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

**Form Status:** Not Started

**Site Name:** (1204) Icahn School of Medicine at Mount  
Sinai

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

**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:	[ ]
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090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL - New  
Unscheduled Visit**Form Version:** 22-Apr-2020 21:03**Site No:** 1204**Subject No:** 12041078**Generated By:**

(b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB SELF**Form Status:** Not Started**Site Name:** (1204) Icahn School of Medicine at Mount  
Sinai**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 13:11**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	[ ]
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**Header Text:** C4591001

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

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

**Site No:** 1204

**Subject No:** 12041078

**Generated By:**

(b) (4)

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

**Form Status:** Not Started

**Site Name:** (1204) Icahn School of Medicine at Mount  
Sinai

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

**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	[ ]
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090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**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:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount  
Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

**Health Care Utilization**

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

**Health Care Utilization Other**

2.	Other Type of Practitioner Specify:	[ ]
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**Health Care Utilization**

3.	Has the subject been hospitalized due to potential COVID-19 illness?	
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090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)



**Header Text:** C4591001

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

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

**Site No:** 1204

**Subject No:** 12041078

**Generated By:**

(b) (4)

**Form:** ILLNESS DETAILS

**Form Status:** Not Started

**Site Name:** (1204) Icahn School of Medicine at Mount  
Sinai

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

**Illness Details**

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

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**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:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount  
Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

3.	COVID-19 Illness Visit:	
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**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:** 1204**Site Name:** (1204) Icahn School of Medicine at Mount  
Sinai**Subject No:** 12041078**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

**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	[ ]
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**Header Text:** C4591001

**Visit:** Unplanned - New Unscheduled **Form:** DATE OF VISIT  
Visit

**Form Version:** 22-Apr-2020 21:02 **Form Status:** Not Started

**Site No:** 1204 **Site Name:** (1204) Icahn School of Medicine at Mount  
Sinai

**Subject No:** 12041078 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:11

**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:** 1204    **Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078    **Subject Initials:** ---

**Generated By:** (b) (4)    **Generated Time (GMT):** 29-Mar-2021 13:11

**Unplanned Assessments**

1.	Assessments	
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090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001

**Visit:** End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT

**Form Version:** 15-Sep-2020 21:55 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation/Death :	Oct/28/2020
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:** 1204

**Subject No:** 12041078

**Generated By:**

(b) (4)

**Form:** DISPOSITION - FOLLOW-UP

**Form Status:** Not Started

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

**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 **Form:** DATE OF VISIT - REPEAT SWAB  
- New Unscheduled Visit

**Form Version:** 10-Oct-2020 15:57 **Form Status:** Not Started

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Repeat Swab**

3.	COVID-19 Repeat Swab:	
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**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:** 1204**Site Name:** (1204) Icahn School of Medicine at Mount Sinai**Subject No:** 12041078**Subject Initials:** ---**Generated By:****Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

**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	[ ]
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**Header Text:** C4591001

**Visit:** Logs

**Form:** ADVERSE EVENT REPORT

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

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Swollen lymph nodes neck area (left side )	Feb/5/2021 12:00	YES	<a href="#">Repeating Pages</a>

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

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

**Form Status:** Data Complete

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Swollen lymph nodes neck area (left side )]
4.	Start Date Time:	Feb/5/2021 12:00
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	1

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**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

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

**Form Status:** Data Complete

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

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).	NO
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.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO

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**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

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

**Form Status:** Data Complete

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

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12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERING/RESOLVING
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

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**Header Text:** C4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

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

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

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

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1204

**Subject No:** 12041078

**Generated By:**

(b) (4)

**Form:** MEDICATION ERROR

**Form Status:** Not Started

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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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	[ ]

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001

**Visit:** Logs

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

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

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

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



**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:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

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**Concomitant Medications**

1.	What is the medication identifier?	[ ]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	Medication:  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:	//

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

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

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Form Status:** Not Started

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

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**Concomitant Medications**

1.	What is the medication identifier?	[ ]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	Medication:  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?	

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**Header Text:** C4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

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

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

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

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** RADIATION TREATMENT

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

**Form Status:** Not Started

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

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**Radiation Treatment**

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

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**Header Text:** C4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

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

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

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

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** TRANSFUSIONS

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

**Form Status:** Not Started

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

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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:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount  
Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

**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:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount  
Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

**Vital Signs**

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

**Vital Signs Details**

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

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** VACCINATION

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

**Form Status:** Not Started

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount  
Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

**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?	

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (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:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount  
Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

**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:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount  
Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

