

**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:** 1152

**Site Name:** (1152) California Research Foundation

**Subject No:** 11521260

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:56

[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

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1152

**Subject No:** 11521260

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

**Form:** MAIN INFORMED CONSENT

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

**Site Name:** (1152) California Research Foundation

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/31/2020
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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:** 1152

**Site Name:** (1152) California Research Foundation

**Subject No:** 11521260

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[11521260]
2.	Birth Date:	(b) (6) /1952
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:	

**Header Text:** c4591001

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

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

**Site No:** 1152

**Subject No:** 11521260

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

**Form:** DATE OF VISIT

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

**Site Name:** (1152) California Research Foundation

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Aug/31/2020
2.	Erroneous Visit	

**Header Text:** c4591001

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

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

**Site No:** 1152

**Subject No:** 11521260

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

**Form:** INCLUSION/EXCLUSION CRITERIA

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

**Site Name:** (1152) California Research Foundation

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:56

**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
----	---	----------------

**Header Text:** c4591001

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

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

**Site No:** 1152

**Subject No:** 11521260

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

**Form:** DISPOSITION - SCREENING

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

**Site Name:** (1152) California Research Foundation

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

**Disposition - Screening**

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

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1152

Subject No: 11521260

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[hypertension]
	Start Date:	UNK/UNK/1997
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[hypercholesterolemia]
	Start Date:	UNK/UNK/2006
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Type II diabetes]
	Start Date:	Mar/UNK/2020
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[prostate cancer]
	Start Date:	UNK/UNK/2007
	Ongoing:	NO End Date: UNK/UNK/2008

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**Header Text:** c4591001

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

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

**Site No:** 1152

**Subject No:** 11521260

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

**Form:** GENERAL MEDICAL HISTORY

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

**Site Name:** (1152) California Research Foundation

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:56

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[low back pain]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[diabetic neuropathy]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[asthma]
	Start Date:	Dec/UNK/1952
	Ongoing:	YES
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[prostatism]
	Start Date:	UNK/UNK/2007
	Ongoing:	YES
1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[tonsillectomy]
	Start Date:	UNK/UNK/1961
	Ongoing:	NO End Date: UNK/UNK/1961

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**Header Text:** c4591001

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

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

**Site No:** 1152

**Subject No:** 11521260

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

**Form:** GENERAL MEDICAL HISTORY

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

**Site Name:** (1152) California Research Foundation

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:56

1.j	Line/MH Number:	[10]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[failed prostatectomy]
	Start Date:	UNK/UNK/2007
	Ongoing:	NO End Date: UNK/UNK/2007
1.k	Line/MH Number:	[11]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[hiatal hernia]
	Start Date:	UNK/UNK/1988
	Ongoing:	NO End Date: UNK/UNK/1988
1.l	Line/MH Number:	[12]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[hiatal hernia repair]
	Start Date:	UNK/UNK/1988
	Ongoing:	NO End Date: UNK/UNK/1988
1.m	Line/MH Number:	[13]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[morbid obesity]
	Start Date:	UNK/UNK/1980
	Ongoing:	YES

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**Header Text:** c4591001

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

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

**Site No:** 1152

**Subject No:** 11521260

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

**Form:** VITAL SIGNS - BASELINE

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

**Site Name:** (1152) California Research Foundation

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Aug/31/2020
2.	Weight:	[384.0]
3.	Unit:	LB
4.	Height:	[69.0]
5.	Unit:	in
6.	Body Mass Index:	[56.7]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[97.9]
	Unit:	F
	Temperature Location:	ORAL CAVITY

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**Header Text:** c4591001

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

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

**Site No:** 1152

**Subject No:** 11521260

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

**Form:** RANDOMIZATION

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

**Site Name:** (1152) California Research Foundation

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Aug/31/2020
2.	Randomization Number:	[247040]
3.	Randomization Group:	[ ]

**Header Text:** c4591001

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

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

**Site No:** 1152

**Subject No:** 11521260

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site Name:** (1152) California Research Foundation

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BP9KRR]
5.b	Sample ID	[BP9KRS]
5.c	Sample ID	[BP9KRT]
5.d	Sample ID	[BNWJPH]

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**Header Text:** c4591001  
**Visit:** V1\_DAY1\_VAX1\_L  
**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1152  
**Subject No:** 11521260  
**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB  
**Form Status:** Data Complete, Locked, Frozen, Verified  
**Site Name:** (1152) California Research Foundation  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BPYL3Z]
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**Header Text:** c4591001

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

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

**Site No:** 1152

**Subject No:** 11521260

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

**Form:** VACCINATION

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

**Site Name:** (1152) California Research Foundation

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Aug/31/2020 09:59
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

**Header Text:** c4591001

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

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

**Site No:** 1152

**Subject No:** 11521260

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

**Form:** REACTOGENICITY DIARY

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

**Site Name:** (1152) California Research Foundation

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:56

[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:** 1152

**Subject No:** 11521260

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

**Form:** DATE OF VISIT

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

**Site Name:** (1152) California Research Foundation

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Sep/21/2020
2.	Erroneous Visit	



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1152

**Subject No:** 11521260

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

**Form:** VITAL SIGNS - TEMP

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

**Site Name:** (1152) California Research Foundation

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Sep/21/2020
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**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[98.0]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae2fca\Final\Final On: 01-Apr-2021 03:52 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1152

**Subject No:** 11521260

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

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

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

**Site Name:** (1152) California Research Foundation

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/21/2020
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	[BPOSCH]
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090177e196ae2fca\Final\Final On: 01-Apr-2021 03:52 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1152

**Subject No:** 11521260

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

**Form:** VACCINATION

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

**Site Name:** (1152) California Research Foundation

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:56

[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/21/2020 08:11
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

090177e196ae2fca\Final\Final On: 01-Apr-2021 03:52 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1152

**Subject No:** 11521260

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

**Form:** DATE OF VISIT

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

**Site Name:** (1152) California Research Foundation

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Oct/19/2020
2.	Erroneous Visit	

**Header Text:** c4591001

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

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

**Site No:** 1152

**Subject No:** 11521260

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site Name:** (1152) California Research Foundation

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/19/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[sSHORT DRAW. NO RETAIN SAMPLE OBTAINED]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BRJGC6]
5.b	Sample ID	[BRJGC7]

090177e196ae2fca\Final\Final On: 01-Apr-2021 03:52 (GMT)

**Header Text:** c4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1152

**Site Name:** (1152) California Research Foundation

**Subject No:** 11521260

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:56

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

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

**Form Status:** Not Started

**Site No:** 1152

**Site Name:** (1152) California Research Foundation

**Subject No:** 11521260

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:56

**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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090177e196ae2fca\Final\Final On: 01-Apr-2021 03:52 (GMT)

**Header Text:** c4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1152

**Site Name:** (1152) California Research Foundation

**Subject No:** 11521260

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:56

**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:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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

**Form Status:** Not Started

**Site No:** 1152

**Site Name:** (1152) California Research Foundation

**Subject No:** 11521260

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:56

**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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090177e196ae2fca\Final\Final On: 01-Apr-2021 03:52 (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:** 1152

**Site Name:** (1152) California Research Foundation

**Subject No:** 11521260

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:56

**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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**Header Text:** c4591001

