

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1006

**Subject No:** 10061245

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

**Form:** COHORT\_SELECTION

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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

090177e196b72787\Final\Final On: 06-Apr-2021 19:07 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1006

**Subject No:** 10061245

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

**Form:** MAIN INFORMED CONSENT

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Dec/10/2020
----	--------------	--

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1006

**Subject No:** 10061245

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

**Form:** DEMOGRAPHY

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[10061245]
2.	Birth Date:	(b) (6) 2005
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

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**Header Text:** c4591001

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

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

**Site No:** 1006

**Subject No:** 10061245

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

**Form:** DATE OF VISIT

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Dec/10/2020
2.	Erroneous Visit	

**Header Text:** c4591001

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

**Form Version:** 10-Oct-2020 16:00

**Site No:** 1006

**Subject No:** 10061245

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

**Form:** INCLUSION/EXCLUSION CRITERIA

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

**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 _____
----	---	-------------------------

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**Header Text:** c4591001

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

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

**Site No:** 1006

**Subject No:** 10061245

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

**Form:** DISPOSITION - SCREENING

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

**Disposition - Screening**

1.	Date of Completion/Discontinuation/Death	Dec/10/2020
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:** 1006

**Subject No:** 10061245

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

**Form:** GENERAL MEDICAL HISTORY

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

**Form Comments**

**Medical History Details**

1.	Line/MH Number:	Not Applicable [ ]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	Not Applicable [ ]
	Start Date:	Not Applicable //
	Ongoing:	Not Applicable

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**Header Text:** c4591001

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

**Form Version:** 15-Sep-2020 21:57

**Site No:** 1006

**Subject No:** 10061245

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

**Form:** HIV STATUS

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

**HIV Status**

1.	Select appropriate response - What is the subject HIV status?	The subject is NOT known to be HIV POSITIVE
----	---	---



**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 10-Dec-2020 02:29**Site No:** 1006**Subject No:** 10061245**Generated By:** (b) (4)**Form:** VITAL SIGNS - BASELINE**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36**eCRF Audit Trail History****Vital Signs**

1.	Date:	Dec/10/2020
2.	Weight:	[108.6]
3.	Unit:	LB
4.	Height:	[64.0]
5.	Unit:	in
6.	Body Mass Index:	[18.6]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[99.2]
	Unit:	F
	Temperature Location:	ORAL CAVITY

**Header Text:** c4591001

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

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

**Site No:** 1006

**Subject No:** 10061245

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

**Form:** RANDOMIZATION

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Dec/10/2020
2.	Randomization Number:	[21869]
3.	Randomization Group:	[ ]

**Header Text:** c4591001

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

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

**Site No:** 1006

**Subject No:** 10061245

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

**eCRF Audit Trail History**

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Dec/10/2020
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	[BCSY0L]
5.b	Sample ID	[BCSY0M]
5.c	Sample ID	[BS8WJM]

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**Header Text:** c4591001

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

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

**Site No:** 1006

**Subject No:** 10061245

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

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

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Dec/10/2020
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	[BH24DK]
-----	-----------	----------

090177e196b72787\Final\Final On: 06-Apr-2021 19:07 (GMT)

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 10-Dec-2020 02:26**Site No:** 1006**Subject No:** 10061245**Generated By:** (b) (4)**Form:** VACCINATION**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36**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:	Dec/10/2020 12:11
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

**Header Text:** c4591001

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

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

**Site No:** 1006

**Subject No:** 10061245

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

**Form:** REACTOGENICITY DIARY

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

**Reactogenicity Diary**

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

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1006

**Subject No:** 10061245

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

**Form:** DATE OF VISIT

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Dec/29/2020
2.	Erroneous Visit	

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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1006

**Subject No:** 10061245

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

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

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

**eCRF Audit Trail History**

**Vaccination Symptoms Diary - Symptom Resolved Dates**

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

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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1006

**Subject No:** 10061245

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

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

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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

090177e196b72787\Final\Final On: 06-Apr-2021 19:07 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Dec-2020 02:27

**Site No:** 1006

**Subject No:** 10061245

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

**Form:** VITAL SIGNS - TEMP

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Dec/29/2020
----	-------	-------------

**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[98.6]
	Unit:	F
	Temperature Location:	ORAL CAVITY

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1006

**Subject No:** 10061245

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

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

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Dec/29/2020
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	[BRL0SH]
-----	-----------	----------

090177e196b72787\Final\Final On: 06-Apr-2021 19:07 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1006

**Subject No:** 10061245

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

**Form:** VACCINATION

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

**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:	Dec/29/2020 11:37
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196b72787\Final\Final On: 06-Apr-2021 19:07 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1006

**Subject No:** 10061245

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

**Form:** DATE OF VISIT

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

**Date of Visit**

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

090177e196b72787\Final\Final On: 06-Apr-2021 19:07 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1006

**Subject No:** 10061245

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

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

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

**eCRF Audit Trail History**

**Vaccination Symptoms Diary - Symptom Resolved Dates**

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

090177e196b72787\Final\Final On: 06-Apr-2021 19:07 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1006

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject No:** 10061245

**Subject Initials:** ---

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

**Generated Time (GMT):** 06-Apr-2021 15:36

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

090177e196b72787\Final\Final On: 06-Apr-2021 19:07 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1006

**Subject No:** 10061245

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

**eCRF Audit Trail History**

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/26/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BRBMW0]
5.b	Sample ID	[BRBMW1]
5.c	Sample ID	[BJ7MNZ]

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**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1006

**Subject No:** 10061245

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

**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:** 1006

**Subject No:** 10061245

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Visit:** V5\_MONTH12\_L

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

**Site No:** 1006

**Subject No:** 10061245

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

**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:** 1006**Subject No:** 10061245**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Status:** Not Started**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Visit:** V6\_MONTH24\_L

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

**Site No:** 1006

**Subject No:** 10061245

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V6\_MONTH24\_L

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

**Site No:** 1006

**Subject No:** 10061245

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

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

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

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

**Form Status:** Not Started

**Site No:** 1006

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject No:** 10061245

**Subject Initials:** ---

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

**Generated Time (GMT):** 06-Apr-2021 15:36

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL - New Unscheduled Visit**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19**Form Version:** 20-Feb-2021 02:17**Form Status:** Not Started**Site No:** 1006**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject No:** 10061245**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36**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:	[ ]
----	------------------------	-----