**Contact Outcome**

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

**Header Text:** C4591001

**Visit:** Potential ReVax Initial Contact - **Form:** DATE OF VISIT  
Unscheduled

**Form Version:** 22-Apr-2020 21:02      **Form Status:** Data Complete, Frozen, Verified

**Site No:** 1204      **Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078      **Subject Initials:** ---

**Generated By:** (b) (4)      **Generated Time (GMT):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Jan/6/2021
2.	Erroneous Visit	

**Header Text:** C4591001

**Visit:** Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION  
Unscheduled

**Form Version:** 10-Dec-2020 02:25      **Form Status:** Data Complete, Frozen, Verified

**Site No:** 1204      **Site Name:** (1204) Icahn School of Medicine at Mount  
Sinai

**Subject No:** 12041078      **Subject Initials:** ---

**Generated By:**      **Generated Time (GMT):** 29-Mar-2021 13:11  
(b) (4)

[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  Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2
----	---	--

**Header Text:** C4591001

**Visit:** V101\_VAX3

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

**Site No:** 1204

**Subject No:** 12041078

**Generated By:**

(b) (4)

**Form:** DATE OF VISIT

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

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Jan/14/2021
2.	Erroneous Visit	

**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form:** INFORMED CONSENT - FURTHER VACCINATION

**Form Version:** 10-Dec-2020 02:31

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

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

[eCRF Audit Trail History](#)

**Informed Consent - Further Vaccination**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/14/2021
----	--------------	--



**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form:** INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

**Form Version:** 10-Dec-2020 02:30

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

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

**Form Comments**

**Inclusion Criteria Not Met**

1.	Description of Inclusion Criterion Not Met	Not Applicable _____
----	--	-------------------------

**Exclusion Criteria Met**

2.	Description of Exclusion Criterion Met	Not Applicable _____
----	--	-------------------------

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form:** DISPOSITION - SCREENING FOR FURTHER VACCINATION

**Form Version:** 10-Dec-2020 02:31

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

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

[eCRF Audit Trail History](#)

**Disposition - Screening for Further Vaccination**

1.	Date of Completion/Discontinuation/Death :	Jan/14/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/14/2021
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	[BPVRYJ]
5.b	Sample ID	[BS1GXC]
5.c	Sample ID	[BS1GXB]
5.d	Sample ID	[BS1GWJ]

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001

**Visit:** V101\_VAX3

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

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

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

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/14/2021
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	[BPVRYK]
-----	-----------	----------

**Header Text:** C4591001

**Visit:** V101\_VAX3

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

**Site No:** 1204

**Subject No:** 12041078

**Generated By:**

(b) (4)

**Form:** VACCINATION

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

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/14/2021 15:30
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

**Form:** TREATMENT UNBLINDED

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

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

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

[eCRF Audit Trail History](#)

**Treatment Unblinded**

1.	Date Treatment Unblinded :	Jan/11/2021
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:** 1204

**Subject No:** 12041078

**Generated By:**

(b) (4)

**Form:** WITHDRAWAL OF CONSENT

**Form Status:** Not Started

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

**Withdrawal Of Consent**

1.	Withdrawal of Consent Date :	//
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090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

**Form:** DEATH DETAILS CODED

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

**Form Status:** Not Started

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

**Death Details**

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

**Cause of Death**

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



**Header Text:** C4591001

**Visit:** V102\_VAX4

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

**Site No:** 1204

**Subject No:** 12041078

**Generated By:**

(b) (4)

**Form:** DATE OF VISIT

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

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Feb/4/2021
2.	Erroneous Visit	

**Header Text:** C4591001

**Visit:** V102\_VAX4

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

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

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

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/4/2021
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	[BPVS2Z]
-----	-----------	----------

**Header Text:** C4591001

**Visit:** V102\_VAX4

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

**Site No:** 1204

**Subject No:** 12041078

**Generated By:**

(b) (4)

**Form:** VACCINATION

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

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Feb/4/2021 15:10
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1204

**Subject No:** 12041078

**Generated By:**

(b) (4)

**Form:** DATE OF VISIT

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

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Mar/5/2021
2.	Erroneous Visit	

**Header Text:** C4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1204

**Subject No:** 12041078

**Generated By:**

(b) (4)

**Form:** CONTACT OUTCOME

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

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

**Contact Outcome**

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Mar/5/2021
3.	Comments:	[ ]

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001

**Visit:** V104\_MONTH6

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

**Site No:** 1204

**Subject No:** 12041078

**Generated By:**

(b) (4)

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** C4591001

**Visit:** V104\_MONTH6

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

**Site No:** 1204

**Subject No:** 12041078

**Generated By:**

(b) (4)

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

**Contact Outcome**

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

**Header Text:** C4591001

**Visit:** V105\_MONTH18

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

**Site No:** 1204

**Subject No:** 12041078

**Generated By:**

(b) (4)

