

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1009

**Subject No:** 10091342

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

**Form:** COHORT SELECTION

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

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

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

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1009

**Subject No:** 10091342

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

**Form:** MAIN INFORMED CONSENT

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

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Dec/14/2020
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**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1009

**Subject No:** 10091342

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

**Form:** DEMOGRAPHY

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

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[10091342]
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:	

090177e196ae30a1\Final\Final On: 01-Apr-2021 04:10 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091342

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

**Form:** DATE OF VISIT

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

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Dec/14/2020
2.	Erroneous Visit	

**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091342

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

**Form:** INCLUSION/EXCLUSION CRITERIA

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

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[Form Comments](#)

**Inclusion Criteria Not Met**

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

**Exclusion Criteria Met**

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

**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091342

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

**Form:** DISPOSITION - SCREENING

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

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**eCRF Audit Trail History**

**Disposition - Screening**

1.	Date of Completion/Discontinuation /Death	Dec/14/2020
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:** 1009

**Subject No:** 10091342

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

**Form:** GENERAL MEDICAL HISTORY

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

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[eczema, bilateral hands]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Ketamine allergy]
	Start Date:	UNK/UNK/2007
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Allergic Rhinitis]
	Start Date:	UNK/UNK/2007
	Ongoing:	YES

090177e196ae30a1\Final\Final On: 01-Apr-2021 04:10 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091342

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

**Form:** HIV STATUS

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

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[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:** 1009**Subject No:** 10091342**Generated By:** (b) (4)**Form:** VITAL SIGNS - BASELINE**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12**eCRF Audit Trail History****Vital Signs**

1.	Date:	Dec/14/2020
2.	Weight:	[135.6]
3.	Unit:	LB
4.	Height:	[69.0]
5.	Unit:	in
6.	Body Mass Index:	[20.0]

**Vital Signs Details**

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

**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091342

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

**Form:** RANDOMIZATION

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

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Dec/14/2020
2.	Randomization Number:	[22452]
3.	Randomization Group:	[ ]

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South**Subject No:** 10091342**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Dec/14/2020
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	[BR5BJB]
5.b	Sample ID	[BR5BJC]
5.c	Sample ID	[BSJ3MK]

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject No:** 10091342**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Dec/14/2020
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	[BGH023]
-----	-----------	----------

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 10-Dec-2020 02:26**Site No:** 1009**Subject No:** 10091342**Generated By:** (b) (4)**Form:** VACCINATION**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12**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/14/2020 18:25
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:** 1009

**Subject No:** 10091342

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

**Form:** REACTOGENICITY DIARY

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

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

**Reactogenicity Diary**

1.	Select appropriate response - Reactogenicity diary collection	YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT
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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1009

**Subject No:** 10091342

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

**Form:** DATE OF VISIT

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

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

**Date of Visit**

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

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**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Frozen, Verified**Site No:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject No:** 10091342**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12[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



**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Frozen, Verified**Site No:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South**Subject No:** 10091342**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12

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

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1009

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South

**Subject No:** 10091342

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

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

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1009

**Subject No:** 10091342

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

**Form:** VITAL SIGNS - TEMP

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

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Jan/4/2021
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**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[98.1]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae30a1\Final\Final On: 01-Apr-2021 04:10 (GMT)

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject No:** 10091342**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12[eCRF Audit Trail History](#)**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BR9F6V]
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**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form Version:** 10-Dec-2020 02:26**Site No:** 1009**Subject No:** 10091342**Generated By:** (b) (4)**Form:** VACCINATION**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12**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:	Jan/4/2021 17:11
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:** V3\_MONTH1\_POSTVAX2\_L

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

**Site No:** 1009

**Subject No:** 10091342

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

**Form:** DATE OF VISIT

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

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

**Date of Visit**

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

**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:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject No:** 10091342**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12[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

**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:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject No:** 10091342**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12

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



**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091342

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

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

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

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

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

090177e196ae30a1\Final\Final On: 01-Apr-2021 04:10 (GMT)

**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject No:** 10091342**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Feb/5/2021
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	[BR61Y8]
5.b	Sample ID	[BR61Y9]
5.c	Sample ID	[BSJ48W]

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1009

**Subject No:** 10091342

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**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:** 1009**Subject No:** 10091342**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY**Form Status:** Not Started**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12**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:** 1009

**Subject No:** 10091342

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001**Visit:** V5\_MONTH12\_L**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South**Subject No:** 10091342**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12**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:** 1009

**Subject No:** 10091342

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

090177e196ae30a1\Final\Final On: 01-Apr-2021 04:10 (GMT)

**Header Text:** c4591001**Visit:** V6\_MONTH24\_L**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South**Subject No:** 10091342**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

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

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

**Site No:** 1009

**Subject No:** 10091342

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

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

**Form Status:** Not Started

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

090177e196ae30a1\Final\Final On: 01-Apr-2021 04:10 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL - New  
Unscheduled Visit**Form Version:** 20-Feb-2021 02:17**Site No:** 1009**Subject No:** 10091342**Generated By:** (b) (4)**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19**Form Status:** Not Started**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12**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 Version:** 22-Apr-2020 21:03**Site No:** 1009**Subject No:** 10091342**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB SELF**Form Status:** Not Started**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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**Header Text:** c4591001**Visit:** POT\_COVID\_ILL - New  
Unscheduled Visit**Form Version:** 22-Apr-2020 21:03**Site No:** 1009**Subject No:** 10091342**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB**Form Status:** Not Started**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091342

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

**Form:** HEALTH CARE UTILIZATION

**Form Status:** Not Started

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**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?	
----	--	--

090177e196ae30a1\Final\Final On: 01-Apr-2021 04:10 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091342