**Header Text:** c4591001**Visit:** POT\_COVID\_ILL - New Unscheduled Visit**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1006**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject No:** 10061245**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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**Header Text:** c4591001**Visit:** POT\_COVID\_ILL - New Unscheduled Visit**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1006**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject No:** 10061245**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

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

**Form:** HEALTH CARE UTILIZATION

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

**Form Status:** Not Started

**Site No:** 1006

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject No:** 10061245

**Subject Initials:** ---

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

**Generated Time (GMT):** 06-Apr-2021 15:36

**Health Care Utilization**

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

**Health Care Utilization Other**

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

**Health Care Utilization**

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

090177e196b72787\Final\Final On: 06-Apr-2021 19:07 (GMT)

**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:** 1006

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject No:** 10061245

**Subject Initials:** ---

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

**Generated Time (GMT):** 06-Apr-2021 15:36

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

**Site No:** 1006

**Subject No:** 10061245

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

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

**Form Status:** Not Started

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

**Header Text:** c4591001**Visit:** POT\_COVID\_CONVA - New  
Unscheduled Visit**Form Version:** 22-Apr-2020 21:03**Site No:** 1006**Subject No:** 10061245**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Status:** Not Started**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1006

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject No:** 10061245

**Subject Initials:** ---

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

**Generated Time (GMT):** 06-Apr-2021 15:36

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Repeat Swab**

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

090177e196b72787\Final\Final On: 06-Apr-2021 19:07 (GMT)

**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:** 1006**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject No:** 10061245**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Visit:** Logs

**Form:** ADVERSE EVENT REPORT

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

**Site No:** 1006

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject No:** 10061245

**Subject Initials:** ---

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

**Generated Time (GMT):** 06-Apr-2021 15:36

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Hives face	Dec/12/2020 UNK: UNK	NO End Date Time:  Dec/31/2020 UNK:UNK	<a href="#">Repeating Pages</a>
2.	ADVERSE EVENT	2	Hives trunk	Dec/12/2020 UNK: UNK	NO End Date Time:  Dec/15/2020 UNK:UNK	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1006

**Subject No:** 10061245

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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[Form Audit Trail](#)

#### Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Hives face]
4.	Start Date Time:	Dec/12/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Dec/31/2020 UNK:UNK
6.	Toxicity Grade:	1
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

090177e196b72787\Final\Final On: 06-Apr-2021 19:07 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1006

**Subject No:** 10061245

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1006**Subject No:** 10061245**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, Frozen**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36

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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)	[Hives trunk]
4.	Start Date Time:	Dec/12/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Dec/15/2020 UNK:UNK
6.	Toxicity Grade:	1
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1006

**Subject No:** 10061245

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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

**Header Text:** c4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

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

**Site No:** 1006

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject No:** 10061245

**Subject Initials:** ---

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

**Generated Time (GMT):** 06-Apr-2021 15:36

#	Catego ry	Medication Er ror	Start Da te	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1006

**Subject No:** 10061245

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

**Form:** MEDICATION ERROR

**Form Status:** Not Started

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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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	[ ]

090177e196b72787\Final\Final On: 06-Apr-2021 19:07 (GMT)

**Header Text:** c4591001

**Visit:** Logs

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

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

**Site No:** 1006

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject No:** 10061245

**Subject Initials:** ---

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

**Generated Time (GMT):** 06-Apr-2021 15:36

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

**Site No:** 1006

**Subject No:** 10061245

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

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

**Form Status:** Not Started

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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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:	//

**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Site No:** 1006

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject No:** 10061245

**Subject Initials:** ---

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

**Generated Time (GMT):** 06-Apr-2021 15:36

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1006

**Subject No:** 10061245

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

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Status:** Not Started

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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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?	

090177e196b72787\Final\Final On: 06-Apr-2021 19:07 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

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

**Site No:** 1006

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject No:** 10061245

**Subject Initials:** ---

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

**Generated Time (GMT):** 06-Apr-2021 15:36

#	Categor y	Treatment Identifi er	Con Non-Drug Treatments Pre-specifi ed	Treatmen t	Start Dat e	Form Instance
1.						<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1006

**Subject No:** 10061245

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

**Form:** RADIATION TREATMENT

**Form Status:** Not Started

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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**Radiation Treatment**

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

**Header Text:** c4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

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

**Site No:** 1006

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject No:** 10061245

**Subject Initials:** ---

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

**Generated Time (GMT):** 06-Apr-2021 15:36

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1006

**Subject No:** 10061245

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

**Form:** TRANSFUSIONS

**Form Status:** Not Started

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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

**Header Text:** c4591001**Visit:** Unplanned - New Unscheduled Visit**Form Version:** 22-Apr-2020 21:02**Site No:** 1006**Subject No:** 10061245**Generated By:** (b) (4)**Form:** DATE OF VISIT**Form Status:** Not Started**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	



**Header Text:** c4591001

**Visit:** Unplanned - New Unscheduled Visit

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

**Site No:** 1006

**Subject No:** 10061245

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

**Form:** UNPLANNED VISIT

**Form Status:** Not Started

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

**Unplanned Assessments**

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

**Header Text:** c4591001**Visit:** Unplanned Vaccination - Unscheduled**Form:** DATE OF VISIT**Form Version:** 22-Apr-2020 21:02**Form Status:** Not Started**Site No:** 1006**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject No:** 10061245**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36**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:** 1006

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject No:** 10061245

**Subject Initials:** ---

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

**Generated Time (GMT):** 06-Apr-2021 15:36

**Vital Signs**

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

**Vital Signs Details**

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

**Header Text:** c4591001**Visit:** Unplanned Vaccination - Unscheduled**Form:** VACCINATION**Form Version:** 10-Dec-2020 02:26**Form Status:** Not Started**Site No:** 1006**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject No:** 10061245**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36**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?	