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	



**Header Text:** C4591001

**Visit:** V105\_MONTH18

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

**Site No:** 1204

**Subject No:** 12041078

**Generated By:**

(b) (4)

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

**Contact Outcome**

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

**Header Text:** C4591001

**Visit:**  
FURTHER\_VACCINATION\_EOT -  
Unscheduled

**Form:** DISPOSITION - TREATMENT

**Form Version:** 20-Feb-2021 02:26

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

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation/Death :	Mar/5/2021
2.	Phase of Disposition:	OPEN LABEL TREATMENT
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** C4591001

**Visit:** Subject Status - Unscheduled

**Form:** SUBJECT STATUS

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

**Form Status:** Data Complete, Verified

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

[eCRF Audit Trail History](#)

**Subject Status**

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/28/2020

**Header Text:** C4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

**Form Status:** Data Complete, Verified

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount  
Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

[eCRF Audit Trail History](#)

**Casebook Signature Form**

1.	Casebook Signature	Click Here to Enable
----	--------------------	----------------------

**Header Text:** C4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

**Form Status:** Data Complete, Verified

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount  
Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

[Audit Trail](#)

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

- CRF\_Sign
- CRF\_Sign\_1

Name	Signature Meaning	Date	Type	Action
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**Header Text:** C4591001

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

**Form:** INCLUSION/EXCLUSION CRITERIA -  
Comments

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

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

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount  
Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

[Back to Form](#)

Item	Date	User	Comment
Form	Sep-09-2020 18:39:07 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form:** INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION - Comments

**Form Version:** 10-Dec-2020 02:30

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

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-14-2021 17:15:24 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (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, Verified

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount  
Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

[Back to Form](#)

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

- CRF\_Sign
- CRF\_Sign\_1

Name	Signature Meaning	Date	Type	Action
(b) (6)	N/A	Feb-04-2021 17:08:55 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated

**Affidavit:**

N/A

Judith Aberg	Approved	Jan-25-2021 14:02:06 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
-----------------	----------	--	------	--------

**Affidavit:**

By my dated signature below, I, JudithAberg, 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.

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (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, Verified

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount  
Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

(b) (6)	N/A	Jan-12-2021 16:50:33 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

(b) (6)	Approved	Oct-30-2020 10:27:08 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, (b) (6) , 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.

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT SELECTION - eCRF Audit Trail History

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

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

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

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

Date	Location	User	Value	Reason
Sep-09-2020 18:38:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Sep-09-2020 18:38:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> STAGE 3 COHORT S	Initial Entry

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

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

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

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

[Back to Form](#)

*1. Consent Was:*

Date	Location	User	Value	Reason
Sep-09-2020 18:38:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> OBTAINED Date Written Cons ent Obtained  Sep/9/2020	Initial Entry

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1204

**Subject No:** 12041078

**Generated By:**

(b) (4)

**Form:** DEMOGRAPHY - eCRF Audit Trail History

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

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

[Back to Form](#)

**1. Subject ID**

Date	Location	User	Value	Reason
Sep-09-2020 18:38:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 12041078	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Sep-09-2020 18:38:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6) 1976	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Sep-09-2020 18:38:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> MALE	Initial Entry

**4. Ethnicity:**

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

**Form:** DEMOGRAPHY - eCRF Audit Trail History

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

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

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

Date	Location	User	Value	Reason
Sep-09-2020 18:38:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> NOT HISPANIC O R LATINO(A) OR OF SPANISH ORIG IN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-09-2020 18:38:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> WHITE	Initial Entry

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1204

**Subject No:** 12041078

**Generated By:**

(b) (4)

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

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

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

[Back to Form](#)

*1. Date of Visit*

Date	Location	User	Value	Reason
Sep-09-2020 18:38:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> Sep/9/2020	Initial Entry

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1204

**Subject No:** 12041078

**Generated By:**

(b) (4)

**Form:** DISPOSITION - SCREENING - eCRF Audit Trail History

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

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

[Back to Form](#)

**1. Date of Completion/Discontinuation/Death**

Date	Location	User	Value	Reason
Sep-09-2020 18:39:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Sep/9/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Sep-09-2020 18:39:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Sep-09-2020 18:39:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1204**Subject No:** 12041078**Generated By:**

(b) (4)

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1204) Icahn School of Medicine at Mount Sinai**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 13:11[Back to Form](#)*1.a*

Date	Location	User	Value	Reason
Sep-09-2020 18:40:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Nu</b> 1 <b>mber:</b> <b>Medical Hist</b> Herniat <b>ory Term:</b> ed Disc <b>Start Date:</b> Oct/1/2 019 <b>Ongoing:</b> YES	Initial Entry

*1.a Line/MH Number:*

Date	Location	User	Value	Reason
Sep-09-2020 18:40:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

