

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT SELECTION

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

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

**Site No:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

[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:** MAIN INFORMED CONSENT

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

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

**Site No:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/21/2020
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**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** DEMOGRAPHY

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

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

**Site No:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[12701142]
2.	Birth Date:	(b) (6)/1973
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER
6.	Racial Designation:	

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**Header Text:** c4591001

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

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

**Site No:** 1270

**Subject No:** 12701142

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

**Form:** DATE OF VISIT

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

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** c4591001

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

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

**Site No:** 1270

**Subject No:** 12701142

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

**Form:** INCLUSION/EXCLUSION CRITERIA

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

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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

**Form Version:** 15-Sep-2020 21:52

**Site No:** 1270

**Subject No:** 12701142

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

**Form:** DISPOSITION - SCREENING

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

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Disposition - Screening**

1.	Date of Completion/Discontinuation /Death	Sep/21/2020
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:** 1270

**Subject No:** 12701142

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

**Form:** GENERAL MEDICAL HISTORY

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

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Dyslipidemia]
	Start Date:	Mar/6/2019
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Central Serous Choroidopathy]
	Start Date:	Feb/17/2009
	Ongoing:	YES

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**Header Text:** c4591001

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

**Form Version:** 15-Sep-2020 21:56

**Site No:** 1270

**Subject No:** 12701142

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

**Form:** VITAL SIGNS - BASELINE

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

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Sep/21/2020
2.	Weight:	[67.1]
3.	Unit:	kg
4.	Height:	[167.6]
5.	Unit:	cm
6.	Body Mass Index:	[23.9]

**Vital Signs Details**

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



**Header Text:** c4591001

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

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

**Site No:** 1270

**Subject No:** 12701142

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

**Form:** RANDOMIZATION

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

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Sep/21/2020
2.	Randomization Number:	[94919]
3.	Randomization Group:	[ ]

**Header Text:** c4591001

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

**Site No:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
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	[BP1FGP]
5.b	Sample ID	[BPJ2P4]
5.c	Sample ID	[BPJ2NT]

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**Header Text:** c4591001

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

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

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

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

**Site No:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

[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	[BP1DZX]
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090177e196ad2fed\Final\Final On: 01-Apr-2021 03:08 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1270

**Subject No:** 12701142

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

**Form:** VACCINATION

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

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

<b>Vaccination</b>		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/21/2020 14:07
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
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

090177e196ad2fed\Final\Final On: 01-Apr-2021 03:08 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1270

**Subject No:** 12701142

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

**Form:** REACTOGENICITY DIARY

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

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

[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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090177e196ad2fed\Final\Final On: 01-Apr-2021 03:08 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** DATE OF VISIT

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

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

**Site No:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Oct/12/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VITAL SIGNS - TEMP

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

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

**Site No:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Oct/12/2020
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**Vital Signs Details**

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

090177e196ad2fed\Final\Final On: 01-Apr-2021 03:08 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Oct/12/2020
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	[BP1F3G]
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090177e196ad2fed\Final\Final On: 01-Apr-2021 03:08 (GMT)



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1270

**Subject No:** 12701142

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

**Form:** VACCINATION

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

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

[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:	Oct/12/2020 16:14
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
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

090177e196ad2fed\Final\Final On: 01-Apr-2021 03:08 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1270 **Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Nov/12/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1270 **Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Nov/12/2020
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	[BRFF67]
5.b	Sample ID	[BPJ2Y3]
5.c	Sample ID	[BPJ2YJ]

090177e196ad2fed\Final\Final On: 01-Apr-2021 03:08 (GMT)

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1270

**Subject No:** 12701142

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1270

**Subject No:** 12701142

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

**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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090177e196ad2fed\Final\Final On: 01-Apr-2021 03:08 (GMT)

**Header Text:** c4591001

**Visit:** V5\_MONTH12\_L

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

**Site No:** 1270

**Subject No:** 12701142

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V5\_MONTH12\_L

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

**Site No:** 1270

**Subject No:** 12701142

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

**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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090177e196ad2fed\Final\Final On: 01-Apr-2021 03:08 (GMT)

**Header Text:** c4591001

**Visit:** V6\_MONTH24\_L

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

**Site No:** 1270

**Subject No:** 12701142

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	



**Header Text:** c4591001

**Visit:** V6\_MONTH24\_L

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Form Status:** Not Started

**Site No:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

**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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090177e196ad2fed\Final\Final On: 01-Apr-2021 03:08 (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:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