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

**Form:** ILLNESS DETAILS

**Form Status:** Not Started

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**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:** 1009

**Subject No:** 10091342

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

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

**Form Status:** Not Started

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**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:** 1009**Subject No:** 10091342**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY**Form Status:** Not Started**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12**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\_REPEAT\_SWAB -  
New Unscheduled Visit

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

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

**Form Status:** Not Started

**Site No:** 1009

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South

**Subject No:** 10091342

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Repeat Swab**

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

090177e196ae30a1\Final\Final On: 01-Apr-2021 04:10 (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:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South**Subject No:** 10091342**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12**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:** Logs

**Form:** ADVERSE EVENT REPORT

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

**Site No:** 1009

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject No:** 10091342

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	swollen cervical lymph nodes bilateral	Jan/31/2021 UNK:UNK	NO End Date Time:  Feb/2/2021 UNK: UNK	<a href="#">Repeating Pages</a>

090177e196ae30a1\Final\Final On: 01-Apr-2021 04:10 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1009

**Subject No:** 10091342

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

### Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[swollen cervical lymph nodes bilateral]
4.	Start Date Time:	Jan/31/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/2/2021 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

090177e196ae30a1\Final\Final On: 01-Apr-2021 04:10 (GMT)

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1009**Subject No:** 10091342**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, Frozen**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12

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:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [unknown]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
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:** 1009

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject No:** 10091342

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1009

**Subject No:** 10091342

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

**Form:** MEDICATION ERROR

**Form Status:** Not Started

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[Back to Form](#)

**Medication Error**

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

090177e196ae30a1\Final\Final On: 01-Apr-2021 04:10 (GMT)

**Header Text:** c4591001

**Visit:** Logs

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

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

**Site No:** 1009

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South

**Subject No:** 10091342

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

#	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:** 1009

**Subject No:** 10091342

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

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

**Form Status:** Not Started

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[Back to Form](#)

**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:** 1009

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject No:** 10091342

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

#	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:** 1009

**Subject No:** 10091342

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

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Status:** Not Started

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[Back to Form](#)

**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?	

090177e196ae30a1\Final\Final On: 01-Apr-2021 04:10 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

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

**Site No:** 1009

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject No:** 10091342

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1009

**Subject No:** 10091342

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

**Form:** RADIATION TREATMENT

**Form Status:** Not Started

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[Back to Form](#)

**Radiation Treatment**

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

090177e196ae30a1\Final\Final On: 01-Apr-2021 04:10 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

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

**Site No:** 1009

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject No:** 10091342

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

#	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:** 1009

**Subject No:** 10091342

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

**Form:** TRANSFUSIONS

**Form Status:** Not Started

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[Back to Form](#)

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

090177e196ae30a1\Final\Final On: 01-Apr-2021 04:10 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned - New Unscheduled Visit

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1009

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject No:** 10091342

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	



**Header Text:** c4591001

**Visit:** Unplanned - New Unscheduled Visit

**Form:** UNPLANNED VISIT

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

**Form Status:** Not Started

**Site No:** 1009

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject No:** 10091342

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

**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:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South**Subject No:** 10091342**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12**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:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South**Subject No:** 10091342**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12**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:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South**Subject No:** 10091342**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12**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 Version:** 10-Oct-2020 15:57

**Site No:** 1009

**Subject No:** 10091342

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

**Form:** CONTACT OUTCOME - MONTH 1

**Form Status:** Not Started

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

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

**Site No:** 1009

**Subject No:** 10091342

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

**Form:** CONTACT OUTCOME - MONTH 6

**Form Status:** Not Started

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**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:** 1009

**Subject No:** 10091342

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

090177e196ae30a1\Final\Final On: 01-Apr-2021 04:10 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091342

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

**Form:** INFORMED CONSENT - ASYMPTOMATIC  
SURVEILLANCE

**Form Status:** Not Started

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**Informed Consent - Asymptomatic Surveillance**

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



**Header Text:** c4591001**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled**Form Version:** 22-Apr-2020 21:03**Site No:** 1009**Subject No:** 10091342**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY**Form Status:** Not Started**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12**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:** V201\_SURVEIL\_CONSENT -  
Unscheduled**Form Version:** 22-Apr-2020 21:03**Site No:** 1009**Subject No:** 10091342**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB**Form Status:** Not Started**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12**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:** End of Treatment - Unscheduled

**Form:** DISPOSITION - TREATMENT

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

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

**Site No:** 1009

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject No:** 10091342

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation/Death :	Feb/5/2021
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

090177e196ae30a1\Final\Final On: 01-Apr-2021 04:10 (GMT)

**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:** 1009

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South

**Subject No:** 10091342

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

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

**Form:** FURTHER VACCINATION CONFIRMATION

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

**Form Status:** Not Started

**Site No:** 1009

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South

**Subject No:** 10091342

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

**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:** 1009

**Subject No:** 10091342

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

**Form:** TREATMENT UNBLINDED

**Form Status:** Not Started

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**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:** 1009

**Subject No:** 10091342

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

**Form:** WITHDRAWAL OF CONSENT

**Form Status:** Not Started

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**Withdrawal Of Consent**

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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1009

**Subject No:** 10091342

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

**Form:** DEATH DETAILS CODED

**Form Status:** Not Started

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

#### 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:** 1009

**Subject No:** 10091342

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

**Form:** DISPOSITION - FOLLOW-UP

**Form Status:** Not Started

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**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:** 1009