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

**Form:** ILLNESS DETAILS

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

**Form Status:** Not Started

**Site No:** 1152

**Site Name:** (1152) California Research Foundation

**Subject No:** 11521260

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:56

**Illness Details**

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

**Header Text:** c4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1152

**Site Name:** (1152) California Research Foundation

**Subject No:** 11521260

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:56

**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:** 1152

**Site Name:** (1152) California Research Foundation

**Subject No:** 11521260

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:56

**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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090177e196ae2fca\Final\Final On: 01-Apr-2021 03:52 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned - New Unscheduled Visit

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1152

**Site Name:** (1152) California Research Foundation

**Subject No:** 11521260

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:56

**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:** 1152

**Site Name:** (1152) California Research Foundation

**Subject No:** 11521260

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:56

**Unplanned Assessments**

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

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

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

**Site No:** 1152

**Subject No:** 11521260

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

**Form:** DISPOSITION - TREATMENT

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

**Site Name:** (1152) California Research Foundation

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation/Death :	Oct/19/2020
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:** 1152

**Subject No:** 11521260

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

**Form:** DISPOSITION - FOLLOW-UP

**Form Status:** Not Started

**Site Name:** (1152) California Research Foundation

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:56

**Disposition - Follow-Up**

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

**Header Text:** c4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1152

**Site Name:** (1152) California Research Foundation

**Subject No:** 11521260

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:56

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Repeat Swab**

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

**Header Text:** c4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1152

**Site Name:** (1152) California Research Foundation

**Subject No:** 11521260

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:56

**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	[ ]
----	-----------	-----

090177e196ae2fca\Final\Final On: 01-Apr-2021 03:52 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** ADVERSE EVENT REPORT

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

**Site No:** 1152

**Site Name:** (1152) California Research Foundation

**Subject No:** 11521260

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:56

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	malignant melanoma	Sep/4/2020 UNK: UNK	NO End Date Time:  Oct/8/2020 UNK:UNK	<a href="#">Repeating Pages</a>
2.	ADVERSE EVENT	2	Diarrhea	Feb/12/2021 14:30	NO End Date Time:  Feb/12/2021 15:30	<a href="#">Repeating Pages</a>

090177e196ae2fca\Final\Final On: 01-Apr-2021 03:52 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1152

**Subject No:** 11521260

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1152) California Research Foundation

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:56

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[Form Audit Trail](#)

**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[malignant melanoma]
4.	Start Date Time:	Sep/4/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/8/2020 UNK:UNK
6.	Toxicity Grade:	3
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).	YES  Is this serious event associated with congenital anomaly or birth defect? NO  Did this serious event result in death? NO  Did this serious event require or prolong hospitalization? YES  Did this serious event result in persistent or significant disability/incapacity? NO  Is this serious event life threatening? NO  Other medically important serious event YES
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

090177e196ae2fca\Final\Final On: 01-Apr-2021 03:52 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1152

**Subject No:** 11521260

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1152) California Research Foundation

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:56

9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [unknown]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020405723]

090177e196ae2fca\Final\Final On: 01-Apr-2021 03:52 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1152

**Subject No:** 11521260

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1152) California Research Foundation

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:56

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Diarrhea]
4.	Start Date Time:	Feb/12/2021 14:30
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/12/2021 15:30
6.	Toxicity Grade:	1
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

090177e196ae2fca\Final\Final On: 01-Apr-2021 03:52 (GMT)

<b>Header Text:</b> c4591001	<b>Form:</b> ADVERSE EVENT REPORT
<b>Visit:</b> Logs - Unscheduled	<b>Form Status:</b> Data Complete, Frozen
<b>Form Version:</b> 22-Apr-2020 21:02	<b>Site Name:</b> (1152) California Research Foundation
<b>Site No:</b> 1152	<b>Subject Initials:</b> ---
<b>Subject No:</b> 11521260	<b>Generated Time (GMT):</b> 29-Mar-2021 11:56
<b>Generated By:</b> (b) (4)	

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



**Header Text:** c4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

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

**Site No:** 1152

**Site Name:** (1152) California Research Foundation

**Subject No:** 11521260

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:56

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

090177e196ae2fca\Final\Final On: 01-Apr-2021 03:52 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1152

**Subject No:** 11521260

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

**Form:** MEDICATION ERROR

**Form Status:** Not Started

**Site Name:** (1152) California Research Foundation

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:56

[Back to Form](#)

**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	[ ]

090177e196ae2fca\Final\Final On: 01-Apr-2021 03:52 (GMT)

**Header Text:** c4591001

**Visit:** Logs

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

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

**Site No:** 1152

**Site Name:** (1152) California Research Foundation

**Subject No:** 11521260

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:56

#	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:** 1152

**Site Name:** (1152) California Research Foundation

**Subject No:** 11521260

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:56

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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:	//

090177e196ae2fca\Final\Final On: 01-Apr-2021 03:52 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Site No:** 1152

**Site Name:** (1152) California Research Foundation

**Subject No:** 11521260

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:56

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

090177e196ae2fca\Final\Final On: 01-Apr-2021 03:52 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1152

**Subject No:** 11521260

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

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Status:** Not Started

**Site Name:** (1152) California Research Foundation

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:56

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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?	

090177e196ae2fca\Final\Final On: 01-Apr-2021 03:52 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

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

**Site No:** 1152

**Site Name:** (1152) California Research Foundation

**Subject No:** 11521260

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:56

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

**Site No:** 1152

**Subject No:** 11521260

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

**Form:** RADIATION TREATMENT

**Form Status:** Not Started

**Site Name:** (1152) California Research Foundation

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:56

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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?	



**Header Text:** c4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

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

**Site No:** 1152

**Site Name:** (1152) California Research Foundation

**Subject No:** 11521260

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:56

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1152

**Subject No:** 11521260

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

**Form:** TRANSFUSIONS

**Form Status:** Not Started

**Site Name:** (1152) California Research Foundation

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:56

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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:** 1152

**Site Name:** (1152) California Research Foundation

**Subject No:** 11521260

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:56

**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:** 1152

**Site Name:** (1152) California Research Foundation

**Subject No:** 11521260

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:56

**Vital Signs**

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

**Vital Signs Details**

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** VACCINATION

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

**Form Status:** Not Started

**Site No:** 1152

**Site Name:** (1152) California Research Foundation

**Subject No:** 11521260

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:56

**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?	

090177e196ae2fca\Final\Final On: 01-Apr-2021 03:52 (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:** 1152

**Site Name:** (1152) California Research Foundation

**Subject No:** 11521260

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:56

**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:** 1152

**Site Name:** (1152) California Research Foundation

**Subject No:** 11521260

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:56

**Contact Outcome**

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

**Header Text:** c4591001

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

**Form:** DATE OF VISIT

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

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

**Site No:** 1152

**Site Name:** (1152) California Research Foundation

**Subject No:** 11521260

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Jan/20/2021
2.	Erroneous Visit	



**Header Text:** c4591001

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

**Form:** FURTHER VACCINATION CONFIRMATION

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

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

**Site No:** 1152

**Site Name:** (1152) California Research Foundation

**Subject No:** 11521260

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:56

[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:** Disposition - Unscheduled

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

**Site No:** 1152

**Subject No:** 11521260

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

**Form:** TREATMENT UNBLINDED

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

**Site Name:** (1152) California Research Foundation

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

**Treatment Unblinded**

1.	Date Treatment Unblinded :	Jan/20/2021
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:** 1152

**Subject No:** 11521260

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

**Form:** WITHDRAWAL OF CONSENT

**Form Status:** Not Started

**Site Name:** (1152) California Research Foundation

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:56

**Withdrawal Of Consent**

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

090177e196ae2fca\Final\Final On: 01-Apr-2021 03:52 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1152