**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:** 1006

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject No:** 10061245

**Subject Initials:** ---

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

**Generated Time (GMT):** 06-Apr-2021 15:36

**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:** 1006

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject No:** 10061245

**Subject Initials:** ---

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

**Generated Time (GMT):** 06-Apr-2021 15:36

**Contact Outcome**

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

**Header Text:** c4591001

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

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

**Site No:** 1006

**Subject No:** 10061245

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

090177e196b72787\Final\Final On: 06-Apr-2021 19:07 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1006

**Subject No:** 10061245

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

**Form:** INFORMED CONSENT - ASYMPTOMATIC  
SURVEILLANCE

**Form Status:** Not Started

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

**Informed Consent - Asymptomatic Surveillance**

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



**Header Text:** c4591001**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled**Form Version:** 22-Apr-2020 21:03**Site No:** 1006**Subject No:** 10061245**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Status:** Not Started**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36**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:** V201\_SURVEIL\_CONSENT -  
Unscheduled**Form Version:** 22-Apr-2020 21:03**Site No:** 1006**Subject No:** 10061245**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB**Form Status:** Not Started**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36**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:** End of Treatment - Unscheduled

**Form Version:** 10-Dec-2020 02:29

**Site No:** 1006

**Subject No:** 10061245

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

**Form:** DISPOSITION - TREATMENT

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation/Death :	Jan/26/2021
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** c4591001**Visit:** Potential ReVax Initial Contact -  
Unscheduled**Form:** DATE OF VISIT**Form Version:** 22-Apr-2020 21:02**Form Status:** Not Started**Site No:** 1006**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject No:** 10061245**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

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

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

**Site No:** 1006

**Subject No:** 10061245

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

**Form:** FURTHER VACCINATION CONFIRMATION

**Form Status:** Not Started

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

**Further Vaccination Confirmation**

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	
----	---	--

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 10-Dec-2020 02:27

**Site No:** 1006

**Subject No:** 10061245

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

**Form:** TREATMENT UNBLINDED

**Form Status:** Not Started

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

**Treatment Unblinded**

1.	Date Treatment Unblinded :	//
2.	Primary Reason for Unblinding:	

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1006

**Subject No:** 10061245

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

**Form:** WITHDRAWAL OF CONSENT

**Form Status:** Not Started

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

**Withdrawal Of Consent**

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

090177e196b72787\Final\Final On: 06-Apr-2021 19:07 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1006

**Subject No:** 10061245

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

**Form:** DEATH DETAILS CODED

**Form Status:** Not Started

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

**Death Details**

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

**Cause of Death**

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



**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

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

**Site No:** 1006

**Subject No:** 10061245

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

**Form:** DISPOSITION - FOLLOW-UP

**Form Status:** Not Started

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

**Disposition - Follow-Up**

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

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1006

**Subject No:** 10061245

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

**Form:** SUBJECT STATUS

**Form Status:** Data Complete, Verified

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

**Subject Status**

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Jan/26/2021

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

**Site No:** 1006

**Subject No:** 10061245

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

**Form:** CASEBOOK SIGNATURE FORM

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

**Casebook Signature Form**

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

090177e196b72787\Final\Final On: 06-Apr-2021 19:07 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

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

**Site No:** 1006

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject No:** 10061245

**Subject Initials:** ---

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

**Generated Time (GMT):** 06-Apr-2021 15:36

[Audit Trail](#)

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
James Peterson	Approved	Mar-11-2021 17:28:21 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed

**Affidavit:**

By my dated signature below, I, JamesPeterson, 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 Version:** 10-Oct-2020 16:00

**Site No:** 1006

**Subject No:** 10061245

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

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

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

[Back to Form](#)

Item	Date	User	Comment
Form	Dec-10-2020 18:27:31 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [REDACTED] [REDACTED]	Not Applicable

**Header Text:** c4591001

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

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

**Site No:** 1006

**Subject No:** 10061245

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

**Form:** GENERAL MEDICAL HISTORY - Comments

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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Item	Date	User	Comment
Form	Dec-10-2020 18:28:11 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [REDACTED] [REDACTED]	Not Applicable

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

**Site No:** 1006

**Subject No:** 10061245

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

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

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

[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
James Peterson	Approved	Mar-11-2021 17:28:21 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed

**Affidavit:**

By my dated signature below, I, JamesPeterson, 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.

090177e196b72787\Final\Final On: 06-Apr-2021 19:07 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1006

**Subject No:** 10061245

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

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

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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

Date	Location	User	Value	Reason
Dec-10-2020 18:25:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	<b>Data Entry:</b> 06 OCT 2020	Initial Entry

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

Date	Location	User	Value	Reason
Dec-10-2020 18:25:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

090177e196b72787\Final\Final On: 06-Apr-2021 19:07 (GMT)



**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1006

**Subject No:** 10061245

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

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

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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**I. Consent Was:**

Date	Location	User	Value	Reason
Dec-10-2020 18:26:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	<b>Data Entry:</b> OBTAINED Date Written Consent Obtai ned  Dec/10/2020	Initial Entry

090177e196b72787\Final\Final On: 06-Apr-2021 19:07 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1006

**Subject No:** 10061245

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

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

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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**1. Subject ID**

Date	Location	User	Value	Reason
Dec-10-2020 18:25:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 10061245	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Dec-10-2020 18:25:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6) 2005	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Dec-10-2020 18:26:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	<b>Data Entry:</b> MALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Dec-10-2020 18:26:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	<b>Data Entry:</b> NOT HISPANIC OR LATIN O(A) OR OF SPANISH ORI GIN	Initial Entry

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

Date	Location	User	Value	Reason
Dec-10-2020 18:26:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	<b>Data Entry:</b> WHITE	Initial Entry

090177e196b72787\Final\Final On: 06-Apr-2021 19:07 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1006

**Subject No:** 10061245

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

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

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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*1. Date of Visit*

Date	Location	User	Value	Reason
Dec-10-2020 18:27:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	<b>Data Entry:</b> Dec/10/2020	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1006

**Subject No:** 10061245

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

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

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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

Date	Location	User	Value	Reason
Dec-10-2020 18:27:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	<b>Data Entry:</b> Dec/10/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Dec-10-2020 18:27:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Dec-10-2020 18:27:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196b72787\Final\Final On: 06-Apr-2021 19:07 (GMT)