**Subject No:** 10091342

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

**Form:** SUBJECT STATUS

**Form Status:** Data Complete, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

**Subject Status**

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Feb/5/2021

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

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

**Site No:** 1009

**Subject No:** 10091342

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

**Form:** CASEBOOK SIGNATURE FORM

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

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

**Casebook Signature Form**

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

090177e196ae30a1\Final\Final On: 01-Apr-2021 04:10 (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:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South**Subject No:** 10091342**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12[Audit Trail](#)

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
Shane Christensen	Approved	Mar-11-2021 22:19:40 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed

**Affidavit:**

By my dated signature below, I, ShaneChristensen, 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:** 1009

**Subject No:** 10091342

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

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

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

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[Back to Form](#)

Item	Date	User	Comment
Form	Dec-15-2020 07:59:09 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Done

**Header Text:** c4591001**Visit:** Investigator Signature -  
Unscheduled**Form:** CASEBOOK SIGNATURE FORM - Signature History**Form Version:** 22-Apr-2020 21:04**Form Status:** Data Complete, Signed, Verified**Site No:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South**Subject No:** 10091342**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12[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
Shane Christensen	Approved	Mar-11-2021 22:19:40 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed

**Affidavit:**

By my dated signature below, I, ShaneChristensen, 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:** COHORT\_SELECTION

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

**Site No:** 1009

**Subject No:** 10091342

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

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

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

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[Back to Form](#)

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

Date	Location	User	Value	Reason
Dec-15-2020 07:58:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 01 DEC 2020	Initial Entry

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

Date	Location	User	Value	Reason
Dec-15-2020 07:58:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

090177e196ae30a1\Final\Final On: 01-Apr-2021 04:10 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1009

**Subject No:** 10091342

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

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

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

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[Back to Form](#)

**1. Consent Was:**

Date	Location	User	Value	Reason
Dec-15-2020 07:58:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Dec/14/2020	Initial Entry



**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1009

**Subject No:** 10091342

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

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

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

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[Back to Form](#)

**1. Subject ID**

Date	Location	User	Value	Reason
Dec-15-2020 07:58:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 10091342	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Dec-15-2020 07:58:05 (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-15-2020 07:58:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> MALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Dec-15-2020 07:58:51 (UTC-07:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT HISPANIC OR LATI NO(A) OR OF SPANISH	Initial Entry

090177e196ae30a1\Final\Final On: 01-Apr-2021 04:10 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1009

**Subject No:** 10091342

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

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

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

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

Mountain Time (US  
& Canada)

ORIGIN

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

Date	Location	User	Value	Reason
Dec-15-2020 07:58:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> WHITE	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091342

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

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

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

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[Back to Form](#)

***1. Date of Visit***

Date	Location	User	Value	Reason
Dec-15-2020 07:59:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/14/2020	Initial Entry

090177e196ae30a1\Final\Final On: 01-Apr-2021 04:10 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091342

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

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

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

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[Back to Form](#)

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

Date	Location	User	Value	Reason
Dec-15-2020 07:59:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/14/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Dec-15-2020 07:59:22 (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-15-2020 07:59:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae30a1\Final\Final On: 01-Apr-2021 04:10 (GMT)

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1009**Subject No:** 10091342**Generated By:** (b) (4)**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12[Back to Form](#)**1.a**

Date	Location	User	Value	Reason
Dec-15-2020 07:59:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Nu</b> 1 <b>mber:</b> <b>Medical Hist</b> eczema, bila <b>ory Term:</b> teral hands <b>Start Date:</b> UNK/UNK/ 2018 <b>Ongoing:</b> YES	Initial Entry

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

Date	Location	User	Value	Reason
Dec-15-2020 07:59:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

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

Date	Location	User	Value	Reason
Dec-15-2020 07:59:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> eczema, bilateral hands	Initial Entry

**1.a Start Date:**

**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091342

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

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

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

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

Date	Location	User	Value	Reason
Dec-15-2020 07:59:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2018	Initial Entry

**1.a Ongoing:**

Date	Location	User	Value	Reason
Dec-15-2020 07:59:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**1.b**

Date	Location	User	Value	Reason
Jan-05-2021 11:14:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Line/MH Nu</b> 2 <b>mber:</b> <b>Medical Hist</b> Ketamine <b>ory Term:</b> allergy <b>Start Date:</b> UNK/UN K/2007 <b>Ongoing:</b> YES	Transcription Error
Jan-04-2021 16:49:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH N</b> 2 <b>umber:</b> <b>Medical Hi</b> Ketamine a <b>story Term</b> llergy, apne : a	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091342

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

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

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

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

			<b>Start Date:</b> UNK/UNK /2007	
			<b>Ongoing:</b> YES	

**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091342

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

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

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

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

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

Date	Location	User	Value	Reason
Jan-04-2021 16:49:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

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

Date	Location	User	Value	Reason
Jan-05-2021 13:50:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.
Jan-05-2021 11:14:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Jan-05-2021 11:14:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Ketamine allergy	Transcription Error
Jan-05-2021 01:39:47 (UTC-07:00) Mountain	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Multiple concepts in the term KETAMINE

090177e196ae30a1\Final\Final On: 01-Apr-2021 04:10 (GMT)



**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1009**Subject No:** 10091342**Generated By:** (b) (4)**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12

Time (US & Canada)				ALLERGY, APNEA. Split the term into KETAMINE ALLERGY and APNEA and report as 2 separate entries. Thank you.
Jan-04-2021 16:49:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (b) (4)	<b>Data Entry:</b> Keta mine allergy, apnea	Initial Entry

**1.b Start Date:**

Date	Location	User	Value	Reason
Jan-04-2021 16:49:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (b) (4)	<b>Data Entry:</b> UNK/UNK/2007	Initial Entry