**Subject No:** 11521260

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

**Form:** DEATH DETAILS CODED

**Form Status:** Not Started

**Site Name:** (1152) California Research Foundation

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:56

**Death Details**

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

**Cause of Death**

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

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1152

**Subject No:** 11521260

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

**Form:** DATE OF VISIT

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

**Site Name:** (1152) California Research Foundation

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Jan/22/2021
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1152

**Subject No:** 11521260

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

**Form:** INFORMED CONSENT - FURTHER VACCINATION

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

**Site Name:** (1152) California Research Foundation

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

**Informed Consent - Further Vaccination**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/22/2021
----	--------------	--

**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:** 1152

**Site Name:** (1152) California Research Foundation

**Subject No:** 11521260

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:56

**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
----	---	----------------

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1152

**Subject No:** 11521260

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

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

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

**Site Name:** (1152) California Research Foundation

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

**Disposition - Screening for Further Vaccination**

1.	Date of Completion/Discontinuation/Death :	Jan/22/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[ ]



**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1152

**Subject No:** 11521260

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site Name:** (1152) California Research Foundation

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/22/2021
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	[BRD6C4]
5.b	Sample ID	[BRD6C5]
5.c	Sample ID	[BS6KKV]

090177e196ae2fca\Final\Final On: 01-Apr-2021 03:52 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1152

**Subject No:** 11521260

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

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

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

**Site Name:** (1152) California Research Foundation

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/22/2021
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	[BRRL75]
-----	-----------	----------

090177e196ae2fca\Final\Final On: 01-Apr-2021 03:52 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1152

**Subject No:** 11521260

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

**Form:** VACCINATION

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

**Site Name:** (1152) California Research Foundation

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:56

[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/22/2021 11:46
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
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

090177e196ae2fca\Final\Final On: 01-Apr-2021 03:52 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1152

**Subject No:** 11521260

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

**Form:** DATE OF VISIT

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

**Site Name:** (1152) California Research Foundation

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Feb/12/2021
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1152

**Subject No:** 11521260

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

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

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

**Site Name:** (1152) California Research Foundation

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/12/2021
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	[BRRLFB]
-----	-----------	----------

090177e196ae2fca\Final\Final On: 01-Apr-2021 03:52 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1152

**Subject No:** 11521260

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

**Form:** VACCINATION

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

**Site Name:** (1152) California Research Foundation

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:56

[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/12/2021 10:17
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
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

090177e196ae2fca\Final\Final On: 01-Apr-2021 03:52 (GMT)

**Header Text:** c4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1152

**Subject No:** 11521260

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1152) California Research Foundation

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:56

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1152

**Subject No:** 11521260

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

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

**Site Name:** (1152) California Research Foundation

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:56

**Contact Outcome**

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



**Header Text:** c4591001

**Visit:** V104\_MONTH6

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

**Site No:** 1152

**Subject No:** 11521260

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1152) California Research Foundation

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:56

**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:** 1152

**Subject No:** 11521260

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

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

**Site Name:** (1152) California Research Foundation

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:56

**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:** 1152

**Subject No:** 11521260

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1152) California Research Foundation

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:56

**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:** 1152

**Subject No:** 11521260

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

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

**Site Name:** (1152) California Research Foundation

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:56

**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:** Not Started

**Site No:** 1152

**Site Name:** (1152) California Research Foundation

**Subject No:** 11521260

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:56

**Disposition - Treatment**

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

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1152

**Subject No:** 11521260

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

**Form:** SUBJECT STATUS

**Form Status:** Data Complete, Verified

**Site Name:** (1152) California Research Foundation

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

**Subject Status**

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/19/2020

**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:** 1152

**Site Name:** (1152) California Research Foundation

**Subject No:** 11521260

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

**Casebook Signature Form**

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

**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:** 1152

**Site Name:** (1152) California Research Foundation

**Subject No:** 11521260

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:56

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

**Site No:** 1152

**Subject No:** 11521260

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

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

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

**Site Name:** (1152) California Research Foundation

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:56

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-31-2020 11:03:44 (UTC-08:00) Pacific Time (US & Canada)	(b)(4),(b)(6)	Not Applicable

090177e196ae2fca\Final\Final On: 01-Apr-2021 03:52 (GMT)

**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:** 1152

**Site Name:** (1152) California Research Foundation

**Subject No:** 11521260

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:56

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-22-2021 15:33:23 (UTC-08:00) Pacific Time (US & Canada)	(b)(4),(b)(6)	Not Applicable

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1152

**Site Name:** (1152) California Research Foundation

**Subject No:** 11521260

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:56

[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	Jan-25-2021 22:45:07 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated

**Affidavit:**

N/A

Donald Brandon	Approved	Jan-25-2021 20:53:16 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
----------------	----------	---	------	--------

**Affidavit:**

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

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

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

(b) (6)	N/A	Jan-22-2021 15:32:26 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Donald Brandon	Approved	Dec-02-2020 08:47:18 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, DonaldBrandon, 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.

090177e196ae2fca\Final\Final On: 01-Apr-2021 03:52 (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:** 1152

**Site Name:** (1152) California Research Foundation

**Subject No:** 11521260

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:56

(b) (6)	N/A	Dec-01-2020 12:46:35 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Donald Brandon	Approved	Oct-30-2020 11:51:22 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
----------------	----------	---	------	--------

**Affidavit:**

By my dated signature below, I, DonaldBrandon, 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.

090177e196ae2fca\Final\Final On: 01-Apr-2021 03:52 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1152

**Subject No:** 11521260

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

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

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

**Site Name:** (1152) California Research Foundation

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:56

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

Date	Location	User	Value	Reason
Aug-31-2020 11:02:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<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
Aug-31-2020 11:02:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

090177e196ae2fca\Final\Final On: 01-Apr-2021 03:52 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1152

**Subject No:** 11521260

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

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

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

**Site Name:** (1152) California Research Foundation

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:56

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**I. Consent Was:**

Date	Location	User	Value	Reason
Aug-31-2020 11:02:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Aug/31/2020	Initial Entry

Header Text: c4591001

Visit: COHORT\_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1152

Subject No: 11521260

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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**1. Subject ID**

Date	Location	User	Value	Reason
Aug-31-2020 11:02:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 11521260	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Aug-31-2020 11:02:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6) 1952	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Aug-31-2020 11:03:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> MALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Aug-31-2020 11:03:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Aug-31-2020 11:03:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> WHITE	Initial Entry

090177e196ae2fca\Final\Final On: 01-Apr-2021 03:52 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1152

**Subject No:** 11521260

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

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

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

**Site Name:** (1152) California Research Foundation

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:56

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*I. Date of Visit*

Date	Location	User	Value	Reason
Aug-31-2020 11:03:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Aug/31/2020	Initial Entry



**Header Text:** c4591001

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

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

**Site No:** 1152

**Subject No:** 11521260

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

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

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

**Site Name:** (1152) California Research Foundation

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:56

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

Date	Location	User	Value	Reason
Aug-31-2020 11:03:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Aug/31/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Aug-31-2020 11:03:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Aug-31-2020 11:03:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae2fca\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1152

Subject No: 11521260

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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**I.a**

Date	Location	User	Value	Reason
Aug-31-2020 11:04:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 1 <b>Medical History Term:</b> hypertension <b>Start Date:</b> UNK/UNK/1997 <b>Ongoing:</b> YES	Initial Entry