**Header Text:** c4591001

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

**Form Version:** 15-Sep-2020 21:57

**Site No:** 1006

**Subject No:** 10061245

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

**Form:** HIV STATUS - eCRF Audit Trail History

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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***1. Select appropriate response - What is the subject HIV status?***

Date	Location	User	Value	Reason
Dec-10-2020 18:28:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	<b><u>Data Entry:</u></b> The subject is NOT known to be HIV POSITIVE	Initial Entry

**Header Text:** c4591001

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

**Form Version:** 10-Dec-2020 02:29

**Site No:** 1006

**Subject No:** 10061245

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

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

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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**1. Date:**

Date	Location	User	Value	Reason
Dec-10-2020 18:29:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	<b>Data Entry:</b> Dec/10/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Dec-10-2020 18:29:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	<b>Data Entry:</b> 108.6	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Dec-10-2020 18:29:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	<b>Data Entry:</b> LB	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Dec-10-2020 18:29:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	<b>Data Entry:</b> 64.0	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Dec-10-2020 18:29:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	<b>Data Entry:</b> in	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
Dec-10-2020 18:29:01	ACV0PFEINFP6000	auto calc	<b>Data Entry:</b>	Initial Entry

090177e196b72787\Final\Final On: 06-Apr-2021 19:07 (GMT)

**Header Text:** c4591001

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

**Form Version:** 10-Dec-2020 02:29

**Site No:** 1006

**Subject No:** 10061245

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

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

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

(UTC-07:00) Mountain  
Time (US & Canada)

(autocalc) 18.6

**7.a**

Date	Location	User	Value	Reason
Dec-10-2020 18:29:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	<b>Data Entry:</b> Record Identifier: Temperature: 99.2 Temperature Unit: Temperature Location: Cavity:	Initial Entry

**7.a Record Identifier:**

Date	Location	User	Value	Reason
Dec-10-2020 18:29:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	<b>Data Entry:</b> 1	Initial Entry

**7.a Temperature:**

Date	Location	User	Value	Reason
Dec-10-2020 18:29:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	<b>Data Entry:</b> 99.2	Initial Entry

**7.a Unit:**

Date	Location	User	Value	Reason
Dec-10-2020 18:29:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	<b>Data Entry:</b> F	Initial Entry

**7.a Temperature Location:**

Date	Location	User	Value	Reason
Dec-10-2020 18:29:01 (UTC-07:00) Mountain	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196b72787\Final\Final On: 06-Apr-2021 19:07 (GMT)

**Header Text:** c4591001

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

**Form Version:** 10-Dec-2020 02:29

**Site No:** 1006

**Subject No:** 10061245

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

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

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

Time (US & Canada)

(b) (4), (b) (6)

090177e196b72787\Final\Final On: 06-Apr-2021 19:07 (GMT)



**Header Text:** c4591001

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

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

**Site No:** 1006

**Subject No:** 10061245

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

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

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Dec-10-2020 18:29:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	<b>Data Entry:</b> Dec/10/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Dec-10-2020 18:29:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	<b>Data Entry:</b> 21869	Initial Entry

090177e196b72787\Final\Final On: 06-Apr-2021 19:07 (GMT)

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1006**Subject No:** 10061245**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Dec-10-2020 18:29:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Dec-10-2020 18:29:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Dec-11-2020 11:40:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-11-2020 10:26:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-10-2020 18:29:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-10-2020 18:29:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1006

**Subject No:** 10061245

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

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

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

Dec/10/2020

**5.a**

Date	Location	User	Value	Reason
Dec-11-2020 11:40:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u><b>Data Entry:</b></u> <b>Sample ID:</b> BCSY0L	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Dec-11-2020 11:40:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u><b>Data Entry:</b></u> BCSY0L	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Dec-11-2020 11:40:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u><b>Data Entry:</b></u> <b>Sample ID:</b> BCSY0M	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Dec-11-2020 11:40:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u><b>Data Entry:</b></u> BCSY0M	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Dec-11-2020 11:40:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u><b>Data Entry:</b></u> <b>Sample ID:</b> BS8WJM	Initial Entry

090177e196b72787\Final\Final On: 06-Apr-2021 19:07 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1006

**Subject No:** 10061245

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

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

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

**5.c Sample ID**

Date	Location	User	Value	Reason
Dec-11-2020 11:40:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> BS8WJM	Initial Entry

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1006**Subject No:** 10061245**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Dec-10-2020 18:30:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Dec-10-2020 18:30:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Dec-11-2020 11:41:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-11-2020 10:26:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-10-2020 18:30:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-10-2020 18:30:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1006

**Subject No:** 10061245

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

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

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

Dec/10/2020

**5.a**

Date	Location	User	Value	Reason
Dec-11-2020 11:41:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BH24DK	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Dec-11-2020 11:41:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BH24DK	Initial Entry

090177e196b72787\Final\Final On: 06-Apr-2021 19:07 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1006

**Subject No:** 10061245

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

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

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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

Date	Location	User	Value	Reason
Dec-10-2020 18:30:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Dec-10-2020 18:30:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Dec-10-2020 18:30:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Dec-10-2020 18:30:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	<b>Data Entry:</b> Dec/10/2020 12:11	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Dec-10-2020 18:30:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Dec-10-2020 18:30:34	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196b72787\Final\Final On: 06-Apr-2021 19:07 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1006

**Subject No:** 10061245

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

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

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

(UTC-07:00) Mountain  
Time (US & Canada)

(b) (4), (b)  
(6)

LEFT

**7. Route:**

Date	Location	User	Value	Reason
Dec-10-2020 18:30:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Dec-10-2020 18:30:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED O BSERVATION 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
Dec-10-2020 18:30:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

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**Header Text:** c4591001

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

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

**Site No:** 1006

**Subject No:** 10061245

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

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

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Dec-10-2020 18:30:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	<b>Data Entry:</b> YES - REACTOGENICITY E-DIARY COLLECTED FO R THIS SUBJECT	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1006

**Subject No:** 10061245

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

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

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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*1. Date of Visit*

Date	Location	User	Value	Reason
Dec-30-2020 07:45:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/29/2020	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1006