3.	COVID-19 Illness Visit:	
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**Header Text:** c4591001

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

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

**Site No:** 1270

**Subject No:** 12701142

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

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

**Form Status:** Not Started

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

**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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090177e196ad2fed\Final\Final On: 01-Apr-2021 03:08 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1270

**Subject No:** 12701142

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

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

**Form Status:** Not Started

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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

090177e196ad2fed\Final\Final On: 01-Apr-2021 03:08 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1270

**Subject No:** 12701142

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

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

**Form Status:** Not Started

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

**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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090177e196ad2fed\Final\Final On: 01-Apr-2021 03:08 (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:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

**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:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

**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:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

**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:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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

090177e196ad2fed\Final\Final On: 01-Apr-2021 03:08 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_REPEAT\_SWAB **Form:** DATE OF VISIT - REPEAT SWAB  
- New Unscheduled Visit

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

**Site No:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Repeat Swab**

3.	COVID-19 Repeat Swab:	
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**Header Text:** c4591001

**Visit:** POT\_COVID\_REPEAT\_SWAB - New Unscheduled Visit      **Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

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

**Site No:** 1270      **Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142      **Subject Initials:** ---

**Generated By:** (b) (4)      **Generated Time (GMT):** 29-Mar-2021 18:51

**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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090177e196ad2fed\Final\Final On: 01-Apr-2021 03:08 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1270 **Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 18:51

**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:** 1270    **Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142    **Subject Initials:** ---

**Generated By:** (b) (4)    **Generated Time (GMT):** 29-Mar-2021 18:51

**Unplanned Assessments**

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

**Header Text:** c4591001

**Visit:** Logs

**Form:** ADVERSE EVENT REPORT

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

**Site No:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Swollen left superficial cervical lymph node	Sep/22/2020 07:00	NO End Date Time:  Sep/23/2020 07:00	<a href="#">Repeating Pages</a>
2.	ADVERSE EVENT	2	Fever	Oct/13/2020 UNK:UNK	NO End Date Time:  Oct/14/2020 UNK:UNK	<a href="#">Repeating Pages</a>

090177e196ad2fed\Final\Final On: 01-Apr-2021 03:08 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

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

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

**Site No:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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[eCRF Audit Trail History](#)

[Form Audit Trail](#)

**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Swollen left superficial cervical lymph node]
4.	Start Date Time:	Sep/22/2020 07:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/23/2020 07:00
6.	Toxicity Grade:	1

090177e196ad2fed\Final\Final On: 01-Apr-2021 03:08 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1270

**Subject No:** 12701142

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

**Form:** ADVERSE EVENT REPORT

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

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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
12.	Was a Non-Drug Treatment given?	NO

090177e196ad2fed\Final\Final On: 01-Apr-2021 03:08 (GMT)



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

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

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

**Site No:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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	[ ]

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1270

**Subject No:** 12701142

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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[Form Audit Trail](#)

### Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Fever]
4.	Start Date Time:	Oct/13/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/14/2020 UNK:UNK
6.	Toxicity Grade:	1

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

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

**Form Status:** Data Complete, Frozen

**Site No:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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
12.	Was a Non-Drug Treatment given?	NO

090177e196ad2fed\Final\Final On: 01-Apr-2021 03:08 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

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

**Form Status:** Data Complete, Frozen

**Site No:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** MEDICATION ERROR

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

**Form Status:** Not Started

**Site No:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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**Medication Error**

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

090177e196ad2fed\Final\Final On: 01-Apr-2021 03:08 (GMT)

**Header Text:** c4591001

**Visit:** Logs

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

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

**Site No:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

#	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:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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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:	//

090177e196ad2fed\Final\Final On: 01-Apr-2021 03:08 (GMT)



**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Site No:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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

090177e196ad2fed\Final\Final On: 01-Apr-2021 03:08 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Form Status:** Not Started

**Site No:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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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?	

090177e196ad2fed\Final\Final On: 01-Apr-2021 03:08 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

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

**Site No:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** RADIATION TREATMENT

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

**Form Status:** Not Started

**Site No:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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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?	