*1.a Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:*

Date	Location	User	Value	Reason
Sep-09-2020 18:40:22 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Herniated Disc	Initial Entry



**Header Text:** C4591001

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

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

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

Eastern Time (US & Canada)

**1.a Start Date:**

Date	Location	User	Value	Reason
Sep-09-2020 18:40:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/1/2019	Initial Entry

**1.a Ongoing:**

Date	Location	User	Value	Reason
Sep-09-2020 18:40:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**1.b**

Date	Location	User	Value	Reason
Sep-11-2020 10:45:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH</b> 2 <b>Number:</b> <b>Medical H</b> Vasectomy <b>istory Ter</b> <b>m:</b>	Initial Entry

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1204

**Subject No:** 12041078

**Generated By:**

(b) (4)

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

			<b>Start Date</b> UNK/UN : K/2014	
			<b>Ongoing:</b> NO	
			End Date :	
			UNK/U NK/201 4	

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

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

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

**1.b Line/MH Number:**

Date	Location	User	Value	Reason
Sep-11-2020 10:45:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

**1.b Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Sep-11-2020 10:45:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Vasectomy	Initial Entry

**1.b Start Date:**

Date	Location	User	Value	Reason
Sep-11-2020 10:45:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2014	Initial Entry

**1.b Ongoing:**

Date	Location	User	Value	Reason
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090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

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

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

Sep-11-2020 10:45:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> NO End Date:  UNK/UNK/2014	Initial Entry
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**Header Text:** C4591001

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

**Form Version:** 21-Aug-2020 02:51

**Site No:** 1204

**Subject No:** 12041078

**Generated By:**

(b) (4)

**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

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

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

[Back to Form](#)

**1. Date:**

Date	Location	User	Value	Reason
Sep-09-2020 18:41:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Sep/9/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Sep-09-2020 18:41:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> 170.0	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Sep-09-2020 18:41:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> LB	Initial Entry

**4. Height:**

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001

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

**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:51

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

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

Date	Location	User	Value	Reason
Sep-09-2020 18:41:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> 66.0	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Sep-09-2020 18:41:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> in	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
Sep-09-2020 18:41:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 27.4	Initial Entry

**7.a**

Date	Location	User	Value	Reason
Sep-09-2020 18:41:01	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b>	Initial Entry

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001

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

**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:51

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

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

(UTC-05:00)  
Eastern Time (US  
& Canada)

**Record Identifier:** 1  
**Temperature:** 99.4  
**Temperature Unit:** F  
**Temperature Location:** ORAL CAVIT  
**Y:** Y

**7.a Record Identifier:**

Date	Location	User	Value	Reason
Sep-09-2020 18:41:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> 1	Initial Entry

**7.a Temperature:**

Date	Location	User	Value	Reason
Sep-09-2020 18:41:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> 99.4	Initial Entry

**7.a Unit:**

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001

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

**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:51

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

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

Date	Location	User	Value	Reason
Sep-09-2020 18:41:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> F	Initial Entry

**7.a Temperature Location:**

Date	Location	User	Value	Reason
Sep-09-2020 18:41:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)



**Header Text:** C4591001

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

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

**Site No:** 1204

**Subject No:** 12041078

**Generated By:**

(b) (4)

**Form:** RANDOMIZATION - eCRF Audit Trail History

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

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Sep-09-2020 18:41:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/9/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Sep-09-2020 18:41:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 85740	Initial Entry

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1204

**Subject No:** 12041078

**Generated By:**

(b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

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

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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**1. Data Origin**

Date	Location	User	Value	Reason
Sep-09-2020 18:41:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-09-2020 18:41:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-10-2020 10:32:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-10-2020	ACV0PFEINFP6000	(b) (6)	Query 1: Opened	'Sample

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (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:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

04:07:42 (UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-09-2020 18:41:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-09-2020 18:41:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Sep/9/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-10-2020 10:32:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I</b> BNWL3 <b>D:</b> W	Initial Entry

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (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:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

**5.a Sample ID**

Date	Location	User	Value	Reason
Sep-10-2020 10:32:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BNWL3W	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Sep-10-2020 10:32:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID BNWL3 : X	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Sep-10-2020 10:32:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BNWL3X	Initial Entry

**5.c**

Date	Location	User	Value	Reason
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090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (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:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

Sep-10-2020 10:32:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID</b> BPYM3 : R	Initial Entry
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**5.c Sample ID**

Date	Location	User	Value	Reason
Sep-10-2020 10:32:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPYM3R	Initial Entry

**5.d**

Date	Location	User	Value	Reason
Sep-10-2020 10:32:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID</b> BNWL3 : M	Initial Entry