**Subject No:** 10061245

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

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES - eCRF Audit Trail History

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Dec-30-2020 07:45:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Dec-30-2020 07:45:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FE VE R <b>Were fever or systemic sy N</b> <b>mptoms present on the last O</b> <b>day the Subject Diary was</b> <b>completed?:</b>	Initial Entry

**2.a Symptom:**

Date	Location	User	Value	Reason
Dec-30-2020 07:45:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry

**2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Dec-30-2020 07:45:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.b**

Date	Location	User	Value	Reason
Dec-30-2020 07:45:57 (UTC-07:00) Mountain	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FA	Initial Entry

090177e196b72787\Final\Final On: 06-Apr-2021 19:07 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1006

**Subject No:** 10061245

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

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES - eCRF Audit Trail History

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

Time (US & Canada)		(b) (4), (b) (6)	TI GU E  Were fever or systemic sy NO mptoms present on the las t day the Subject Diary w as completed?:	
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**2.b Symptom:**

Date	Location	User	Value	Reason
Dec-30-2020 07:45:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> FATIGUE	Initial Entry

**2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Dec-30-2020 07:45:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

**2.c**

Date	Location	User	Value	Reason
Dec-30-2020 07:45:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: HE AD AC HE  Were fever or systemic sy NO mptoms present on the la st day the Subject Diary was completed?:	Initial Entry

090177e196b72787\Final\Final On: 06-Apr-2021 19:07 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1006

**Subject No:** 10061245

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

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES - eCRF Audit Trail History

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

**2.c Symptom:**

Date	Location	User	Value	Reason
Dec-30-2020 07:45:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> HEADACHE	Initial Entry

**2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Dec-30-2020 07:45:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

**2.d**

Date	Location	User	Value	Reason
Dec-30-2020 07:45:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: CH IL LS Were fever or systemic sy NO mptoms present on the last day the Subject Diary was completed?:	Initial Entry

**2.d Symptom:**

Date	Location	User	Value	Reason
Dec-30-2020 07:45:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> CHILLS	Initial Entry

**2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Dec-30-2020 07:45:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

**2.e**

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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1006

**Subject No:** 10061245

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

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES - eCRF Audit Trail History

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

Date	Location	User	Value	Reason
Dec-30-2020 07:45:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> VO MIT ING  <b>Were fever or systemic sy NO mptoms present on the la st day the Subject Diary was completed?:</b>	Initial Entry

**2.e Symptom:**

Date	Location	User	Value	Reason
Dec-30-2020 07:45:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> VOMITING	Initial Entry

**2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Dec-30-2020 07:45:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.f**

Date	Location	User	Value	Reason
Dec-30-2020 07:45:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> DIA RR HE A  <b>Were fever or systemic sy NO mptoms present on the la st day the Subject Diary was completed?:</b>	Initial Entry

090177e196b72787\Final\Final On: 06-Apr-2021 19:07 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1006

**Subject No:** 10061245

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

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES - eCRF Audit Trail History

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

**2.f Symptom:**

Date	Location	User	Value	Reason
Dec-30-2020 07:45:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u><b>Data Entry:</b></u> DIARRHEA	Initial Entry

**2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Dec-30-2020 07:45:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u><b>Data Entry:</b></u> NO	Initial Entry

**2.g**

Date	Location	User	Value	Reason
Dec-30-2020 07:45:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u><b>Data Entry:</b></u> <b>Symptom::</b> NEW OR WORSE NED MU SCLE PA IN  <b>Were fever or syste NO</b> <b>mic symptoms prese</b> <b>nt on the last day th</b> <b>e Subject Diary was</b> <b>completed?:</b>	Initial Entry

090177e196b72787\Final\Final On: 06-Apr-2021 19:07 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1006

**Subject No:** 10061245

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

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES - eCRF Audit Trail History

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

**2.g Symptom:**

Date	Location	User	Value	Reason
Dec-30-2020 07:45:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NEW OR WORSENER MUSCLE PAIN	Initial Entry

**2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Dec-30-2020 07:45:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

**2.h**

Date	Location	User	Value	Reason
Dec-30-2020 07:45:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <b>Symptom::</b> NEW OR WORSENER JOINT PAIN  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

**2.h Symptom:**

Date	Location	User	Value	Reason
Dec-30-2020 07:45:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NEW OR WORSENER JOINT PAIN	Initial Entry

**2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Dec-30-2020 07:45:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196b72787\Final\Final On: 06-Apr-2021 19:07 (GMT)



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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**Site No:** 1006

**Subject No:** 10061245

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

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES - eCRF Audit Trail History

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

**3. Injection Site Location:**

Date	Location	User	Value	Reason
Dec-30-2020 07:45:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> DELTOID MUSCLE	Initial Entry

**4. Injection Site Body Side:**

Date	Location	User	Value	Reason
Dec-30-2020 07:45:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> LEFT	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Dec-30-2020 07:45:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Injection Site Reaction:: RE DN ESS  Were injection site reactio NO ns present on the last day the Subject Diary was co mpleted?:	Initial Entry

**5.a Injection Site Reaction:**

Date	Location	User	Value	Reason
Dec-30-2020 07:45:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> REDNESS	Initial Entry

**5.a Were injection site reactions present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Dec-30-2020 07:45:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

**5.b**

090177e196b72787\Final\Final On: 06-Apr-2021 19:07 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1006

**Subject No:** 10061245

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

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES - eCRF Audit Trail History

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

Date	Location	User	Value	Reason
Dec-30-2020 07:45:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> SW ELL ING  <b>Were injection site reacti NO ons present on the last da y the Subject Diary was c ompleted?:</b>	Initial Entry

**5.b Injection Site Reaction:**

Date	Location	User	Value	Reason
Dec-30-2020 07:45:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SWELLING	Initial Entry

**5.b Were injection site reactions present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Dec-30-2020 07:45:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Dec-30-2020 07:45:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reactio PAIN A n::</b> T INJE CTION SITE  <b>Were injection site rea NO ctions present on the l ast day the Subject Di ary was completed?:</b>	Initial Entry

090177e196b72787\Final\Final On: 06-Apr-2021 19:07 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1006