090177e196ad2fed\Final\Final On: 01-Apr-2021 03:08 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

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

**Site No:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** TRANSFUSIONS

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

**Form Status:** Not Started

**Site No:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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

**Header Text:** c4591001

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

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

**Site No:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation/Death :	Nov/12/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

090177e196ad2fed\Final\Final On: 01-Apr-2021 03:08 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

**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:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

**Vital Signs**

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

**Vital Signs Details**

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

090177e196ad2fed\Final\Final On: 01-Apr-2021 03:08 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** VACCINATION

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

**Form Status:** Not Started

**Site No:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

**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?	

090177e196ad2fed\Final\Final On: 01-Apr-2021 03:08 (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:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

**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:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT - **Form:** DATE OF VISIT  
Unscheduled

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

**Site No:** 1270 **Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 18:51

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

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

**Form:** INFORMED CONSENT - ASYMPTOMATIC  
SURVEILLANCE

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

**Form Status:** Not Started

**Site No:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

**Informed Consent - Asymptomatic Surveillance**

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

**Header Text:** c4591001

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

**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY

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

**Form Status:** Not Started

**Site No:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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

090177e196ad2fed\Final\Final On: 01-Apr-2021 03:08 (GMT)

**Header Text:** c4591001**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1270**Site Name:** (1270) Kaiser Permanente Sacramento**Subject No:** 12701142**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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



**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

**Form:** DISPOSITION - FOLLOW-UP

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

**Form Status:** Not Started

**Site No:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

**Disposition - Follow-Up**

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

**Header Text:** c4591001

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

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

**Site No:** 1270      **Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142      **Subject Initials:** ---

**Generated By:** (b) (4)      **Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Jan/26/2021
2.	Erroneous Visit	

**Header Text:** c4591001

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

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

**Site No:** 1270      **Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142      **Subject Initials:** ---

**Generated By:** (b) (4)      **Generated Time (GMT):** 29-Mar-2021 18:51

[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 and NOT confirmed to have received only placebo at Vaccination 1/2
----	---	---

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** TREATMENT UNBLINDED

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

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

**Site No:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Treatment Unblinded**

1.	Date Treatment Unblinded :	Jan/26/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** WITHDRAWAL OF CONSENT

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

**Form Status:** Not Started

**Site No:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

**Withdrawal Of Consent**

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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** DEATH DETAILS CODED

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

**Form Status:** Not Started

**Site No:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

**Death Details**

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

**Cause of Death**

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

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form:** SUBJECT STATUS

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

**Form Status:** Data Complete, Verified

**Site No:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Subject Status**

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Nov/12/2020

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

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

**Site No:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Casebook Signature Form**

1.	Casebook Signature	Click Here to Enable
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**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

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

**Site No:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

[Audit Trail](#)

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
Nicola Klein	Approved	Mar-09-2021 17:12:17 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

**Affidavit:**

By my dated signature below, I, NicolaKlein, 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.

**Header Text:** c4591001

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

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

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

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

**Site No:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
Form	Sep-21-2020 17:28:05 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

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

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

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

**Site No:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

[Back to Form](#)

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
Nicola Klein	Approved	Mar-09-2021 17:12:17 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

**Affidavit:**

By my dated signature below, I, NicolaKlein, 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-26-2021 20:10:32 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Nicola Klein	Approved	Nov-16-2020 14:38:41 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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090177e196ad2fed\Final\Final On: 01-Apr-2021 03:08 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

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

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

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

**Site No:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

**Affidavit:**

By my dated signature below, I, NicolaKlein, 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	Nov-13-2020 13:04:15 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Nicola Klein	Approved	Nov-04-2020 14:07:00 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, NicolaKlein, 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.

090177e196ad2fed\Final\Final On: 01-Apr-2021 03:08 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

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

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

**Site No:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

[Back to Form](#)

*1. Select appropriate response - Protocol version*

Date	Location	User	Value	Reason
Sep-21-2020 17:27:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Sep-21-2020 17:27:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

090177e196ad2fed\Final\Final On: 01-Apr-2021 03:08 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

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

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

**Site No:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Consent Was:**

Date	Location	User	Value	Reason
Sep-21-2020 17:27:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Sep/21/2020	Initial Entry

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1270

**Subject No:** 12701142

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

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

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

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Subject ID**

Date	Location	User	Value	Reason
Sep-21-2020 17:27:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 12701142	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Sep-21-2020 17:27:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6)/1973	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Sep-21-2020 17:27:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> MALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
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090177e196ad2fed\Final\Final On: 01-Apr-2021 03:08 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