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1204

**Subject No:** 12041078

**Generated By:**

(b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

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

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

**5.d Sample ID**

Date	Location	User	Value	Reason
Sep-10-2020 10:32:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> BNWL3M	Initial Entry

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (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:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

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**1. Data Origin**

Date	Location	User	Value	Reason
Sep-09-2020 18:41:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-09-2020 18:41:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-10-2020 10:31:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-10-2020	ACV0PFEINFP6000	(b) (6)	Query 1: Opened	'Sample

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (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:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

04:07:57 (UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-09-2020 18:41:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-09-2020 18:41:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Sep/9/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-10-2020 10:31:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID BPYM3 : K	Initial Entry

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (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:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

**5.a Sample ID**

Date	Location	User	Value	Reason
Sep-10-2020 10:31:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> BPYM3K	Initial Entry

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1204

**Subject No:** 12041078

**Generated By:**

(b) (4)

**Form:** VACCINATION - eCRF Audit Trail History

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

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Sep-09-2020 18:42:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Sep-09-2020 18:42:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Sep-09-2020 18:42:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1204

**Subject No:** 12041078

**Generated By:**

(b) (4)

**Form:** VACCINATION - eCRF Audit Trail History

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

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

Date	Location	User	Value	Reason
Sep-09-2020 18:42:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> Sep/9/2020 17:20	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Sep-09-2020 18:42:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Sep-09-2020 18:42:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Sep-09-2020 18:42:27 (UTC-05:00)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001

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

**Form:** VACCINATION - eCRF Audit Trail History

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

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

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

Eastern Time (US & Canada)

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Sep-09-2020 18:42:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OBSERVATION 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
Sep-09-2020 18:42:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001

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

**Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

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

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

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

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*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Sep-09-2020 18:42:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> NO - REACTOGEN ICITY E-DIARY N OT COLLECTED F OR THIS SUBJECT	Initial Entry

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1204

**Subject No:** 12041078

**Generated By:**

(b) (4)

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

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

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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*1. Date of Visit*

Date	Location	User	Value	Reason
Sep-30-2020 20:24:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/30/2020	Initial Entry

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 15-Sep-2020 21:54

**Site No:** 1204

**Subject No:** 12041078

**Generated By:**

(b) (4)

**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

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

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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**1. Date:**

Date	Location	User	Value	Reason
Sep-30-2020 20:24:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/30/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-30-2020 20:24:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier:</b> : <b>Temperature:</b> <b>Temperature Unit:</b> <b>Temperature Location:</b> <b>Temperature Unit:</b> TY	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
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090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:54

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

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

Sep-30-2020 20:24:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry
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**2.a Temperature:**

Date	Location	User	Value	Reason
Sep-30-2020 20:24:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 98.3	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Sep-30-2020 20:24:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> F	Initial Entry

**2.a Temperature Location:**

Date	Location	User	Value	Reason
Sep-30-2020 20:24:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)



**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 15-Sep-2020 21:54

**Site No:** 1204

**Subject No:** 12041078

**Generated By:**

(b) (4)

**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

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

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

& Canada)

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (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:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

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**1. Data Origin**

Date	Location	User	Value	Reason
Sep-30-2020 17:12:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-30-2020 17:12:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-30-2020 17:12:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-30-2020	ACV0PFEINFP6000	auto query	Query 1: Candidate	'Sample

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (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:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

17:12:42 (UTC-05:00) Eastern Time (US & Canada)		(autoquery)		Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-30-2020 17:12:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Sep/30/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-30-2020 17:12:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BPYN3P	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Sep-30-2020 17:12:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPYN3P	Initial Entry

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1204

**Subject No:** 12041078

**Generated By:**

(b) (4)

**Form:** VACCINATION - eCRF Audit Trail History

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

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Sep-30-2020 20:25:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Sep-30-2020 20:25:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Sep-30-2020 20:25:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION - eCRF Audit Trail History

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

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

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

Date	Location	User	Value	Reason
Sep-30-2020 20:25:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/30/2020 16:09	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Sep-30-2020 20:25:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Sep-30-2020 20:25:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Sep-30-2020 20:25:33 (UTC-05:00)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION - eCRF Audit Trail History

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

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

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

Eastern Time (US & Canada)

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Sep-30-2020 20:25:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OBSERVATION 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
Sep-30-2020 20:25:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001

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

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

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

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

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

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*1. Date of Visit*

Date	Location	User	Value	Reason
Oct-31-2020 07:13:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-30-2020 10:24:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Oct-30-2020 05:23:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: The treatment period is defined as 1st vaccination visit through the 1-month post vaccination visit after the 2nd vaccination. Please complete treatment disposition

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1204 **Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:11

				CRF and update date of EOT to match date of blood sample collection date at visit 3.
Oct-28-2020 15:54:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Oct/28/2020	Initial Entry