**Subject No:** 10061245

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

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES - eCRF Audit Trail History

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

**5.c Injection Site Reaction:**

Date	Location	User	Value	Reason
Dec-30-2020 07:45:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PAIN AT INJECTION SITE	Initial Entry

**5.c Were injection site reactions present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Dec-30-2020 07:45:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form Version:** 10-Dec-2020 02:27**Site No:** 1006**Subject No:** 10061245**Generated By:** (b) (4)**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36[Back to Form](#)**1. Date:**

Date	Location	User	Value	Reason
Dec-30-2020 07:48:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-30-2020 07:48:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Vital Signs Date is not same as Vaccination Date in the same visit. Please review and update as appropriate or clarify.
Dec-30-2020 07:46:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Dec/29/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Dec-30-2020 07:46:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> <b>Record Identifier:</b> 1 : <b>Temperature:</b> 98.6 <b>Temperature Unit</b> F : <b>Temperature Loc</b> ORAL CAV <b>ation::</b> ITY	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Dec-30-2020 07:46:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> 1	Initial Entry

**2.a Temperature:**

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Dec-2020 02:27

**Site No:** 1006

**Subject No:** 10061245

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

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

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

Date	Location	User	Value	Reason
Dec-30-2020 07:46:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 98.6	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Dec-30-2020 07:46:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> F	Initial Entry

**2.a Temperature Location:**

Date	Location	User	Value	Reason
Dec-30-2020 07:46:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> ORAL CAVITY	Initial Entry

090177e196b72787\Final\Final On: 06-Apr-2021 19:07 (GMT)

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1006**Subject No:** 10061245**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Dec-30-2020 07:46:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Dec-30-2020 07:46:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Dec-30-2020 07:47:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-30-2020 07:46:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-30-2020 07:46:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Dec/29/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Dec-30-2020 07:47:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BRL0SH	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1006

**Subject No:** 10061245

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

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

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

**5.a Sample ID**

Date	Location	User	Value	Reason
Dec-30-2020 07:47:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<u><b>Data Entry:</b></u> BRL0SH	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1006

**Subject No:** 10061245

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

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

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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

Date	Location	User	Value	Reason
Dec-30-2020 07:48:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Dec-30-2020 07:48:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Dec-30-2020 07:48:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Dec-30-2020 07:48:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Dec-30-2020 07:48:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-30-2020 07:48:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/29/2020 11:37	Transcription Error
Dec-30-2020 07:48:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Dose Date is not equal to Date of Visit 29/Dec/2020 of the corresponding Visit. Please review



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1006

**Subject No:** 10061245

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

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

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

				and update as appropriate.
Dec-30-2020 07:48:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Dose Date, 30/Dec/2020 11:37 is a future date relative to when it was entered on 30/Dec/2020 07:48. Please correct.
Dec-30-2020 07:48:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/30/2020 11:37	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Dec-30-2020 07:48:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Dec-30-2020 07:48:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Dec-30-2020 07:48:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Dec-30-2020 07:48:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED O BSERVATION PERIOD	Initial Entry

090177e196b72787\Final\On: 06-Apr-2021 19:07 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1006

**Subject No:** 10061245

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

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

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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

Date	Location	User	Value	Reason
Dec-30-2020 07:48:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<u>Data Entry:</u> YES	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1006

**Subject No:** 10061245

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

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

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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**I. Date of Visit**

Date	Location	User	Value	Reason
Jan-27-2021 13:33:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Clo sed	Auto closed by Validation Check: VC_SV001_08
Jan-27-2021 09:20:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: An swere d	Updated EOT CRF.
Jan-27-2021 01:11:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Op ened	DMW7007250;Visit 3 Date is entered, but Disposition - Treatment form is not completed. Please review and update as appropriate.
Jan-26-2021 16:11:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : Jan/26 /2021	Initial Entry

090177e196b72787\Final\Final On: 06-Apr-2021 19:07 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1006

**Subject No:** 10061245

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

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES - eCRF Audit Trail History

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Jan-26-2021 16:12:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Jan-26-2021 16:12:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FE VE R <b>Were fever or systemic sy N</b> <b>mptoms present on the last O</b> <b>day the Subject Diary was</b> <b>completed?:</b>	Initial Entry

**2.a Symptom:**

Date	Location	User	Value	Reason
Jan-26-2021 16:12:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry

**2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Jan-26-2021 16:12:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.b**

Date	Location	User	Value	Reason
Jan-26-2021 16:12:17 (UTC-07:00) Mountain	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FA	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1006

**Subject No:** 10061245

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

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES - eCRF Audit Trail History

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

Time (US & Canada)		(b) (4), (b) (6)	TI GU E  Were fever or systemic sy NO mptoms present on the las t day the Subject Diary w as completed?:	
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**2.b Symptom:**

Date	Location	User	Value	Reason
Jan-26-2021 16:12:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> FATIGUE	Initial Entry

**2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Jan-26-2021 16:12:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

**2.c**

Date	Location	User	Value	Reason
Jan-26-2021 16:12:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: HE AD AC HE  Were fever or systemic sy NO mptoms present on the la st day the Subject Diary was completed?:	Initial Entry

090177e196b72787\Final\Final On: 06-Apr-2021 19:07 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1006

**Subject No:** 10061245

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

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES - eCRF Audit Trail History

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

**2.c Symptom:**

Date	Location	User	Value	Reason
Jan-26-2021 16:12:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> HEADACHE	Initial Entry

**2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Jan-26-2021 16:12:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

**2.d**

Date	Location	User	Value	Reason
Jan-26-2021 16:12:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: CH IL LS Were fever or systemic sy NO mptoms present on the las t day the Subject Diary wa s completed?:	Initial Entry

**2.d Symptom:**

Date	Location	User	Value	Reason
Jan-26-2021 16:12:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> CHILLS	Initial Entry

**2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Jan-26-2021 16:12:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

**2.e**

090177e196b72787\Final\Final On: 06-Apr-2021 19:07 (GMT)

**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form Version:** 10-Dec-2020 02:30**Site No:** 1006**Subject No:** 10061245**Generated By:** (b) (4)**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36