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

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

**Site No:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

Sep-21-2020 17:27:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry
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**5. Race: (Check X all that apply):**

Date	Location	User	Value	Reason
Sep-21-2020 17:27:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	Initial Entry

090177e196ad2fed\Final\Final On: 01-Apr-2021 03:08 (GMT)



**Header Text:** c4591001

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

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

**Site No:** 1270

**Subject No:** 12701142

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

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

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

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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*1. Date of Visit*

Date	Location	User	Value	Reason
Sep-21-2020 17:27:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/21/2020	Initial Entry

090177e196ad2fed\Final\Final On: 01-Apr-2021 03:08 (GMT)

**Header Text:** c4591001

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

**Form Version:** 15-Sep-2020 21:52

**Site No:** 1270

**Subject No:** 12701142

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

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

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

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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

Date	Location	User	Value	Reason
Sep-21-2020 17:28:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/21/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Sep-21-2020 17:28:21 (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
Sep-21-2020 17:28:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ad2fed\Final\Final On: 01-Apr-2021 03:08 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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*1.a*

Date	Location	User	Value	Reason
Sep-21-2020 17:28:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Nu mber:</b> 1 <b>Medical History Term:</b> Dyslipidemia <b>Start Date:</b> Mar/6/2019 <b>Ongoing:</b> YES	Initial Entry

*1.a Line/MH Number:*

Date	Location	User	Value	Reason
Sep-21-2020 17:28:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

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

Date	Location	User	Value	Reason
Sep-21-2020 17:28:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dyslipidemia	Initial Entry

090177e196ad2fed\Final\Final On: 01-Apr-2021 03:08 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

**1.a Start Date:**

Date	Location	User	Value	Reason
Sep-21-2020 17:28:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/6/2019	Initial Entry

**1.a Ongoing:**

Date	Location	User	Value	Reason
Sep-21-2020 17:28:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**1.b**

Date	Location	User	Value	Reason
Sep-21-2020 17:29:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH 2</b> <b>Number:</b> <b>Medical History T</b> Central Ser <b>erm:</b> tous Choro dopathy <b>Start Date:</b> Feb/17/200 9 <b>Ongoing:</b> YES	Initial Entry

090177e196ad2fed\Final\Final On: 01-Apr-2021 03:08 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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

Date	Location	User	Value	Reason
Sep-21-2020 17:29:01 (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
Sep-21-2020 17:29:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Central Serous Choro idopathy	Initial Entry

**1.b Start Date:**

Date	Location	User	Value	Reason
Sep-21-2020 17:29:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/17/2009	Initial Entry

**1.b Ongoing:**

Date	Location	User	Value	Reason
Sep-21-2020 17:29:01	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ad2fed\Final\Final On: 01-Apr-2021 03:08 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

(UTC-08:00) Pacific Time (US & Canada)				
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**Header Text:** c4591001

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

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

**Form Version:** 15-Sep-2020 21:56

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

**Site No:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Date:**

Date	Location	User	Value	Reason
Sep-21-2020 17:30:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/21/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Sep-21-2020 17:30:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 67.1	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Sep-21-2020 17:30:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> kg	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
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090177e196ad2fed\Final\Final On: 01-Apr-2021 03:08 (GMT)

**Header Text:** c4591001

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

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

**Form Version:** 15-Sep-2020 21:56

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

**Site No:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

Sep-21-2020 17:30:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 167.6	Initial Entry
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**5. Unit:**

Date	Location	User	Value	Reason
Sep-21-2020 17:30:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> cm	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
Sep-21-2020 17:30:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 23.9	Initial Entry

**7.a**

Date	Location	User	Value	Reason
Sep-21-2020 17:30:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier:</b> <b>Temperature:</b> 99.4	Initial Entry

090177e196ad2fed\Final\Final On: 01-Apr-2021 03:08 (GMT)



**Header Text:** c4591001

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

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

**Form Version:** 15-Sep-2020 21:56

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

**Site No:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

			<b>Temperatu F re Unit:</b> <b>Temperatu ORAL re Location CAVIT :: Y</b>
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**7.a Record Identifier:**

Date	Location	User	Value	Reason
Sep-21-2020 17:30:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> 1	Initial Entry

**7.a Temperature:**

Date	Location	User	Value	Reason
Sep-21-2020 17:30:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> 99.4	Initial Entry