**I.a Line/MH Number:**

Date	Location	User	Value	Reason
Aug-31-2020 11:04:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

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

Date	Location	User	Value	Reason
Aug-31-2020 11:04:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> hypertension	Initial Entry

**I.a Start Date:**

Date	Location	User	Value	Reason
Aug-31-2020 11:04:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> UNK/UNK/1997	Initial Entry

**I.a Ongoing:**

Date	Location	User	Value	Reason
Aug-31-2020 11:04:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> YES	Initial Entry

**I.b**

090177e196ae2fca\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1152

Subject No: 11521260

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

Date	Location	User	Value	Reason
Aug-31-2020 11:05:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Number: 2 <b>Medical History</b> hypercholesterolemia <b>Term:</b> lemia <b>Start Date:</b> UNK/UNK/2006 <b>Ongoing:</b> YES	Initial Entry

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

Date	Location	User	Value	Reason
Aug-31-2020 11:05:35 (UTC-08:00) Pacific 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
Aug-31-2020 11:05:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> hypercholesterolemia	Initial Entry

**1.b Start Date:**

Date	Location	User	Value	Reason
Aug-31-2020 11:05:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> UNK/UNK/2006	Initial Entry

**1.b Ongoing:**

Date	Location	User	Value	Reason
Aug-31-2020 11:05:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> YES	Initial Entry

**1.c**

Date	Location	User	Value	Reason
Aug-31-2020 11:06:09	ACV0PFEINFP6000	auto calc	<b>Data Entry:</b>	Initial Entry

090177e196ae2fca\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1152

Subject No: 11521260

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

(UTC-08:00) Pacific Time (US & Canada)		(autocalc)	<b>Line/MH Number:</b> 3 <b>Medical History Te</b> <b>rm:</b> Type II diabe tes <b>Start Date:</b> Mar/UNK/20 20 <b>Ongoing:</b> YES
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**I.c Line/MH Number:**

Date	Location	User	Value	Reason
Aug-31-2020 11:06:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

**I.c Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Aug-31-2020 11:06:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Type II diabetes	Initial Entry

**I.c Start Date:**

Date	Location	User	Value	Reason
Aug-31-2020 11:06:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Mar/UNK/2020	Initial Entry

**I.c Ongoing:**

Date	Location	User	Value	Reason
Aug-31-2020 11:06:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> YES	Initial Entry

**I.d**

Date	Location	User	Value	Reason
Aug-31-2020 11:08:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Numbe</b> 4 <b>r:</b>	Initial Entry

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Header Text: c4591001

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Form Version: 22-Apr-2020 21:03

Site No: 1152

Subject No: 11521260

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Site Name: (1152) California Research Foundation

Subject Initials: ---

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			<b>Medical History Term:</b> prostate cancer <b>Start Date:</b> UNK/UNK/2007 <b>Ongoing:</b> NO End Date: UNK/UNK/2008	
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**I.d Line/MH Number:**

Date	Location	User	Value	Reason
Aug-31-2020 11:08:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 4	Initial Entry

**I.d Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Aug-31-2020 11:08:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> prostate cancer	Initial Entry

**I.d Start Date:**

Date	Location	User	Value	Reason
Aug-31-2020 11:08:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> UNK/UNK/2007	Initial Entry

**I.d Ongoing:**

Date	Location	User	Value	Reason
Aug-31-2020 11:08:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> NO End Date: UNK/UNK/2008	Initial Entry

**I.e**

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1152

Subject No: 11521260

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

Aug-31-2020 11:08:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 5 <b>Medical History Term:</b> low back pain <b>Start Date:</b> UNK/UNK/2010 <b>Ongoing:</b> YES	Initial Entry
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*I.e Line/MH Number:*

Date	Location	User	Value	Reason
Aug-31-2020 11:08:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 5	Initial Entry

*I.e Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:*

Date	Location	User	Value	Reason
Aug-31-2020 11:08:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> low back pain	Initial Entry

*I.e Start Date:*

Date	Location	User	Value	Reason
Aug-31-2020 11:08:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> UNK/UNK/2010	Initial Entry

*I.e Ongoing:*

Date	Location	User	Value	Reason
Aug-31-2020 11:08:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> YES	Initial Entry

*I.f*

Date	Location	User	Value	Reason
Aug-31-2020 11:52:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> <b>Line/MH Number:</b> 6	New Information

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**Header Text:** c4591001

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

**Site No:** 1152

**Subject No:** 11521260

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

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

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**Generated Time (GMT):** 29-Mar-2021 11:56

			<b>Medical History</b> diabetic neuro <b>Term:</b> pathy <b>Start Date:</b> UNK/UNK/2 018 <b>Ongoing:</b> YES	
Aug-31-2020 11:09:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 6 <b>Medical History</b> neuropathy <b>Term:</b> <b>Start Date:</b> UNK/UNK/ 2018 <b>Ongoing:</b> YES	Initial Entry

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Header Text: c4591001

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Site No: 1152

Subject No: 11521260

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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***If Line/MH Number:***

Date	Location	User	Value	Reason
Aug-31-2020 11:09:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 6	Initial Entry

***If Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

Date	Location	User	Value	Reason
Aug-31-2020 11:52:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> diabetic neuropathy	New Information
Aug-31-2020 11:09:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> neuropathy	Initial Entry

***If Start Date:***

Date	Location	User	Value	Reason
Aug-31-2020 11:09:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> UNK/UNK/2018	Initial Entry

***If Ongoing:***

Date	Location	User	Value	Reason
Aug-31-2020 11:09:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> YES	Initial Entry

***I.g***

Date	Location	User	Value	Reason
Aug-31-2020 11:09:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 7 <b>Medical History Term:</b> asthma <b>Start Date:</b> Dec/UNK/1952 <b>Ongoing:</b> YES	Initial Entry

090177e196ae2fca\Final\Final On: 01-Apr-2021 03:52 (GMT)



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Subject No: 11521260

Generated By: (b) (4)

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Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

**I.g Line/MH Number:**

Date	Location	User	Value	Reason
Aug-31-2020 11:09:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 7	Initial Entry

**I.g Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Aug-31-2020 11:09:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> asthma	Initial Entry

**I.g Start Date:**

Date	Location	User	Value	Reason
Aug-31-2020 11:09:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Dec/UNK/1952	Initial Entry

**I.g Ongoing:**

Date	Location	User	Value	Reason
Aug-31-2020 11:09:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> YES	Initial Entry

**I.h**

Date	Location	User	Value	Reason
Aug-31-2020 11:10:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 8 <b>Medical History Term:</b> prostatism <b>Start Date:</b> UNK/UNK/2007 <b>Ongoing:</b> YES	Initial Entry

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Subject No: 11521260

Generated By: (b) (4)

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Subject Initials: ---

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**I.h Line/MH Number:**

Date	Location	User	Value	Reason
Aug-31-2020 11:10:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 8	Initial Entry

**I.h Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Aug-31-2020 11:10:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> prostatism	Initial Entry

**I.h Start Date:**

Date	Location	User	Value	Reason
Aug-31-2020 11:10:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> UNK/UNK/2007	Initial Entry

**I.h Ongoing:**

Date	Location	User	Value	Reason
Aug-31-2020 11:10:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> YES	Initial Entry

**I.i**

Date	Location	User	Value	Reason
Aug-31-2020 11:11:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 9 <b>Medical History Term:</b> tonsillectomy <b>Start Date:</b> UNK/UNK/1961 <b>Ongoing:</b> NO End Date: UNK/UNK/1961	Initial Entry