**1.b Ongoing:**

Date	Location	User	Value	Reason
Jan-04-2021 16:49:05 (UTC-07:00)	ACV0PFEINFP6000	Madison Ellis (b) (4)	<b>Data Entry:</b> YES	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091342

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

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

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

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

Mountain Time (US  
& Canada)

*I.c*

Date	Location	User	Value	Reason
Jan-04-2021 16:50:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 3 <b>Medical History Term:</b> Allergic Rhinitis <b>Start Date:</b> UNK/UNK/2007 <b>Ongoing:</b> YES	Initial Entry

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject No:** 10091342**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12***I.c Line/MH Number:***

Date	Location	User	Value	Reason
Jan-04-2021 16:50:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

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

Date	Location	User	Value	Reason
Jan-04-2021 16:50:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (b) (4)	<b>Data Entry:</b> Allergic Rhinitis	Initial Entry

***I.c Start Date:***

Date	Location	User	Value	Reason
Jan-04-2021 16:50:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (b) (4)	<b>Data Entry:</b> UNK/UNK/2007	Initial Entry

***I.c Ongoing:***

Date	Location	User	Value	Reason
Jan-04-2021 16:50:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (b) (4)	<b>Data Entry:</b> YES	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091342

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

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

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

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[Back to Form](#)

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

Date	Location	User	Value	Reason
Dec-15-2020 07:59:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</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:** 1009

**Subject No:** 10091342

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

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

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

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[Back to Form](#)

**1. Date:**

Date	Location	User	Value	Reason
Dec-15-2020 08:00:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/14/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Dec-15-2020 08:00:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 135.6	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Dec-15-2020 08:00:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LB	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Dec-15-2020 08:00:23 (UTC-07:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 69.0	Initial Entry

090177e196ae30a1\Final\Final On: 01-Apr-2021 04:10 (GMT)

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 10-Dec-2020 02:29**Site No:** 1009**Subject No:** 10091342**Generated By:** (b) (4)**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12Mountain Time (US  
& Canada)**5. Unit:**

Date	Location	User	Value	Reason
Dec-15-2020 08:00:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> in	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
Dec-15-2020 08:00:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 20.0	Initial Entry

**7.a**

Date	Location	User	Value	Reason
Dec-15-2020 08:00:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> <b>Temperature:</b> 98.0 <b>Temperature</b> F <b>Unit:</b> <b>Temperature</b> ORAL C <b>Location::</b> AVITY	Initial Entry

**7.a Record Identifier:**

Date	Location	User	Value	Reason
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**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 10-Dec-2020 02:29**Site No:** 1009**Subject No:** 10091342**Generated By:** (b) (4)**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12

Dec-15-2020 08:00:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry
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**7.a Temperature:**

Date	Location	User	Value	Reason
Dec-15-2020 08:00:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 98.0	Initial Entry

**7.a Unit:**

Date	Location	User	Value	Reason
Dec-15-2020 08:00:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> F	Initial Entry

**7.a Temperature Location:**

Date	Location	User	Value	Reason
Dec-15-2020 08:00:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091342

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

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

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

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[Back to Form](#)

**1. Randomization Date :**

Date	Location	User	Value	Reason
Dec-15-2020 08:00:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/14/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Dec-15-2020 08:00:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 22452	Initial Entry



**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091342

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

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

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

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[Back to Form](#)

**1. Data Origin**

Date	Location	User	Value	Reason
Dec-15-2020 08:00:45 (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-15-2020 08:00:45 (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-15-2020 08:02:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-15-2020 08:00:45 (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

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South**Subject No:** 10091342**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12

				correct as appropriate.
Dec-15-2020 08:00:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Dec/14/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Dec-15-2020 08:02:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BR5BJB	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Dec-15-2020 08:02:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR5BJB	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Dec-15-2020 08:02:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BR5BJC	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091342

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

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

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

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**5.b Sample ID**

Date	Location	User	Value	Reason
Dec-15-2020 08:02:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR5BJC	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Dec-15-2020 08:02:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BSJ3MK	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Dec-15-2020 08:02:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BSJ3MK	Initial Entry

090177e196ae30a1\Final\Final On: 01-Apr-2021 04:10 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091342

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

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

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

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[Back to Form](#)

**1. Data Origin**

Date	Location	User	Value	Reason
Dec-15-2020 08:00:53 (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-15-2020 08:00:53 (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-15-2020 08:03:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-15-2020 08:00:53 (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

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South**Subject No:** 10091342**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12

				correct as appropriate.
Dec-15-2020 08:00:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Dec/14/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Dec-15-2020 08:03:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BGH023	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Dec-15-2020 08:03:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BGH023	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091342

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

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

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

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[Back to Form](#)

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

Date	Location	User	Value	Reason
Dec-15-2020 08:01:18 (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-15-2020 08:01:18 (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-15-2020 08:01:18 (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-15-2020 08:01:18 (UTC-07:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/14/2020 18:25	Initial Entry

090177e196ae30a1\Final\Final On: 01-Apr-2021 04:10 (GMT)

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 10-Dec-2020 02:26**Site No:** 1009**Subject No:** 10091342**Generated By:** (b) (4)**Form:** VACCINATION - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12Mountain Time (US  
& Canada)**5. Anatomical Location:**

Date	Location	User	Value	Reason
Dec-15-2020 08:01:18 (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-15-2020 08:01:18 (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-15-2020 08:01:18 (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-15-2020 08:01:18 (UTC-07:00)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFI ED OBSERVATION PERI	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091342

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

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

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

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

Mountain Time (US  
& Canada)

OD

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

Date	Location	User	Value	Reason
Dec-15-2020 08:01:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry



**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091342

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

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

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

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[Back to Form](#)