**7.a Unit:**

Date	Location	User	Value	Reason
Sep-21-2020 17:30:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> F	Initial Entry

090177e196ad2fed\Final\Final On: 01-Apr-2021 03:08 (GMT)

**Header Text:** c4591001

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

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

**Form Version:** 15-Sep-2020 21:56

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

**Site No:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

**7.a Temperature Location:**

Date	Location	User	Value	Reason
Sep-21-2020 17:30:12 (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:** 1270

**Subject No:** 12701142

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

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

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

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Sep-21-2020 17:31:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/21/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Sep-21-2020 17:31:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 94919	Initial Entry

090177e196ad2fed\Final\Final On: 01-Apr-2021 03:08 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1270

**Subject No:** 12701142

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

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

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

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Data Origin**

Date	Location	User	Value	Reason
Sep-21-2020 17:31:26 (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 17:31:26 (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
Sep-21-2020 17:31:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-21-2020 17:31:26 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ad2fed\Final\Final On: 01-Apr-2021 03:08 (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: 1270

Site Name: (1270) Kaiser Permanente Sacramento

Subject No: 12701142

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Sep-21-2020 17:31:26 (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 17:31:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID BP1FG : P	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-21-2020 17:31:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP1FGP	Initial Entry

5.b

Date	Location	User	Value	Reason
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090177e196ad2fed\Final\Final On: 01-Apr-2021 03:08 (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:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

Sep-21-2020 17:31:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BPJ2P4	Initial Entry
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**5.b Sample ID**

Date	Location	User	Value	Reason
Sep-21-2020 17:31:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPJ2P4	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Sep-21-2020 17:32:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID</b> BPJ2N : T	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Sep-21-2020 17:32:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPJ2NT	Initial Entry

090177e196ad2fed\Final\Final On: 01-Apr-2021 03:08 (GMT)

**Header Text:** c4591001

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

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

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

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

**Site No:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Data Origin**

Date	Location	User	Value	Reason
Sep-21-2020 17:32:32 (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 17:32:32 (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 17:32:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-21-2020 17:32:32 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ad2fed\Final\Final On: 01-Apr-2021 03:08 (GMT)

**Header Text:** c4591001

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

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

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

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

**Site No:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Sep-21-2020 17:32:32 (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 17:32:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID BP1DZ : X	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Sep-21-2020 17:32:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP1DZX	Initial Entry

090177e196ad2fed\Final\Final On: 01-Apr-2021 03:08 (GMT)



**Header Text:** c4591001

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

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

**Site No:** 1270

**Subject No:** 12701142

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

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

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

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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

Date	Location	User	Value	Reason
Sep-21-2020 17:33:08 (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 17:33:08 (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 17:33:08 (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
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090177e196ad2fed\Final\Final On: 01-Apr-2021 03:08 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

Sep-21-2020 17:33:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Sep/21/2020 14:07	Initial Entry
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**5. Anatomical Location:**

Date	Location	User	Value	Reason
Sep-21-2020 17:33:08 (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 17:33:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> RIGHT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Sep-21-2020 17:33:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

090177e196ad2fed\Final\Final On: 01-Apr-2021 03:08 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1270

**Subject No:** 12701142

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

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

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

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Sep-21-2020 17:33:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPE CIFIED OBSERVATIO N 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 17:33:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ad2fed\Final\Final On: 01-Apr-2021 03:08 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1270

**Subject No:** 12701142

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

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

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

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Sep-21-2020 17:33:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO - REACTOGENI CITY E-DIARY NO T COLLECTED FO R THIS SUBJECT	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1270

**Subject No:** 12701142

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

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

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

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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*1. Date of Visit*

Date	Location	User	Value	Reason
Oct-12-2020 17:58:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/12/2020	Initial Entry

090177e196ad2fed\Final\Final On: 01-Apr-2021 03:08 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1270

**Subject No:** 12701142

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

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

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

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Date:**

Date	Location	User	Value	Reason
Oct-12-2020 17:59:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/12/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Oct-12-2020 17:59:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> <b>Temperature:</b> 99.4 <b>Temperature Unit:</b> <b>Temperature Location:</b> ORAL CAVIT <b>Y</b>	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Oct-12-2020 17:59:17 (UTC-08:00) Pacific Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