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (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:** 1204 **Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:11

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**1. Data Origin**

Date	Location	User	Value	Reason
Oct-28-2020 15:54:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-28-2020 15:54:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-28-2020 18:06:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-28-2020	ACV0PFEINFP6000	auto query	Query 1: Candidate	'Sample

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (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: 1204 Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041078 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 29-Mar-2021 13:11

15:54:59 (UTC-05:00) Eastern Time (US & Canada)		(autoquery)		Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-28-2020 15:54:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Oct/28/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-28-2020 18:06:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID BRC01 : 6	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-28-2020 18:06:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRC016	Initial Entry

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (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: 1204 Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041078 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 29-Mar-2021 13:11

& Canada)				
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5.b

Date	Location	User	Value	Reason
Oct-28-2020 18:13:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> Sample I BSMGW D: 7	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-28-2020 18:13:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> BSMGW7	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-28-2020 18:13:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> Sample I BSMGW D: 4	Initial Entry

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**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:** 1204 **Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:11

**5.c Sample ID**

Date	Location	User	Value	Reason
Oct-28-2020 18:13:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BSMGW4	Initial Entry

**5.d**

Date	Location	User	Value	Reason
Oct-28-2020 18:13:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample I BSMGW D: 3	Initial Entry

**5.d Sample ID**

Date	Location	User	Value	Reason
Oct-28-2020 18:13:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BSMGW3	Initial Entry

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001

**Visit:** End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:55 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1204 **Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:11

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**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Oct-30-2020 10:23:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/28/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Oct-30-2020 10:23:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Oct-30-2020 10:23:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1204

**Subject No:** 12041078

**Generated By:**

(b) (4)

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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Date	Location	User	Value	Reason
Mar-05-2021 18:26:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

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**1. Category:**

Date	Location	User	Value	Reason
Mar-05-2021 18:26:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Mar-05-2021 18:26:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Mar-05-2021 18:26:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Swollen lymph nodes neck area (left side )	Initial Entry

**4. Start Date Time:**

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

Date	Location	User	Value	Reason
Mar-05-2021 18:26:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/5/2021 12:00	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Mar-05-2021 18:26:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Mar-05-2021 18:26:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**7. Is the adverse event serious?**

**If Yes, NOTIFY PFIZER IMMEDIATELY.**

**Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization;**

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)



**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

*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-05-2021 18:26:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**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-05-2021 18:26:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Mar-05-2021 18:26:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RELATED	Initial Entry

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Mar-05-2021 18:26:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Mar-05-2021 18:26:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Mar-05-2021 18:26:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**13. What was the outcome of this adverse event?:**

Date	Location	User	Value	Reason
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**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

Mar-05-2021 18:26:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERING/RES OLVING	Initial Entry
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**14. Did the adverse event cause the subject to be discontinued from the study?**

Date	Location	User	Value	Reason
Mar-05-2021 18:26:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001

**Visit:** Potential ReVax Initial Contact - **Form:** DATE OF VISIT - eCRF Audit Trail History  
Unscheduled

**Form Version:** 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified

**Site No:** 1204 **Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:11

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*1. Date of Visit*

Date	Location	User	Value	Reason
Feb-25-2021 07:35:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Closed	Response satisfies query
Feb-24-2021 19:41:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Feb-24-2021 19:41:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Jan/6/2021	New Information
Feb-24-2021 17:35:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Opened	Please verify if the date of subject confirmation to unblinded was on 06Jan2021. Update CRF as needed.

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001

**Visit:** Potential ReVax Initial Contact - **Form:** DATE OF VISIT - eCRF Audit Trail History  
Unscheduled

**Form Version:** 22-Apr-2020 21:02      **Form Status:** Data Complete, Frozen, Verified

**Site No:** 1204      **Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078      **Subject Initials:** ---

**Generated By:** (b) (4)      **Generated Time (GMT):** 29-Mar-2021 13:11

Jan-12-2021 16:50:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/11/2021	Initial Entry
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**Header Text:** C4591001

**Visit:** Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION -  
Unscheduled eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen, Verified

**Site No:** 1204 **Site Name:** (1204) Icahn School of Medicine at Mount  
Sinai

**Subject No:** 12041078 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 13:11

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*1. Select appropriate response - Is participant willing to return for Vaccination 3?*

Date	Location	User	Value	Reason
Jan-12-2021 16:50:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Participant is willi ng to return for Va ccination 3 Participant is:  eligible per loc al/national reco mmendations a nd confirmed to have received o nly placebo at Vaccination 1/2	Initial Entry

**Header Text:** C4591001

**Visit:** V101\_VAX3

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

**Site No:** 1204

**Subject No:** 12041078

**Generated By:**

(b) (4)