**1. Select appropriate response - Reactogenicity diary collection**

Date	Location	User	Value	Reason
Dec-15-2020 08:01:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES - REACTOGENICIT Y E-DIARY COLLECTE D FOR THIS SUBJECT	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1009

**Subject No:** 10091342

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

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

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

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[Back to Form](#)

**1. Date of Visit**

Date	Location	User	Value	Reason
Jan-04-2021 17:17:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (b) (4)	<b>Data Entry:</b> Jan/4/2021	Initial Entry

090177e196ae30a1\Final\Final On: 01-Apr-2021 04:10 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1009

**Subject No:** 10091342

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

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

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

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[Back to Form](#)

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

Date	Location	User	Value	Reason
Jan-04-2021 17:19:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Jan-04-2021 17:19:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> FE V E R  Were fever or system N ic symptoms present O on the last day the S ubject Diary was co mpleted?:	Initial Entry

**2.a Symptom:**

Date	Location	User	Value	Reason
Jan-04-2021 17:19:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (b) (4)	<b>Data Entry:</b> FEVER	Initial Entry

090177e196ae30a1\Final\Final On: 01-Apr-2021 04:10 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1009

**Subject No:** 10091342

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

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

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

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

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

Date	Location	User	Value	Reason
Jan-04-2021 17:19:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**2.b**

Date	Location	User	Value	Reason
Jan-04-2021 17:19:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> FA TI G UE  <b>Were fever or syste N</b> <b>mic symptoms prese O</b> <b>nt on the last day the</b> <b>Subject Diary was c</b> <b>ompleted?:</b>	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1009

**Subject No:** 10091342

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

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

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

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**2.b Symptom:**

Date	Location	User	Value	Reason
Jan-04-2021 17:19:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (b) (4)	<b>Data Entry:</b> 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-04-2021 17:19:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**2.c**

Date	Location	User	Value	Reason
Jan-04-2021 17:19:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> HE AD AC HE <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

090177e196ae30a1\Final\Final On: 01-Apr-2021 04:10 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1009

**Subject No:** 10091342

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

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

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

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**2.c Symptom:**

Date	Location	User	Value	Reason
Jan-04-2021 17:19:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (b) (4)	<b>Data Entry:</b> 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-04-2021 17:19:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**2.d**

Date	Location	User	Value	Reason
Jan-04-2021 17:19:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> C HI LL S  <b>Were fever or system N</b> <b>ic symptoms present O</b> <b>on the last day the S</b> <b>ubject Diary was co</b> <b>mpleted?:</b>	Initial Entry

090177e196ae30a1\Final\Final On: 01-Apr-2021 04:10 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1009

**Subject No:** 10091342

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

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

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

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**2.d Symptom:**

Date	Location	User	Value	Reason
Jan-04-2021 17:19:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (b) (4)	<b>Data Entry:</b> 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-04-2021 17:19:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**2.e**

Date	Location	User	Value	Reason
Jan-04-2021 17:19:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> VO MI TIN G  <b>Were fever or syste NO mic symptoms prese nt on the last day th e Subject Diary was completed?:</b>	Initial Entry

090177e196ae30a1\Final\Final On: 01-Apr-2021 04:10 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1009

**Subject No:** 10091342

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

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

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

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**2.e Symptom:**

Date	Location	User	Value	Reason
Jan-04-2021 17:19:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (b) (4)	<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-04-2021 17:19:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**2.f**

Date	Location	User	Value	Reason
Jan-04-2021 17:19:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> DI AR RH EA  <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

090177e196ae30a1\Final\Final On: 01-Apr-2021 04:10 (GMT)



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1009

**Subject No:** 10091342

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

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

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

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**2.f Symptom:**

Date	Location	User	Value	Reason
Jan-04-2021 17:19:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (b) (4)	<b>Data Entry:</b> 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-04-2021 17:19:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**2.g**

Date	Location	User	Value	Reason
Jan-04-2021 17:19:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> NEW O R WOR SENED MUSC LE PAI N  <b>Were fever or s</b> NO <b>ystemic sympto</b> <b>ms present on t</b> <b>he last day the S</b> <b>ubject Diary wa</b> <b>s completed?:</b>	Initial Entry

090177e196ae30a1\Final\Final On: 01-Apr-2021 04:10 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1009

**Subject No:** 10091342

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

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

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

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**2.g Symptom:**

Date	Location	User	Value	Reason
Jan-04-2021 17:19:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (b) (4)	<b>Data Entry:</b> NEW OR WORSENER M USCLE 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-04-2021 17:19:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**2.h**

Date	Location	User	Value	Reason
Jan-04-2021 17:19:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> NEW O R WOR SENER JOINT PAIN  <b>Were fever or sy NO</b> <b>stemic symptom</b> <b>s present on the</b> <b>last day the Sub</b> <b>ject Diary was c</b> <b>ompleted?:</b>	Initial Entry

090177e196ae30a1\Final\Final On: 01-Apr-2021 04:10 (GMT)

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Frozen, Verified**Site No:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South**Subject No:** 10091342**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12**2.h Symptom:**

Date	Location	User	Value	Reason
Jan-04-2021 17:19:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (b) (4)	<b>Data Entry:</b> NEW OR WORSENER J OINT 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
Jan-04-2021 17:19:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**3. Injection Site Location:**

Date	Location	User	Value	Reason
Jan-04-2021 17:19:35 (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-04-2021 17:19:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (b) (4)	<b>Data Entry:</b> LEFT	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1009

**Subject No:** 10091342

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

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

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

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**5.a**

Date	Location	User	Value	Reason
Jan-04-2021 17:19:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (b) (4)	<b>Data Entry:</b> <b>Injection Site Reaction:</b> RE DN ES S  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