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Site No: 1152

Subject No: 11521260

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Aug-31-2020 11:11:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 9	Initial Entry

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

Date	Location	User	Value	Reason
Aug-31-2020 11:11:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> tonsillectomy	Initial Entry

***1.i Start Date:***

Date	Location	User	Value	Reason
Aug-31-2020 11:11:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> UNK/UNK/1961	Initial Entry

***1.i Ongoing:***

Date	Location	User	Value	Reason
Aug-31-2020 11:11:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> NO End Date:  UNK/UNK/1961	Initial Entry

***1.j***

Date	Location	User	Value	Reason
Aug-31-2020 11:11:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 10 <b>r:</b> <b>Medical History Term:</b> failed prostatectomy <b>Start Date:</b> UNK/UNK/2007	Initial Entry

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**Header Text:** c4591001

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

**Site No:** 1152

**Subject No:** 11521260

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

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

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**Site Name:** (1152) California Research Foundation

**Subject Initials:** ---

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			<b>Ongoing:</b>	NO	
				End Date:	
				UNK/UNK/	
				2007	

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

Date	Location	User	Value	Reason
Aug-31-2020 11:11:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 10	Initial Entry

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

Date	Location	User	Value	Reason
Aug-31-2020 11:11:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> failed prostatectomy	Initial Entry

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Subject No: 11521260

Generated By: (b) (4)

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**1.j Start Date:**

Date	Location	User	Value	Reason
Aug-31-2020 11:11:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> UNK/UNK/2007	Initial Entry

**1.j Ongoing:**

Date	Location	User	Value	Reason
Aug-31-2020 11:11:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> NO End Date:  UNK/UNK/2007	Initial Entry

**1.k**

Date	Location	User	Value	Reason
Aug-31-2020 11:12:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 11 <b>Medical History:</b> hiatal hernia <b>Term:</b> <b>Start Date:</b> UNK/UNK/1988 <b>Ongoing:</b> NO End Date:  UNK/UNK/ 1988	Initial Entry

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Subject No: 11521260

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Aug-31-2020 11:12:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 11	Initial Entry

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

Date	Location	User	Value	Reason
Aug-31-2020 11:12:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> hiatal hernia	Initial Entry

**1.k Start Date:**

Date	Location	User	Value	Reason
Aug-31-2020 11:12:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> UNK/UNK/1988	Initial Entry

**1.k Ongoing:**

Date	Location	User	Value	Reason
Aug-31-2020 11:12:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> NO End Date: UNK/UNK/1988	Initial Entry

**1.l**

Date	Location	User	Value	Reason
Aug-31-2020 11:13:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Number: 12 <b>r:</b> <b>Medical History:</b> hiatal hernia repair <b>Term:</b> <b>Start Date:</b> UNK/UNK/1988	Initial Entry

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Subject No: 11521260

Generated By: (b) (4)

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			<b>Ongoing:</b>	NO End Date:  UNK/UNK/ 1988
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**1.1 Line/MH Number:**

Date	Location	User	Value	Reason
Aug-31-2020 11:13:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 12	Initial Entry

**1.1 Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Aug-31-2020 11:13:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> hiatal hernia repair	Initial Entry

**1.1 Start Date:**

Date	Location	User	Value	Reason
Aug-31-2020 11:13:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> UNK/UNK/1988	Initial Entry

**1.1 Ongoing:**

Date	Location	User	Value	Reason
Aug-31-2020 11:13:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> NO End Date:  UNK/UNK/1988	Initial Entry

**1.m**

Date	Location	User	Value	Reason
Aug-31-2020 11:15:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 13 <b>Medical History Term:</b> morbid obesity	Initial Entry

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Subject No: 11521260

Generated By: (b) (4)

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			<b>Start Date:</b>	UNK/UNK/1980
			<b>Ongoing:</b>	YES

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

Date	Location	User	Value	Reason
Aug-31-2020 11:15:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 13	Initial Entry

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

Date	Location	User	Value	Reason
Aug-31-2020 11:15:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> morbid obesity	Initial Entry

***1.m Start Date:***

Date	Location	User	Value	Reason
Aug-31-2020 11:15:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> UNK/UNK/1980	Initial Entry

***1.m Ongoing:***

Date	Location	User	Value	Reason
Aug-31-2020 11:15:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> YES	Initial Entry

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Form Version: 21-Aug-2020 02:51

Site No: 1152

Subject No: 11521260

Generated By: (b) (4)

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Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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**1. Date:**

Date	Location	User	Value	Reason
Aug-31-2020 11:17:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Aug/31/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Sep-01-2020 00:12:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Closed	Response satisfies query
Aug-31-2020 11:18:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Answered	Original value is correct
Aug-31-2020 11:17:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Weight 384 is outside of Normal Range 25 - 136 for kg or 50 - 300 for lb.
Aug-31-2020 11:17:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> 384.0	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Aug-31-2020 11:17:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> LB	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Aug-31-2020 11:17:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> 69.0	Initial Entry

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Header Text: c4591001

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Generated By: (b) (4)

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5. Unit:

Date	Location	User	Value	Reason
Aug-31-2020 11:17:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<b>Data Entry:</b> in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-31-2020 11:17:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 56.7	Initial Entry

7.a

Date	Location	User	Value	Reason
Aug-31-2020 11:17:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<b>Data Entry:</b> <b>Record Identifier:</b> 1 : <b>Temperature:</b> 97.9 <b>Temperature Unit</b> F : <b>Temperature Loca</b> ORAL CAV <b>tion::</b> ITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-31-2020 11:17:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<b>Data Entry:</b> 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-31-2020 11:17:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<b>Data Entry:</b> 97.9	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
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090177e196ae2fca\Final\Final On: 01-Apr-2021 03:52 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1152

**Subject No:** 11521260

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

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

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

**Site Name:** (1152) California Research Foundation

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:56

Aug-31-2020 11:17:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<b>Data Entry:</b> F	Initial Entry
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**7.a Temperature Location:**

Date	Location	User	Value	Reason
Aug-31-2020 11:17:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1152

**Subject No:** 11521260

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

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

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

**Site Name:** (1152) California Research Foundation

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:56

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Aug-31-2020 11:17:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<b>Data Entry:</b> Aug/31/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Aug-31-2020 11:17:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<b>Data Entry:</b> 247040	Initial Entry

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: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521260

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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**1. Data Origin**

Date	Location	User	Value	Reason
Aug-31-2020 11:17:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-31-2020 11:17:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Aug-31-2020 22:14:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-31-2020 11:17:46 (UTC-08:00) Pacific 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.
Aug-31-2020 11:17:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<b>Data Entry:</b> YES Date of Collection:  Aug/31/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Aug-31-2020 22:14:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> <b>Sample ID:</b> BP9KRR	Initial Entry

090177e196ae2fca\Final\Final On: 01-Apr-2021 03:52 (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: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521260

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.a Sample ID

Date	Location	User	Value	Reason
Aug-31-2020 22:14:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> BP9KRR	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-31-2020 22:14:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> <b>Sample ID:</b> BP9KRS	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-31-2020 22:14:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> BP9KRS	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-31-2020 22:14:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> <b>Sample ID:</b> BP9KRT	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-31-2020 22:14:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> BP9KRT	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-31-2020 22:15:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> <b>Sample ID:</b> BNWJPH	Initial Entry

090177e196ae2fca\Final\On: 01-Apr-2021 03:52 (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:** 1152