Date	Location	User	Value	Reason
Jan-26-2021 16:12:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> <b>Symptom::</b> VO MIT ING  <b>Were fever or systemic sy NO mptoms present on the la st day the Subject Diary was completed?:</b>	Initial Entry

**2.e Symptom:**

Date	Location	User	Value	Reason
Jan-26-2021 16:12:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> VOMITING	Initial Entry

**2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Jan-26-2021 16:12:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> NO	Initial Entry

**2.f**

Date	Location	User	Value	Reason
Jan-26-2021 16:12:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> <b>Symptom::</b> DIA RR HE A  <b>Were fever or systemic sy NO mptoms present on the la st day the Subject Diary was completed?:</b>	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1006

**Subject No:** 10061245

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

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES - eCRF Audit Trail History

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

**2.f Symptom:**

Date	Location	User	Value	Reason
Jan-26-2021 16:12:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u><b>Data Entry:</b></u> DIARRHEA	Initial Entry

**2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Jan-26-2021 16:12:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u><b>Data Entry:</b></u> NO	Initial Entry

**2.g**

Date	Location	User	Value	Reason
Jan-26-2021 16:12:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u><b>Data Entry:</b></u> <b>Symptom::</b> NEW OR WORSE NED MU SCLE PA IN  <b>Were fever or syste NO</b> <b>mic symptoms prese</b> <b>nt on the last day th</b> <b>e Subject Diary was</b> <b>completed?:</b>	Initial Entry



**Header Text:** c4591001

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

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

**Site No:** 1006

**Subject No:** 10061245

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

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES - eCRF Audit Trail History

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

**2.g Symptom:**

Date	Location	User	Value	Reason
Jan-26-2021 16:12:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSE ENHANCED MUSC LE PAIN	Initial Entry

**2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Jan-26-2021 16:12:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.h**

Date	Location	User	Value	Reason
Jan-26-2021 16:12:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSE ENHANCED JOI INT PAIN  <b>Were fever or syste mic symptoms prese nt on the last day the Subject Diary was co mpleted?:</b> NO	Initial Entry

**2.h Symptom:**

Date	Location	User	Value	Reason
Jan-26-2021 16:12:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSE ENHANCED JOINT P AIN	Initial Entry

**2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Jan-26-2021 16:12:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form Version:** 10-Dec-2020 02:30**Site No:** 1006**Subject No:** 10061245**Generated By:** (b) (4)**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36**3. Injection Site Location:**

Date	Location	User	Value	Reason
Jan-26-2021 16:12:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**4. Injection Site Body Side:**

Date	Location	User	Value	Reason
Jan-26-2021 16:12:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jan-26-2021 16:12:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> RE DN ESS  <b>Were injection site reactio NO ns present on the last day the Subject Diary was co mpleted?:</b>	Initial Entry

**5.a Injection Site Reaction:**

Date	Location	User	Value	Reason
Jan-26-2021 16:12:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> REDNESS	Initial Entry

**5.a Were injection site reactions present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Jan-26-2021 16:12:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**5.b**

**Header Text:** c4591001

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

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

**Site No:** 1006

**Subject No:** 10061245

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

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES - eCRF Audit Trail History

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

Date	Location	User	Value	Reason
Jan-26-2021 16:12:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> <b>Injection Site Reaction::</b> SW ELL ING  <b>Were injection site reacti NO ons present on the last da y the Subject Diary was c ompleted?:</b>	Initial Entry

**5.b Injection Site Reaction:**

Date	Location	User	Value	Reason
Jan-26-2021 16:12:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> SWELLING	Initial Entry

**5.b Were injection site reactions present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Jan-26-2021 16:12:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> NO	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Jan-26-2021 16:12:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> <b>Injection Site Reactio PAIN A n::</b> T INJE CTION SITE  <b>Were injection site rea NO ctions present on the l ast day the Subject Di ary was completed?:</b>	Initial Entry

090177e196b72787\Final\Final On: 06-Apr-2021 19:07 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1006

**Subject No:** 10061245

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

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES - eCRF Audit Trail History

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

**5.c Injection Site Reaction:**

Date	Location	User	Value	Reason
Jan-26-2021 16:12:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> PAIN AT INJECTION SITE	Initial Entry

**5.c Were injection site reactions present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Jan-26-2021 16:12:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> NO	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1006

**Subject No:** 10061245

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

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

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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**1. Data Origin**

Date	Location	User	Value	Reason
Jan-26-2021 16:12:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-26-2021 16:12:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-29-2021 10:47:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-28-2021 02:30:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-26-2021 16:12:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-26-2021 16:12:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Jan/26/2021	Initial Entry

090177e196b72787\Final\Final On: 06-Apr-2021 19:07 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1006

**Subject No:** 10061245

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

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

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

**5.a**

Date	Location	User	Value	Reason
Jan-29-2021 10:47:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BRBMW0	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Jan-29-2021 10:47:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRBMW0	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Jan-29-2021 10:47:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BRBMW1	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Jan-29-2021 10:47:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRBMW1	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Jan-29-2021 10:48:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BJ7MNZ	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Jan-29-2021 10:48:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BJ7MNZ	Initial Entry

090177e196b72787\Final\Final On: 06-Apr-2021 19:07 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1006

**Subject No:** 10061245

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

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

**Form Status:**

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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Date	Location	User	Value	Reason
Dec-30-2020 07:39:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1006

**Subject No:** 10061245

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

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

**Form Status:**

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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Date	Location	User	Value	Reason
Dec-30-2020 07:40:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Form Created	



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1006

**Subject No:** 10061245

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

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

**Form Status:** Data Complete, Frozen

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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**1. Category:**

Date	Location	User	Value	Reason
Dec-30-2020 07:39:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Dec-30-2020 07:39:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**3. Adverse Event:**

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

Date	Location	User	Value	Reason
Dec-30-2020 07:39:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Hives face	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Dec-30-2020 07:39:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/12/2020 UNK:UNK	Initial Entry

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

Date	Location	User	Value	Reason
Feb-02-2021 18:13:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Feb-01-2021 16:17:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	corrct as entered, confirmed at visit 2
Jan-27-2021 18:29:40	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	ClinQuery: Please