**5.a Injection Site Reaction:**

Date	Location	User	Value	Reason
Jan-04-2021 17:19:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (b) (4)	<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-04-2021 17:19:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**5.b**

Date	Location	User	Value	Reason
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090177e196ae30a1\Final\Final On: 01-Apr-2021 04:10 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1009

**Subject No:** 10091342

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

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

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

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

Jan-04-2021 17:19:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (b) (4)	<b>Data Entry:</b> <b>Injection Site React SW</b> <b>ion::</b> EL LIN G  <b>Were injection site NO</b> <b>reactions present o</b> <b>n the last day the S</b> <b>ubject Diary was co</b> <b>mpleted?:</b>	Initial Entry
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**5.b Injection Site Reaction:**

Date	Location	User	Value	Reason
Jan-04-2021 17:19:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (b) (4)	<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-04-2021 17:19:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Jan-04-2021 17:19:35 (UTC-07:00)	ACV0PFEINFP6000	Madison Ellis (b) (4)	<b>Data Entry:</b> <b>Injection Site Rea PAIN</b> <b>ction::</b> AT IN	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1009

**Subject No:** 10091342

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

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

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

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

Mountain Time (US  
& Canada)

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Were injection site  
reactions present  
on the last day the  
Subject Diary  
was completed?:

**5.c Injection Site Reaction:**

Date	Location	User	Value	Reason
Jan-04-2021 17:19:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (b) (4)	<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-04-2021 17:19:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (b) (4)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae30a1\Final\Final On: 01-Apr-2021 04:10 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1009

**Subject No:** 10091342

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

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

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

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[Back to Form](#)

**1. Date:**

Date	Location	User	Value	Reason
Jan-04-2021 17:21:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (b) (4)	<b>Data Entry:</b> Jan/4/2021	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Jan-04-2021 17:21:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (b) (4)	<b>Data Entry:</b> <b>Record Identif 1</b> <b>ier::</b> <b>Temperature:</b> 98.1 <b>Temperature</b> F <b>Unit:</b> <b>Temperature</b> ORAL C <b>Location::</b> AVITY	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Jan-04-2021 17:21:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (b) (4)	<b>Data Entry:</b> 1	Initial Entry

**2.a Temperature:**

Date	Location	User	Value	Reason
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090177e196ae30a1\Final\Final On: 01-Apr-2021 04:10 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1009

**Subject No:** 10091342

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

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

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

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

Jan-04-2021 17:21:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (b) (4)	<b>Data Entry:</b> 98.1	Initial Entry
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**2.a Unit:**

Date	Location	User	Value	Reason
Jan-04-2021 17:21:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (b) (4)	<b>Data Entry:</b> F	Initial Entry

**2.a Temperature Location:**

Date	Location	User	Value	Reason
Jan-04-2021 17:21:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (b) (4)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae30a1\Final\Final On: 01-Apr-2021 04:10 (GMT)



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1009

**Subject No:** 10091342

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

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

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

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[Back to Form](#)

**1. Data Origin**

Date	Location	User	Value	Reason
Jan-04-2021 17:21:45 (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-04-2021 17:21:45 (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
Jan-04-2021 17:22:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-04-2021 17:21:45 (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.

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1009

**Subject No:** 10091342

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

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

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

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

Jan-04-2021 17:21:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (b) (4)	<b>Data Entry:</b> YES Date of Collection:  Jan/4/2021	Initial Entry
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**5.a**

Date	Location	User	Value	Reason
Jan-04-2021 17:22:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (b) (4)	<b>Data Entry:</b> <b>Sample ID:</b> BR9F6V	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Jan-04-2021 17:22:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (b) (4)	<b>Data Entry:</b> BR9F6V	Initial Entry

090177e196ae30a1\Final\Final On: 01-Apr-2021 04:10 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1009

**Subject No:** 10091342

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

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

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

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[Back to Form](#)

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

Date	Location	User	Value	Reason
Jan-04-2021 17:42:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Jan-04-2021 17:42:21 (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
Jan-04-2021 17:42:21 (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
Jan-04-2021 17:42:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (b) (4)	<b>Data Entry:</b> Jan/4/2021 17:11	Initial Entry

090177e196ae30a1\Final\Final On: 01-Apr-2021 04:10 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1009

**Subject No:** 10091342

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

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

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

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Jan-04-2021 17:42:21 (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
Jan-04-2021 17:42:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (b) (4)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Jan-04-2021 17:42:21 (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
Jan-04-2021 17:42:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFI ED OBSERVATION PERI OD	Initial Entry

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

090177e196ae30a1\Final\Final On: 01-Apr-2021 04:10 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1009

**Subject No:** 10091342

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

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

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

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

Date	Location	User	Value	Reason
Jan-04-2021 17:42:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (b) (4)	<b>Data Entry:</b> YES	Initial Entry

**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form Version:** 22-Apr-2020 21:02**Site No:** 1009**Subject No:** 10091342**Generated By:** (b) (4)**Form:** DATE OF VISIT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12[Back to Form](#)***1. Date of Visit***

Date	Location	User	Value	Reason
Feb-09-2021 01:34:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-08-2021 14:17:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Feb-08-2021 03:14:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: The treatment period is defined as 1st vaccination visit through the 1-month post vaccination visit after the 2nd vaccination. Please complete treatment disposition CRF and update date of EOT to match date of visit at visit 3.
Feb-05-2021 13:16:06 (UTC-07:00) Mountain Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/5/2021	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091342

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

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

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

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South

**Subject Initials:** ---

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& Canada)

090177e196ae30a1\Final\Final On: 01-Apr-2021 04:10 (GMT)