**Site Name:** (1152) California Research Foundation

**Subject No:** 11521260

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:56

**5.d Sample ID**

Date	Location	User	Value	Reason
Aug-31-2020 22:15:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> BNWJPH	Initial Entry

**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:** 1152**Site Name:** (1152) California Research Foundation**Subject No:** 11521260**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Aug-31-2020 11:17:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-31-2020 11:17:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Aug-31-2020 19:54:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-31-2020 11:17:53 (UTC-08:00) Pacific 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.
Aug-31-2020 11:17:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<b>Data Entry:</b> YES Date of Collection:  Aug/31/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Aug-31-2020 19:54:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> <b>Sample ID:</b> BPYL3Z	Initial Entry



**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:** 1152

**Site Name:** (1152) California Research Foundation

**Subject No:** 11521260

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:56

**5.a Sample ID**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Aug-31-2020 19:54:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> BPYL3Z	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1152

Subject No: 11521260

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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

Date	Location	User	Value	Reason
Aug-31-2020 11:18:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Aug-31-2020 11:18:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Aug-31-2020 11:18:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Aug-31-2020 11:18:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Aug/31/2020 09:59	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Aug-31-2020 11:18:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Aug-31-2020 11:18:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae2fca\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1152

Subject No: 11521260

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

7. Route:

Date	Location	User	Value	Reason
Aug-31-2020 11:18:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-31-2020 11:18:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OB SERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Aug-31-2020 11:18:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2fca\Final\Final On: 01-Apr-2021 03:52 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1152

**Subject No:** 11521260

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

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

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

**Site Name:** (1152) California Research Foundation

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:56

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*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Aug-31-2020 11:18:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> NO - REACTOGENICITY E-DI ARY NOT COLLECTED FOR T HIS SUBJECT	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1152

**Subject No:** 11521260

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

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

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

**Site Name:** (1152) California Research Foundation

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:56

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*I. Date of Visit*

Date	Location	User	Value	Reason
Sep-21-2020 08:49:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Sep/21/2020	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 15-Sep-2020 21:54

Site No: 1152

Subject No: 11521260

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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**1. Date:**

Date	Location	User	Value	Reason
Sep-21-2020 08:50:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Sep/21/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-21-2020 08:50:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> <b>Record Identifier:</b> 1 : <b>Temperature:</b> 98.0 <b>Temperature Unit</b> F : <b>Temperature Loca</b> ORAL CAV <b>tion::</b> ITY	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Sep-21-2020 08:50:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> 1	Initial Entry

**2.a Temperature:**

Date	Location	User	Value	Reason
Sep-21-2020 08:50:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> 98.0	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Sep-21-2020 08:50:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> F	Initial Entry

090177e196ae2fca\Final\On: 01-Apr-2021 03:52 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1152

**Subject No:** 11521260

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

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

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

**Site Name:** (1152) California Research Foundation

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:56

**2.a Temperature Location:**

Date	Location	User	Value	Reason
Sep-21-2020 08:50:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

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: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521260

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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**1. Data Origin**

Date	Location	User	Value	Reason
Sep-21-2020 08:50:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-21-2020 08:50:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-21-2020 14:55:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-21-2020 08:50:36 (UTC-08:00) Pacific 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-21-2020 08:50:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> YES Date of Collection:  Sep/21/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-21-2020 14:55:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> <b>Sample ID:</b> BPOSCH	Initial Entry

090177e196ae2fca\Final\On: 01-Apr-2021 03:52 (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:** 1152

**Site Name:** (1152) California Research Foundation

**Subject No:** 11521260

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:56

**5.a Sample ID**

Date	Location	User	Value	Reason
Sep-21-2020 14:55:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> BP0SCH	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1152

Subject No: 11521260

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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

Date	Location	User	Value	Reason
Sep-21-2020 08:50:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Sep-21-2020 08:50:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Sep-21-2020 08:50:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Sep-21-2020 08:50:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<b>Data Entry:</b> Sep/21/2020 08:11	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Sep-21-2020 08:50:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Sep-21-2020 08:50:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae2fca\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1152

Subject No: 11521260

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

7. Route:

Date	Location	User	Value	Reason
Sep-21-2020 08:50:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-21-2020 08:50:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OB SERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Sep-21-2020 08:50:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2fca\Final\Final On: 01-Apr-2021 03:52 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1152

**Subject No:** 11521260

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

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

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

**Site Name:** (1152) California Research Foundation

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:56

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*I. Date of Visit*

Date	Location	User	Value	Reason
Oct-19-2020 09:11:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<b>Data Entry:</b> Oct/19/2020	Initial Entry

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: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521260

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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**1. Data Origin**

Date	Location	User	Value	Reason
Oct-19-2020 09:11:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-19-2020 09:11:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-19-2020 18:20:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-19-2020 09:11:28 (UTC-08:00) Pacific 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.
Oct-19-2020 09:11:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<b>Data Entry:</b> YES Date of Collection:  Oct/19/2020	Initial Entry

**4. If no sample was collected or sample was not collected according to protocol, please provide reason:**

Date	Location	User	Value	Reason
Oct-19-2020 18:21:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> SHORT DRAW. NO RETAIN SAMPLE OBTAINED	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: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521260

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.a

Date	Location	User	Value	Reason
Oct-19-2020 18:20:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> <b>Sample ID: BRJGC6</b>	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-19-2020 18:20:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> BRJGC6	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-19-2020 18:20:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> <b>Sample ID: BRJGC7</b>	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-19-2020 18:20:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> BRJGC7	Initial Entry

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**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

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

**Site No:** 1152

**Subject No:** 11521260

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

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

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

**Site Name:** (1152) California Research Foundation

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:56

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

Date	Location	User	Value	Reason
Oct-19-2020 09:11:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Oct/19/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Oct-19-2020 09:11:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Oct-19-2020 09:11:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> COMPLETED	Initial Entry

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1152

**Subject No:** 11521260

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

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

**Form Status:**

**Site Name:** (1152) California Research Foundation

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:56

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Date	Location	User	Value	Reason
Oct-19-2020 17:29:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Form Created	



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1152

**Subject No:** 11521260

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

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

**Form Status:**

**Site Name:** (1152) California Research Foundation

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:56

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Date	Location	User	Value	Reason
Feb-17-2021 11:57:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1152

Subject No: 11521260

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1152) California Research Foundation

Subject Initials: ---

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**1. Category:**

Date	Location	User	Value	Reason
Oct-19-2020 17:29:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Oct-19-2020 17:29:00 (UTC-08:00) Pacific 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
Dec-03-2020 09:52:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 3: Closed	Response satisfies query
Dec-02-2020 19:49:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 3: Answered	WE WILL AS SOON AS WE ARE ABLE TO GET THE MEDICAL RECORDS. THE HOSPITAL HAS SENT THE REQUEST BACK TWICE ALREADY
Dec-02-2020 16:03:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 3: Reissued:Opened	Thank you for your response. Kindly confirm the final diagnosis, duration and dates of hospitalization in a FU report to be added to the safety narrative.
Dec-01-2020 12:46:35 (UTC-08:00) Pacific	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	OK.