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

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

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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*1. Date of Visit*

Date	Location	User	Value	Reason
Jan-14-2021 17:15:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/14/2021	Initial Entry

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form:** INFORMED CONSENT - FURTHER  
VACCINATION - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:31

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

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount  
Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

[Back to Form](#)

**1. Consent Was:**

Date	Location	User	Value	Reason
Jan-14-2021 17:15:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Co nsent Obtained  Jan/14/2021	Initial Entry

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)



**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form:** DISPOSITION - SCREENING FOR FURTHER VACCINATION - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:31

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

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

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**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Jan-14-2021 17:15:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/14/2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Jan-14-2021 17:15:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> REPEAT SCREENING 1	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Jan-14-2021 17:15:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

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

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

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

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**1. Data Origin**

Date	Location	User	Value	Reason
Jan-14-2021 17:15:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-14-2021 17:15:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-14-2021 17:16:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-14-2021	ACV0PFEINFP6000	auto query	Query 1: Candida	'Sample

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

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

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

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

17:15:43 (UTC-05:00) Eastern Time (US & Canada)		(autoquery)	te	Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-14-2021 17:15:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Jan/14/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jan-14-2021 17:16:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BPVRYJ	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Jan-14-2021 17:16:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPVRYJ	Initial Entry

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

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

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

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

& Canada)

**5.b**

Date	Location	User	Value	Reason
Jan-14-2021 17:16:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID</b> BS1GX : C	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Jan-14-2021 17:16:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BS1GXC	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Jan-14-2021 17:16:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID</b> BS1GX : B	Initial Entry

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

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

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

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

**5.c Sample ID**

Date	Location	User	Value	Reason
Jan-14-2021 17:16:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BS1GXB	Initial Entry

**5.d**

Date	Location	User	Value	Reason
Jan-14-2021 17:17:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID BS1GW : J	Initial Entry

**5.d Sample ID**

Date	Location	User	Value	Reason
Jan-14-2021 17:17:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BS1GWJ	Initial Entry

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

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

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

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

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**1. Data Origin**

Date	Location	User	Value	Reason
Jan-14-2021 17:15:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-14-2021 17:15:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-14-2021 17:16:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-14-2021	ACV0PFEINFP6000	auto query	Query 1: Candida	'Sample

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: C4591001

Visit: V101\_VAX3

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1204

Site Name: (1204) Icahn School of Medicine at Mount Sinai

Subject No: 12041078

Subject Initials: ---

Generated By:

Generated Time (GMT): 29-Mar-2021 13:11

(b) (4)

17:15:52 (UTC-05:00) Eastern Time (US & Canada)		(autoquery)	te	Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-14-2021 17:15:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Jan/14/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-14-2021 17:16:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID</b> BPVRY : K	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-14-2021 17:16:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPVRYK	Initial Entry

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

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

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

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

& Canada)

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)



**Header Text:** C4591001

**Visit:** V101\_VAX3

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

**Site No:** 1204

**Subject No:** 12041078

**Generated By:**

(b) (4)

**Form:** VACCINATION - eCRF Audit Trail History

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

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Jan-14-2021 17:16:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Jan-14-2021 17:16:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BNT162b2	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Jan-14-2021 17:16:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form:** VACCINATION - eCRF Audit Trail History

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

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

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

Date	Location	User	Value	Reason
Jan-14-2021 17:16:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/14/2021 15:30	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Jan-14-2021 17:16:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Jan-14-2021 17:16:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Jan-14-2021 17:16:14 (UTC-05:00)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form:** VACCINATION - eCRF Audit Trail History

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

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

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

Eastern Time (US & Canada)

**8. Actual Dose:**

Date	Location	User	Value	Reason
Jan-14-2021 17:16:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30.0	Initial Entry

**9. Unit:**

Date	Location	User	Value	Reason
Jan-14-2021 17:16:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ug	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Jan-14-2021 17:16:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30 MINUTES	Initial Entry

**11. Was the subject observed for at least the protocol specified observation period after**

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form:** VACCINATION - eCRF Audit Trail History

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

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

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

*investigational product administration?*

Date	Location	User	Value	Reason
Jan-14-2021 17:16:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

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

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

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

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**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Jan-12-2021 16:50:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/11/2021	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Jan-12-2021 16:50:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ASSESS ELIGIBI LITY FOR ADDI TIONAL VACCI NATION	Initial Entry

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001

**Visit:** V102\_VAX4

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

**Site No:** 1204

**Subject No:** 12041078

**Generated By:**

(b) (4)

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

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

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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*1. Date of Visit*

Date	Location	User	Value	Reason
Feb-04-2021 19:33:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/4/2021	Initial Entry