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1006**Subject No:** 10061245**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36

(UTC-07:00) Mountain Time (US & Canada)		(b) (4), (b) (6)		confirm end date of AE Hives face as started 2 days after vaccination 1 and resolved after vaccination 2.
Jan-27-2021 06:55:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Jan-26-2021 16:13:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Jan-26-2021 16:13:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Dec/31/2020 UNK:UNK	New Information
Jan-18-2021 14:33:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	clinical: pls confirm ongoing or update end date. Thanks
Jan-18-2021 11:17:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	clinical: reissued
Jan-04-2021 10:52:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	clinical: pls confirm ongoing or update end date. Thanks
Dec-30-2020 07:39:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Dec-30-2020 07:39:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

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

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1006**Subject No:** 10061245**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36***If Yes, NOTIFY PFIZER IMMEDIATELY.******Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).***

Date	Location	User	Value	Reason
Dec-30-2020 07:39:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***8. Is this adverse event the result of a study Medication Error?******If Yes, record the type of medication error on the Medication Error Log.***

Date	Location	User	Value	Reason
Dec-30-2020 07:39:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Dec-30-2020 07:39:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RELATED	Initial Entry

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

Date	Location	User	Value	Reason
Dec-30-2020 07:39:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

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

Date	Location	User	Value	Reason
Dec-30-2020 07:39:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

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

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1006**Subject No:** 10061245**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36

Date	Location	User	Value	Reason
Dec-30-2020 07:39:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Jan-26-2021 16:14:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-26-2021 16:14:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	New Information
Jan-26-2021 16:13:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Hives face: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Dec-30-2020 07:39:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERING/RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Dec-30-2020 07:39:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1006

**Subject No:** 10061245

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

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

**Form Status:** Data Complete, Frozen

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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**1. Category:**

Date	Location	User	Value	Reason
Dec-30-2020 07:40:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Dec-30-2020 07:40:07 (UTC-07:00) Mountain 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
Dec-30-2020 07:40:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Hives trunk	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Dec-30-2020 07:40:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/12/2020 UNK:UNK	Initial Entry

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

Date	Location	User	Value	Reason
Dec-30-2020 07:40:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Dec/15/2020 UNK:UNK	Initial Entry

**6. Toxicity Grade:**

090177e196b72787\Final\Final On: 06-Apr-2021 19:07 (GMT)

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1006**Subject No:** 10061245**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36

Date	Location	User	Value	Reason
Dec-30-2020 07:40:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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).*

Date	Location	User	Value	Reason
Dec-30-2020 07:40:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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
Dec-30-2020 07:40:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Dec-30-2020 07:40:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RELATED	Initial Entry

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

Date	Location	User	Value	Reason
Dec-30-2020 07:40:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1006

**Subject No:** 10061245

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

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

**Form Status:** Data Complete, Frozen

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

Date	Location	User	Value	Reason
Dec-30-2020 07:40:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u><b>Data Entry:</b></u> YES	Initial Entry

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

Date	Location	User	Value	Reason
Dec-30-2020 07:40:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u><b>Data Entry:</b></u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Dec-30-2020 07:40:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u><b>Data Entry:</b></u> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Dec-30-2020 07:40:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u><b>Data Entry:</b></u> NO	Initial Entry

090177e196b72787\Final\Final On: 06-Apr-2021 19:07 (GMT)

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

**Form Version:** 10-Dec-2020 02:29

**Site No:** 1006

**Subject No:** 10061245

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

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

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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

Date	Location	User	Value	Reason
Jan-27-2021 09:20:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/26/2021	Initial Entry
Dec-17-2020 17:04:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information
Dec-10-2020 18:31:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/10/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Jan-27-2021 09:20:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry
Dec-17-2020 17:04:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Changed Information
Dec-10-2020 18:31:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Jan-27-2021 09:20:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry
Dec-18-2020 06:25:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Closed	Response satisfies query



**Header Text:** c4591001**Visit:** End of Treatment - Unscheduled**Form Version:** 10-Dec-2020 02:29**Site No:** 1006**Subject No:** 10061245**Generated By:** (b) (4)**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36

Dec-17-2020 17:04:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Dec-17-2020 17:04:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b>	Changed Information
Dec-14-2020 10:39:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4) [REDACTED]	Query 1: Opened	CLINQUERY: EOT page is entered and status 'completed' captured but subject has only attended V1. EOT 'Completed' only applies after both doses of study vax and visit 3 when treatment phase is completed. Please review and update as appropriate
Dec-10-2020 18:31:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	<b>Data Entry:</b> COMPLETED	Initial Entry

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1006

**Subject No:** 10061245

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

**Form:** SUBJECT STATUS - eCRF Audit Trail History

**Form Status:** Data Complete, Verified

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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**1. Subject Status**

Date	Location	User	Value	Reason
Jan-27-2021 09:20:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Dec-17-2020 17:04:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Changed Information
Dec-10-2020 18:31:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Dec-10-2020 18:29:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Dec-10-2020 18:27:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

**2. Subject Status Date**

Date	Location	User	Value	Reason
Jan-27-2021 09:20:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Jan/26/2021	Initial Entry
Dec-17-2020 17:04:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Dec/10/2020	Changed Information
Dec-17-2020 17:04:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Dec/10/2020	Changed Information
Dec-10-2020 18:31:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Dec/10/2020	Initial Entry
Dec-10-2020 18:29:29 (UTC-07:00) Mountain	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Dec/10/2020	Initial Entry

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1006

**Subject No:** 10061245

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

**Form:** SUBJECT STATUS - eCRF Audit Trail History

**Form Status:** Data Complete, Verified

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

Time (US & Canada)				
Dec-10-2020 18:27:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Dec/10/2020	Initial Entry

090177e196b72787\Final\Final On: 06-Apr-2021 19:07 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

**Site No:** 1006

**Subject No:** 10061245

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

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

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

**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic

**Subject Initials:** ---

**Generated Time (GMT):** 06-Apr-2021 15:36

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*I. Casebook Signature*

Date	Location	User	Value	Reason
Mar-11-2021 17:28:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	James Peterson (b) (4)	<b>Data Entry:</b> Click Here to Enable	Initial Entry