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Header Text: c4591001

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Generated By: (b) (4)

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Form Status: Data Complete, Frozen

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Time (US & Canada)				
Dec-01-2020 12:46:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b> malignant melanoma	OK.
Dec-01-2020 12:06:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 3: Opened	The event term is malignant melanoma. However, it does not match with the verbatim used in the narrative. Kindly confirm the final diagnosis, duration and dates of hospitalization. Thank you.
Nov-04-2020 05:59:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	Response satisfies query
Nov-03-2020 14:12:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Answered	Of course.
Nov-03-2020 11:42:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Reissued:Opened	Appreciate the response. Thank you.
Nov-03-2020 09:04:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Reissued:Candidate	Appreciate the response. Thank you.
Nov-03-2020 05:45:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Samuel Dychter (b) (4)	Query 2: Closed	Response satisfies query
Nov-02-2020 17:15:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2: Answered	I HAVE ANSWERED THIS QUERY 3 TIMES BUT IT WON'T GO AWAY
Nov-02-2020 17:11:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Answered	wE ARE WAITING ON MEDICAL RECORDS

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Subject No: 11521260

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

Nov-02-2020 11:11:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Samuel Dychter (b) (4)	Query 2: Opened	GPD Clin: Can you please elaborate on the detection of the melanoma? Was it not present at the physical examination at baseline?
Nov-01-2020 18:05:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Opened	Kindly confirm if any SARS-CoV-2 (NAAT or other) tests were performed on the SAE submitted to safety. If test performed = YES, please provide FU report with results. If test was NOT done or NOT available, please FU as well. Thanks
Oct-20-2020 10:28:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b> melanoma left shoulder	Changed Information
Oct-19-2020 17:29:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b> melanoma diagnosed	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-19-2020 17:29:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Sep/4/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-20-2020 10:28:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> NO End Date Time:  Oct/8/2020 UNK:UNK	Transcription Error

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Form Status: Data Complete, Frozen

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Subject Initials: ---

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Oct-19-2020 17:29:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> NO End Date Time:  Oct/9/2020 UNK:UNK	Initial Entry
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**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Oct-20-2020 10:30:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> 3	Initial Entry

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

**If Yes, NOTIFY PFIZER IMMEDIATELY.**

**Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).**

Date	Location	User	Value	Reason
Oct-22-2020 11:21:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Closed	Response satisfies query
Oct-22-2020 07:44:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 2: Answered	There ARE no CT results. Someone misread the word "it" for "CT". The "it" in narrative on the SAE form was crossed out and more clearly written as "IT". NOT "CT".
Oct-21-2020 18:58:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Opened	CLIN_ Information from discharge summary would be helpful since reason for hospitalization, other than CT results, is not specified on case narrative. Please consider an update

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Form Status: Data Complete, Frozen

Site Name: (1152) California Research Foundation

Subject Initials: ---

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				or fu SAE form when available. Thank you
Oct-20-2020 03:15:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-19-2020 17:29:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE melanoma diagnosed: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Oct-19-2020 17:29:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<p><b>Data Entry:</b></p> <p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p>	Initial Entry

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Generated By: (b) (4)

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Subject Initials: ---

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			YES	
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**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
Oct-19-2020 17:29:00 (UTC-08:00) Pacific 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
Oct-19-2020 17:29:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment (s), this event is due to:  OTHER  <i>If Other, specify:</i>  unknown	Initial Entry

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

Date	Location	User	Value	Reason
Oct-19-2020 17:29:00 (UTC-08:00) Pacific 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
Oct-19-2020 17:29:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> YES	Initial Entry

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

Date	Location	User	Value	Reason
Oct-19-2020 17:29:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2fca\Final\Final On: 01-Apr-2021 03:52 (GMT)

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Site No: 1152

Subject No: 11521260

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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

Date	Location	User	Value	Reason
Oct-22-2020 03:51:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Closed	SDB outcome updated. Issue resolved
Oct-21-2020 21:00:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Reissued: Candidate	SAE RECON: To check next SAE listing
Oct-21-2020 13:39:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Answered	Will correct and re-fax SAE form.
Oct-21-2020 02:42:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Opened	SAE RECON:AER#2020405723,outcome was reported as UNKNOWN to Safety DB however, recorded as RECOVERED/RESOLVED on AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Oct-19-2020 17:29:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Oct-19-2020 17:29:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b> NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
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090177e196ae2fca\Final\Final On: 01-Apr-2021 03:52 (GMT)



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1152

**Subject No:** 11521260

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

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

**Form Status:** Data Complete, Frozen

**Site Name:** (1152) California Research Foundation

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:56

Oct-20-2020 03:15:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b) (6)	<b>Data Entry:</b> 2020405723	Initial Entry
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090177e196ae2fca\Final\Final On: 01-Apr-2021 03:52 (GMT)

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1152**Subject No:** 11521260**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1152) California Research Foundation**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:56[Back to Form](#)**1. Category:**

Date	Location	User	Value	Reason
Feb-17-2021 11:57:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Feb-17-2021 11:57:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

**3. Adverse Event:***(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Feb-17-2021 11:57:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<b>Data Entry:</b> Diarrhea	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Feb-17-2021 11:57:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<b>Data Entry:</b> Feb/12/2021 14:30	Initial Entry

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

Date	Location	User	Value	Reason
Feb-17-2021 11:57:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<b>Data Entry:</b> NO End Date Time: Feb/12/2021 15:30	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1152

Subject No: 11521260

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

Feb-17-2021 11:57:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<b>Data Entry:</b> 1	Initial Entry
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Feb-17-2021 11:57:29 (UTC-08:00) Pacific 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
Feb-17-2021 11:57:29 (UTC-08:00) Pacific 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
Feb-17-2021 11:57:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<b>Data Entry:</b> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-17-2021 11:57:29 (UTC-08:00) Pacific 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
Feb-17-2021 11:57:29 (UTC-08:00) Pacific	ACV0PFEINFP6000	(b) (6)	<b>Data Entry:</b> NO	Initial Entry

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1152

**Subject No:** 11521260

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

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

**Form Status:** Data Complete, Frozen

**Site Name:** (1152) California Research Foundation

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:56

Time (US & Canada)

(b) (4)

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

Date	Location	User	Value	Reason
Feb-17-2021 11:57:29 (UTC-08:00) Pacific 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
Feb-17-2021 11:57:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

**14. Did the adverse event cause the subject to be discontinued from the study?**

Date	Location	User	Value	Reason
Feb-17-2021 11:57:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae2fca\Final\Final On: 01-Apr-2021 03:52 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1152

**Site Name:** (1152) California Research Foundation

**Subject No:** 11521260

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:56

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*I. Date of Visit*

Date	Location	User	Value	Reason
Jan-22-2021 15:32:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Jan/20/2021	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1152

**Subject No:** 11521260

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

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

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

**Site Name:** (1152) California Research Foundation

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:56

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*1. Select appropriate response - Is participant willing to return for Vaccination 3?*

Date	Location	User	Value	Reason
Jan-22-2021 15:32:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Participant is willing to return for Vaccination 3 Participant is:  eligible per local/national reco mmendations and confirmed to have received only placebo at Vaccination 1/2	Initial Entry

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1152

Subject No: 11521260

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Feb-25-2021 21:52:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Closed	Response satisfies query
Feb-25-2021 15:04:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	changed data per query
Feb-25-2021 15:04:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry</b> : Jan/20/2021	changed data per query
Feb-23-2021 11:10:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW7352846;Date Treatment Unblinded should be equal to or after DOV in REVAX CONTACT visit when Reason is ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION.Please review and update as appropriate.
Jan-22-2021 15:32:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry</b> : Jan/18/2021	Initial Entry

**2. Primary Reason for Unblinding:**

090177e196ae2fca\Final\Final On: 01-Apr-2021 03:52 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1152