**Header Text:** C4591001

**Visit:** V102\_VAX4

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

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

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

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

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**1. Data Origin**

Date	Location	User	Value	Reason
Feb-04-2021 17:08:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Feb-04-2021 17:08:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Feb-04-2021 17:09:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-04-2021	ACV0PFEINFP6000	auto query	Query 1: Candidate	'Sample

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001

**Visit:** V102\_VAX4

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

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

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

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

17:08:55 (UTC-05:00) Eastern Time (US & Canada)		(autoquery)		Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-04-2021 17:08:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Feb/4/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Feb-04-2021 17:09:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BPVS2Z	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Feb-04-2021 17:09:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPVS2Z	Initial Entry

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)



**Header Text:** C4591001

**Visit:** V102\_VAX4

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

**Site No:** 1204

**Subject No:** 12041078

**Generated By:**

(b) (4)

**Form:** VACCINATION - eCRF Audit Trail History

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

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Feb-04-2021 19:34:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Feb-04-2021 19:34:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BNT162b2	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Feb-04-2021 19:34:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001

**Visit:** V102\_VAX4

**Form:** VACCINATION - eCRF Audit Trail History

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

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

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

Date	Location	User	Value	Reason
Feb-04-2021 19:34:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/4/2021 15:10	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Feb-04-2021 19:34:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Feb-04-2021 19:34:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Feb-04-2021 19:34:22 (UTC-05:00)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001

**Visit:** V102\_VAX4

**Form:** VACCINATION - eCRF Audit Trail History

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

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

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

Eastern Time (US & Canada)

**8. Actual Dose:**

Date	Location	User	Value	Reason
Feb-04-2021 19:34:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30.0	Initial Entry

**9. Unit:**

Date	Location	User	Value	Reason
Feb-04-2021 19:34:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ug	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Feb-04-2021 19:34:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30 MINUTES	Initial Entry

**11. Was the subject observed for at least the protocol specified observation period after**

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001

**Visit:** V102\_VAX4

**Form:** VACCINATION - eCRF Audit Trail History

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

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

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

*investigational product administration?*

Date	Location	User	Value	Reason
Feb-04-2021 19:34:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**Header Text:** C4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1204

**Subject No:** 12041078

**Generated By:**

(b) (4)

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

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

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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*1. Date of Visit*

Date	Location	User	Value	Reason
Mar-05-2021 18:22:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/5/2021	Initial Entry

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001

**Visit:** V103\_MONTH1

**Form:** CONTACT OUTCOME - eCRF Audit Trail History

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

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

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

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**1. Contact Type:**

Date	Location	User	Value	Reason
Mar-05-2021 18:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> TELEPHONE VISIT	Initial Entry

**2. Was contact made?**

Date	Location	User	Value	Reason
Mar-05-2021 18:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Contact:  Mar/5/2021	Initial Entry

**Header Text:** C4591001

**Visit:**  
FURTHER\_VACCINATION\_EOT -  
Unscheduled

**Form:** DISPOSITION - TREATMENT - eCRF Audit  
Trail History

**Form Version:** 20-Feb-2021 02:26

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

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount  
Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

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**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Mar-05-2021 18:22:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/5/2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Mar-05-2021 18:22:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> OPEN LABEL TREAT MENT	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Mar-05-2021 18:22:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001

**Visit:** Subject Status - Unscheduled

**Form:** SUBJECT STATUS - eCRF Audit Trail History

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

**Form Status:** Data Complete, Verified

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

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*1. Subject Status*

Date	Location	User	Value	Reason
Oct-30-2020 10:23:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Sep-09-2020 18:41:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Sep-09-2020 18:39:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

*2. Subject Status Date*

Date	Location	User	Value	Reason
Oct-30-2020 10:23:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/28/2020	Initial Entry

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)



**Header Text:** C4591001

**Visit:** Subject Status - Unscheduled

**Form:** SUBJECT STATUS - eCRF Audit Trail History

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

**Form Status:** Data Complete, Verified

**Site No:** 1204

**Site Name:** (1204) Icahn School of Medicine at Mount Sinai

**Subject No:** 12041078

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 13:11

(b) (4)

Sep-09-2020 18:41:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/9/2020	Initial Entry
Sep-09-2020 18:39:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/9/2020	Initial Entry

090177e196ae2f81\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** C4591001

**Visit:** Investigator Signature -  
Unscheduled

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

**Site No:** 1204

**Subject No:** 12041078

**Generated By:**

(b) (4)

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit  
Trail History

**Form Status:** Data Complete, Verified

**Site Name:** (1204) Icahn School of Medicine at Mount  
Sinai

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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*1. Casebook Signature*

Date	Location	User	Value	Reason
Oct-21-2020 10:43:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Click Here to Ena ble	Initial Entry