**Header Text:** c4591001

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

**Site No:** 1009

**Subject No:** 10091342

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

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

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

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[Back to Form](#)

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

Date	Location	User	Value	Reason
Feb-05-2021 13:17:13 (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
Feb-05-2021 13:17:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FE V E R  <b>Were fever or syste N</b> <b>mic symptoms prese O</b> <b>nt on the last day th</b> <b>e Subject Diary was</b> <b>completed?:</b>	Initial Entry

**2.a Symptom:**

Date	Location	User	Value	Reason
Feb-05-2021 13:17:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry



**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091342

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

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

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

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

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

Date	Location	User	Value	Reason
Feb-05-2021 13:17:13 (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
Feb-05-2021 13:17:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FA TI G UE  <b>Were fever or syste N</b> <b>mic symptoms pres O</b> <b>ent on the last day t</b> <b>he Subject Diary wa</b> <b>s completed?:</b>	Initial Entry

090177e196ae30a1\Final\Final On: 01-Apr-2021 04:10 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091342

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

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

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

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**2.b Symptom:**

Date	Location	User	Value	Reason
Feb-05-2021 13:17:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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
Feb-05-2021 13:17:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.c**

Date	Location	User	Value	Reason
Feb-05-2021 13:17:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> HE AD AC HE <b>Were fever or syste</b> NO <b>mic symptoms pres</b> <b>ent on the last day t</b> <b>he Subject Diary w</b> <b>as completed?:</b>	Initial Entry

090177e196ae30a1\Final\Final On: 01-Apr-2021 04:10 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091342

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

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

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

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**2.c Symptom:**

Date	Location	User	Value	Reason
Feb-05-2021 13:17:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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
Feb-05-2021 13:17:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.d**

Date	Location	User	Value	Reason
Feb-05-2021 13:17:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> C HI LL S <b>Were fever or syste N</b> <b>mic symptoms prese O</b> <b>nt on the last day th</b> <b>e Subject Diary was</b> <b>completed?:</b>	Initial Entry

090177e196ae30a1\Final\Final On: 01-Apr-2021 04:10 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091342

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

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

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

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**2.d Symptom:**

Date	Location	User	Value	Reason
Feb-05-2021 13:17:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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
Feb-05-2021 13:17:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.e**

Date	Location	User	Value	Reason
Feb-05-2021 13:17:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> VO MI TIN G  <b>Were fever or syste NO mic symptoms pres ent on the last day the Subject Diary was completed?:</b>	Initial Entry

090177e196ae30a1\Final\Final On: 01-Apr-2021 04:10 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091342

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

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

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

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**2.e Symptom:**

Date	Location	User	Value	Reason
Feb-05-2021 13:17:13 (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
Feb-05-2021 13:17:13 (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
Feb-05-2021 13:17:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> DI AR RH EA  <b>Were fever or syste</b> NO <b>mic symptoms pres</b> <b>ent on the last day t</b> <b>he Subject Diary w</b> <b>as completed?:</b>	Initial Entry

090177e196ae30a1\Final\Final On: 01-Apr-2021 04:10 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091342

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

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

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

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**2.f Symptom:**

Date	Location	User	Value	Reason
Feb-05-2021 13:17:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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
Feb-05-2021 13:17:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.g**

Date	Location	User	Value	Reason
Feb-05-2021 13:17:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW O R WOR SENED MUSC LE PAI N  <b>Were fever or s NO</b> <b>ystemic sympto</b> <b>ms present on t</b> <b>he last day the</b> <b>Subject Diary</b> <b>was completed?</b> :	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091342

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

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

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

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**2.g Symptom:**

Date	Location	User	Value	Reason
Feb-05-2021 13:17:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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
Feb-05-2021 13:17:13 (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
Feb-05-2021 13:17:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR W ORSE NER J OINT P AIN  <b>Were fever or s</b> NO <b>ystemic sympto</b> <b>ms present on t</b> <b>he last day the</b> <b>Subject Diary w</b> <b>as completed?:</b>	Initial Entry

090177e196ae30a1\Final\Final On: 01-Apr-2021 04:10 (GMT)

**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Frozen, Verified**Site No:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South**Subject No:** 10091342**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12**2.h Symptom:**

Date	Location	User	Value	Reason
Feb-05-2021 13:17:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSENER J OINT 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
Feb-05-2021 13:17:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**3. Injection Site Location:**

Date	Location	User	Value	Reason
Feb-05-2021 13:17:13 (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
Feb-05-2021 13:17:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry



**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Frozen, Verified**Site No:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South**Subject No:** 10091342**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12**5.a**

Date	Location	User	Value	Reason
Feb-05-2021 13:17:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction:</b> RE DN ES S  <b>Were injection site reactions present o n the last day the S ubject Diary was co mpleted?:</b> NO	Initial Entry

**5.a Injection Site Reaction:**

Date	Location	User	Value	Reason
Feb-05-2021 13:17:13 (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
Feb-05-2021 13:17:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**5.b**

Date	Location	User	Value	Reason
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**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091342

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

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

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

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

Feb-05-2021 13:17:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b>  SW EL LIN G  <b>Were injection site reactions present o n the last day the S ubject Diary was c ompleted?:</b> NO	Initial Entry
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**5.b Injection Site Reaction:**

Date	Location	User	Value	Reason
Feb-05-2021 13:17:13 (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
Feb-05-2021 13:17:13 (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
Feb-05-2021 13:17:13 (UTC-07:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> PAIN AT IN	Initial Entry

**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form Version:** 10-Dec-2020 02:30**Site No:** 1009**Subject No:** 10091342**Generated By:** (b) (4)**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12