090177e196ad2fed\Final\Final On: 01-Apr-2021 03:08 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

& Canada)

**2.a Temperature:**

Date	Location	User	Value	Reason
Oct-12-2020 17:59:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 99.4	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Oct-12-2020 17:59:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> F	Initial Entry

**2.a Temperature Location:**

Date	Location	User	Value	Reason
Oct-12-2020 17:59:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

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**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:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Data Origin**

Date	Location	User	Value	Reason
Oct-12-2020 17:59:30 (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-12-2020 17:59:30 (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
Oct-12-2020 17:59:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-12-2020 17:59:30 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ad2fed\Final\Final On: 01-Apr-2021 03:08 (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:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Oct-12-2020 17:59:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Oct/12/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-12-2020 17:59:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID BP1F3 : G	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Oct-12-2020 17:59:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP1F3G	Initial Entry

090177e196ad2fed\Final\Final On: 01-Apr-2021 03:08 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1270

**Subject No:** 12701142

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

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

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

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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

Date	Location	User	Value	Reason
Oct-12-2020 18:00:04 (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
Oct-12-2020 18:00:04 (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
Oct-12-2020 18:00:04 (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
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090177e196ad2fed\Final\Final On: 01-Apr-2021 03:08 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1270

Site Name: (1270) Kaiser Permanente Sacramento

Subject No: 12701142

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Oct-12-2020 18:00:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Oct/12/2020 16:14	Initial Entry
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**5. Anatomical Location:**

Date	Location	User	Value	Reason
Oct-12-2020 18:00:04 (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
Oct-12-2020 18:00:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> RIGHT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Oct-12-2020 18:00:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

090177e196ad2fed\Final\Final On: 01-Apr-2021 03:08 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Oct-12-2020 18:00:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPE CIFIED OBSERVATIO N 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
Oct-12-2020 18:00:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> YES	Initial Entry

090177e196ad2fed\Final\Final On: 01-Apr-2021 03:08 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1270 **Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 18:51

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*1. Date of Visit*

Date	Location	User	Value	Reason
Nov-13-2020 13:04:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/12/2020	Initial Entry

090177e196ad2fed\Final\Final On: 01-Apr-2021 03:08 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1270 **Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Data Origin**

Date	Location	User	Value	Reason
Nov-13-2020 13:04:47 (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
Nov-13-2020 13:04:47 (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
Nov-13-2020 13:04:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection : Nov/12/2020	Initial Entry

**5.a**

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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:** 1270 **Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 18:51

Date	Location	User	Value	Reason
Nov-13-2020 13:04:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I</b> BRFF6 <b>D:</b> 7	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Nov-13-2020 13:04:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRFF67	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Nov-13-2020 13:04:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID</b> BPJ2Y : 3	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:** 1270 **Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 18:51

**5.b Sample ID**

Date	Location	User	Value	Reason
Nov-13-2020 13:04:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPJ2Y3	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Nov-13-2020 13:04:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID BPJ2Y : J	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Nov-13-2020 13:04:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPJ2YJ	Initial Entry

090177e196ad2fed\Final\Final On: 01-Apr-2021 03:08 (GMT)



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:**

**Site No:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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Date	Location	User	Value	Reason
Sep-25-2020 13:45:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:**

**Site No:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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Date	Location	User	Value	Reason
Nov-16-2020 14:16:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1270

Site Name: (1270) Kaiser Permanente Sacramento

Subject No: 12701142

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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**1. Category:**

Date	Location	User	Value	Reason
Sep-25-2020 13:45:07 (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
Sep-25-2020 13:45:07 (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
Sep-25-2020 13:45:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Swollen left superficial cervical lymph node	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
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090177e196ad2fed\Final\Final On: 01-Apr-2021 03:08 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

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

**Site No:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

Sep-25-2020 13:45:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Sep/22/2020 07:00	Initial Entry
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**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Sep-25-2020 13:45:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> NO End Date Time: Sep/23/2020 07:00	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Sep-25-2020 13:45:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> 1	Initial Entry

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

**If Yes, NOTIFY PFIZER IMMEDIATELY.**

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

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

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

**Site No:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

Date	Location	User	Value	Reason
Sep-25-2020 13:45:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<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
Sep-25-2020 13:45:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-25-2020 13:45:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> RELATED	Initial Entry

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

Date	Location	User	Value	Reason
Sep-25-2020 13:45:07 (UTC-08:00)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