**Subject No:** 11521260

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

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

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

**Site Name:** (1152) California Research Foundation

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:56

Date	Location	User	Value	Reason
Jan-22-2021 15:32:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> ASSESS ELIGIBILITY FOR AD DITIONAL VACCINATION	Initial Entry



**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1152

**Subject No:** 11521260

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

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

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

**Site Name:** (1152) California Research Foundation

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:56

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*I. Date of Visit*

Date	Location	User	Value	Reason
Jan-22-2021 15:33:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Jan/22/2021	Initial Entry

**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:** 1152

**Site Name:** (1152) California Research Foundation

**Subject No:** 11521260

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:56

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**1. Consent Was:**

Date	Location	User	Value	Reason
Jan-22-2021 15:33:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Jan/22/2021	Initial Entry

**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:** 1152

**Site Name:** (1152) California Research Foundation

**Subject No:** 11521260

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:56

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

Date	Location	User	Value	Reason
Jan-22-2021 15:33:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Jan/22/2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Jan-22-2021 15:33:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> REPEAT SCREENING 1	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Jan-22-2021 15:33:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae2fca\Final\Final On: 01-Apr-2021 03:52 (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: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521260

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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**1. Data Origin**

Date	Location	User	Value	Reason
Jan-22-2021 15:33:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-22-2021 15:33:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-25-2021 14:39:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Closed	Response satisfies query
Jan-25-2021 07:56:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Answered	OK
Jan-25-2021 04:39:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-22-2021 15:33:55 (UTC-08:00) Pacific 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.
Jan-22-2021 15:33:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> YES Date of Collection:	Initial Entry

090177e196ae2fca\Final\Final On: 01-Apr-2021 03:52 (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: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521260

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

			Jan/22/2021	
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5.a

Date	Location	User	Value	Reason
Jan-25-2021 07:56:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> <b>Sample ID: BRD6C4</b>	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-25-2021 07:56:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> BRD6C4	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-25-2021 07:56:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> <b>Sample ID: BRD6C5</b>	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-25-2021 07:56:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> BRD6C5	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-25-2021 07:56:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> <b>Sample ID: BS6KKV</b>	Initial Entry

090177e196ae2fca\Final\Final On: 01-Apr-2021 03:52 (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:** 1152

**Site Name:** (1152) California Research Foundation

**Subject No:** 11521260

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:56

**5.c Sample ID**

Date	Location	User	Value	Reason
Jan-25-2021 07:56:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> BS6KKV	Initial Entry

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: 1152

Site Name: (1152) California Research Foundation

Subject No: 11521260

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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**1. Data Origin**

Date	Location	User	Value	Reason
Jan-22-2021 15:34:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-22-2021 15:34:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-25-2021 22:45:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-25-2021 04:39:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-22-2021 15:34:20 (UTC-08:00) Pacific 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.
Jan-22-2021 15:34:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b> YES Date of Collection:  Jan/22/2021	Initial Entry

5.a

090177e196ae2fca\Final\Final On: 01-Apr-2021 03:52 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
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**Form Version:** 22-Apr-2020 21:03

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

**Site No:** 1152

**Site Name:** (1152) California Research Foundation

**Subject No:** 11521260

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:56

Date	Location	User	Value	Reason
Jan-25-2021 22:45:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> <b>Sample ID:</b> BRRL75	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Jan-25-2021 22:45:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> BRRL75	Initial Entry



Header Text: c4591001

Visit: V101\_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1152

Subject No: 11521260

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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

Date	Location	User	Value	Reason
Jan-22-2021 15:37:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Jan-22-2021 15:37:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BNT162b2	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Jan-22-2021 15:37:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Jan-22-2021 15:37:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<b>Data Entry:</b> Jan/22/2021 11:46	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Jan-22-2021 15:37:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Jan-22-2021 15:37:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<b>Data Entry:</b> RIGHT	Initial Entry

090177e196ae2fca\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1152

Subject No: 11521260

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

7. Route:

Date	Location	User	Value	Reason
Jan-22-2021 15:37:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Jan-22-2021 15:37:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jan-22-2021 15:37:20 (UTC-08:00) Pacific 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-22-2021 15:37:20 (UTC-08:00) Pacific 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 investigational product administration?

Date	Location	User	Value	Reason
Jan-22-2021 15:37:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2fca\Final\On: 01-Apr-2021 03:52 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1152

**Subject No:** 11521260

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

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

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

**Site Name:** (1152) California Research Foundation

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:56

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*I. Date of Visit*

Date	Location	User	Value	Reason
Feb-12-2021 15:13:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<b>Data Entry:</b> Feb/12/2021	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:** 1152**Site Name:** (1152) California Research Foundation**Subject No:** 11521260**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Feb-12-2021 15:13:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Feb-12-2021 15:13:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Feb-12-2021 19:21:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-12-2021 15:13:35 (UTC-08:00) Pacific 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.
Feb-12-2021 15:13:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<b>Data Entry:</b> YES Date of Collection:  Feb/12/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Feb-12-2021 19:21:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> <b>Sample ID:</b> BRRLFB	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:** 1152

**Site Name:** (1152) California Research Foundation

**Subject No:** 11521260

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:56

**5.a Sample ID**

Date	Location	User	Value	Reason
Feb-12-2021 19:21:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> BRRLFB	Initial Entry

Header Text: c4591001

Visit: V102\_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1152

Subject No: 11521260

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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

Date	Location	User	Value	Reason
Feb-12-2021 15:18:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Feb-12-2021 15:18:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BNT162b2	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Feb-12-2021 15:18:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Feb-12-2021 15:18:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<b>Data Entry:</b> Feb/12/2021 10:17	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Feb-12-2021 15:18:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Feb-12-2021 15:18:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<b>Data Entry:</b> RIGHT	Initial Entry

090177e196ae2fca\Final\Final On: 01-Apr-2021 03:52 (GMT)

Header Text: c4591001

Visit: V102\_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1152

Subject No: 11521260

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1152) California Research Foundation

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

7. Route:

Date	Location	User	Value	Reason
Feb-12-2021 15:18:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-12-2021 15:18:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Feb-12-2021 15:18:49 (UTC-08:00) Pacific 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-12-2021 15:18:49 (UTC-08:00) Pacific 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 investigational product administration?

Date	Location	User	Value	Reason
Feb-12-2021 15:18:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2fca\Final\On: 01-Apr-2021 03:52 (GMT)

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1152

**Subject No:** 11521260

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

**Form:** SUBJECT STATUS - eCRF Audit Trail History

**Form Status:** Data Complete, Verified

**Site Name:** (1152) California Research Foundation

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:56

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***1. Subject Status***

Date	Location	User	Value	Reason
Oct-19-2020 09:11:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Aug-31-2020 11:17:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Aug-31-2020 11:03:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

***2. Subject Status Date***

Date	Location	User	Value	Reason
Oct-19-2020 09:11:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/19/2020	Initial Entry
Aug-31-2020 11:17:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/31/2020	Initial Entry
Aug-31-2020 11:03:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/31/2020	Initial Entry

090177e196ae2fca\Final\Final On: 01-Apr-2021 03:52 (GMT)



**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

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

**Form Status:** Data Complete, Verified

**Site No:** 1152

**Site Name:** (1152) California Research Foundation

**Subject No:** 11521260

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:56

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*I. Casebook Signature*

Date	Location	User	Value	Reason
Oct-26-2020 18:21:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Click Here to Enable	Initial Entry