Mountain Time (US & Canada)			JECTI ON SI TE  Were injection si NO te reactions pres ent on the last da y the Subject Dia ry was complete d?:	
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**5.c Injection Site Reaction:**

Date	Location	User	Value	Reason
Feb-05-2021 13:17:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PAIN AT INJECTION SI TE	Initial Entry

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

Date	Location	User	Value	Reason
Feb-05-2021 13:17:13 (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:** 22-Apr-2020 21:03

**Site No:** 1009

**Subject No:** 10091342

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

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

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

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[Back to Form](#)

**1. Data Origin**

Date	Location	User	Value	Reason
Feb-05-2021 13:15:05 (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
Feb-05-2021 13:15:05 (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
Feb-05-2021 13:15:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-05-2021 13:15:05 (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

**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South**Subject No:** 10091342**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12

				correct as appropriate.
Feb-05-2021 13:15:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Feb/5/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Feb-05-2021 13:15:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BR61Y8	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Feb-05-2021 13:15:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR61Y8	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Feb-05-2021 13:15:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BR61Y9	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091342

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

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

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

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

**5.b Sample ID**

Date	Location	User	Value	Reason
Feb-05-2021 13:15:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR61Y9	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Feb-05-2021 13:15:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BSJ48W	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Feb-05-2021 13:15:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BSJ48W	Initial Entry

090177e196ae30a1\Final\Final On: 01-Apr-2021 04:10 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1009

**Subject No:** 10091342

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

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

**Form Status:**

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[Back to Form](#)

Date	Location	User	Value	Reason
Feb-12-2021 11:26:43 (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:** 1009

**Subject No:** 10091342

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

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

**Form Status:** Data Complete, Frozen

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[Back to Form](#)

**1. Category:**

Date	Location	User	Value	Reason
Feb-12-2021 11:26:43 (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
Feb-12-2021 11:26:43 (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
Feb-22-2021 07:43:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-20-2021 13:40:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error



**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1009**Subject No:** 10091342**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12

Feb-20-2021 13:40:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> swollen cervical lymph nodes bilateral	Transcription Error
Feb-14-2021 17:59:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	GPD Clin: Please confirm anatomic location of swollen cervical nodes (Right, Left, Bilateral) and update AE term as appropriate.
Feb-14-2021 17:58:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	issued amended query
Feb-14-2021 17:57:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	GPD CLIN: please confirm location (Left, Right, bilateral) of swollen cervical nodes.
Feb-12-2021 11:26:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> swollen cervical lymph nodes	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
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**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:02**Form Status:** Data Complete, Frozen**Site No:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject No:** 10091342**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12

Feb-12-2021 11:26:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/31/2021 UNK:UNK	Initial Entry
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**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Feb-12-2021 11:26:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Feb/2/2021 UNK:UNK	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Feb-12-2021 11:26:43 (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?****If Yes, NOTIFY PFIZER IMMEDIATELY.**

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

Date	Location	User	Value	Reason
Feb-12-2021 11:26:43	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:02**Form Status:** Data Complete, Frozen**Site No:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject No:** 10091342**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:12(UTC-07:00)  
Mountain Time (US  
& Canada)

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

**8. Is this adverse event the result of a study Medication Error?***If Yes, record the type of medication error on the Medication Error Log.*

Date	Location	User	Value	Reason
Feb-12-2021 11:26:43 (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
Feb-22-2021 10:29:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-20-2021 13:41:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	none, unknown cause
Feb-14-2021 18:01:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	GPD Clin: Did patient have associated symptoms (for example sore throat, URI sxs, etc.)? Please clarify if

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1009**Subject No:** 10091342**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12

				investigator assessment indicates a potential etiology for swollen cervical lymph nodes.
Feb-12-2021 11:26:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  unknown	Initial Entry

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

Date	Location	User	Value	Reason
Feb-12-2021 11:26:43 (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
Feb-12-2021 11:26:43 (UTC-07:00) Mountain Time (US	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:** 1009

**Subject No:** 10091342

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

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

**Form Status:** Data Complete, Frozen

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

& Canada)

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

Date	Location	User	Value	Reason
Feb-12-2021 11:26:43 (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
Feb-12-2021 11:26:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVE D	Initial Entry

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

Date	Location	User	Value	Reason
Feb-12-2021 11:26:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae30a1\Final\Final On: 01-Apr-2021 04:10 (GMT)

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

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

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

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

**Site No:** 1009

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject No:** 10091342

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:12

[Back to Form](#)

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

Date	Location	User	Value	Reason
Feb-08-2021 14:16:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/5/2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Feb-08-2021 14:16:49 (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
Feb-08-2021 14:16:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae30a1\Final\Final On: 01-Apr-2021 04:10 (GMT)

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1009

**Subject No:** 10091342

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

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

**Form Status:** Data Complete, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[Back to Form](#)

**1. Subject Status**

Date	Location	User	Value	Reason
Feb-08-2021 14:16:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Dec-15-2020 08:00:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZ ED	Initial Entry
Dec-15-2020 07:59:22 (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
Feb-08-2021 14:16:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Feb/5/2021	Initial Entry
Dec-15-2020 08:00:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Dec/14/2020	Initial Entry

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**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1009

**Subject No:** 10091342

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

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

**Form Status:** Data Complete, Verified

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

Dec-15-2020 07:59:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b><u>Data Entry:</u></b> Dec/14/2020	Initial Entry
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**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

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

**Site No:** 1009

**Subject No:** 10091342

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

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail  
History

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

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:12

[Back to Form](#)

**1. Casebook Signature**

Date	Location	User	Value	Reason
Mar-10-2021 16:40:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Click Here to Enable	Initial Entry

090177e196ae30a1\Final\Final On: 01-Apr-2021 04:10 (GMT)