090177e196ad2fed\Final\Final On: 01-Apr-2021 03:08 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1270

Site Name: (1270) Kaiser Permanente Sacramento

Subject No: 12701142

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Pacific Time (US & Canada)

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-25-2020 13:45:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-25-2020 13:45:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-25-2020 13:45:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Site No:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

Date	Location	User	Value	Reason
Sep-25-2020 13:45:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Category:**

Date	Location	User	Value	Reason
Nov-16-2020 14:16:00 (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
Nov-16-2020 14:16:00 (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
Nov-16-2020 14:16:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Fever	Initial Entry

**4. Start Date Time:**

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

Date	Location	User	Value	Reason
Nov-16-2020 14:16:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Oct/13/2020 UNK:UN K	Initial Entry

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

Date	Location	User	Value	Reason
Nov-16-2020 14:16:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> NO End Date Time:  Oct/14/2020 UNK: UNK	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Nov-16-2020 14:16:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> 1	Initial Entry

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

**If Yes, NOTIFY PFIZER IMMEDIATELY.**

**Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization;  
Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important**

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

*medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).*

Date	Location	User	Value	Reason
Nov-16-2020 14:16:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<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
Nov-16-2020 14:16:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-16-2020 14:16:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> RELATED	Initial Entry

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

Date	Location	User	Value	Reason
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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

Nov-16-2020 14:16:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry
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**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Nov-16-2020 14:16:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-16-2020 14:16:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-16-2020 14:16:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

090177e196ad2fed\Final\Final On: 01-Apr-2021 03:08 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

**14. Did the adverse event cause the subject to be discontinued from the study?**

Date	Location	User	Value	Reason
Nov-16-2020 14:16:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1270 **Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 18:51

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

Date	Location	User	Value	Reason
Nov-13-2020 13:05:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/12/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Nov-13-2020 13:05:02 (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
Nov-13-2020 13:05:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ad2fed\Final\Final On: 01-Apr-2021 03:08 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1270      **Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142      **Subject Initials:** ---

**Generated By:** (b) (4)      **Generated Time (GMT):** 29-Mar-2021 18:51

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*1. Date of Visit*

Date	Location	User	Value	Reason
Jan-26-2021 20:11:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/26/2021	Initial Entry

090177e196ad2fed\Final\Final On: 01-Apr-2021 03:08 (GMT)

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION -  
Unscheduled eCRF Audit Trail History

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

**Site No:** 1270 **Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 18:51

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*1. Select appropriate response - Is participant willing to return for Vaccination 3?*

Date	Location	User	Value	Reason
Jan-26-2021 20:11:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Participant is willing to return for Vaccinati on 3 Participant is:  eligible and NOT confirmed to have received only plac ebo at Vaccination 1/2	Initial Entry

090177e196ad2fed\Final\Final On: 01-Apr-2021 03:08 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

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

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

**Site No:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Jan-26-2021 20:10:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/26/2021	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Jan-26-2021 20:10:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ASSESS ELIGIBILI TY FOR ADDITION AL VACCINATION	Initial Entry



**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form:** SUBJECT STATUS - eCRF Audit Trail History

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

**Form Status:** Data Complete, Verified

**Site No:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Subject Status**

Date	Location	User	Value	Reason
Nov-13-2020 13:05:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Sep-21-2020 17:31:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Sep-21-2020 17:28:21 (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
Nov-13-2020 13:05:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Nov/12/2020	Initial Entry
Sep-21-2020 17:31:04	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/21/2020	Initial Entry

090177e196ad2fed\Final\Final On: 01-Apr-2021 03:08 (GMT)

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form:** SUBJECT STATUS - eCRF Audit Trail History

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

**Form Status:** Data Complete, Verified

**Site No:** 1270

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject No:** 12701142

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

(UTC-08:00) Pacific Time (US & Canada)				
Sep-21-2020 17:28:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/21/2020	Initial Entry

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

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

**Site No:** 1270

**Subject No:** 12701142

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

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit  
Trail History

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

**Site Name:** (1270) Kaiser Permanente Sacramento

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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*1. Casebook Signature*

Date	Location	User	Value	Reason
Nov-04-2020 13:08:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> Click Here to Enable	Initial Entry

090177e196ad2fed\Final\Final On: 01-Apr-2021 03:08 (GMT)