

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT SELECTION

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

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Cohort Selection**

DO NOT USE THE OPTIONS STAGE 1 NONSENTINEL and STAGE 2 from this CRF. As per protocol amendment 5, STAGE 3 option is equivalent to PHASE 2/3.

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

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1009

**Subject No:** 10091221

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

**Form:** MAIN INFORMED CONSENT

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Oct/19/2020
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**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** DEMOGRAPHY

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

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[10091221]
2.	Birth Date:	(b) (6) 2006
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

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**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091221

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

**Form:** DATE OF VISIT

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

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

**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091221

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

**Form:** INCLUSION/EXCLUSION CRITERIA

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

**Form Comments**

**Inclusion Criteria Not Met**

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

2.	Description of Exclusion Criterion Met	Not Applicable _____
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090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091221

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

**Form:** DISPOSITION - SCREENING

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Disposition - Screening**

1.	Date of Completion/Discontinuation/Death	Oct/19/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** c4591001

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

**Form:** GENERAL MEDICAL HISTORY

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

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[BILATERAL KNEE PAIN]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[BILATERAL ANKLE PAIN]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[BILATERAL HIP PAIN]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES

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**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091221

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

**Form:** GENERAL MEDICAL HISTORY

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

1.d	Line/MH Number:	[4]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[TONSILLITIS]
	Start Date:	Aug/10/2017
	Ongoing:	NO End Date: Apr/UNK/2019
1.e	Line/MH Number:	[5]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[premenarchal]
	Start Date:	(b) (6) 2006
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[facial acne]
	Start Date:	Feb/UNK/2020
	Ongoing:	YES

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**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091221

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

**Form:** HIV STATUS

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

[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
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**Header Text:** c4591001

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

**Form Version:** 10-Oct-2020 16:04

**Site No:** 1009

**Subject No:** 10091221

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

**Form:** VITAL SIGNS - BASELINE

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Oct/19/2020
2.	Weight:	[105.0]
3.	Unit:	LB
4.	Height:	[64.0]
5.	Unit:	in
6.	Body Mass Index:	[18.0]

**Vital Signs Details**

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

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 10-Oct-2020 15:58**Site No:** 1009**Subject No:** 10091221**Generated By:** (b) (4)**Form:** LAB URINALYSIS - PREGNANCY TEST**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject Initials:** ---**Generated Time (GMT):** 10-Nov-2021 20:44[Form Comments](#)[eCRF Audit Trail History](#)**Lab Urinalysis**

1.	Lab Panel:	Not Applicable _____	<a href="#">Comments</a>
2.	Lab Sub-Panel:	Not Applicable _____	<a href="#">Comments</a>
3.	Collection Date:	Not Applicable _____ //	<a href="#">Comments</a>
4.	Laboratory Name and Address (Derived)	Not Applicable _____ [ ]	<a href="#">Comments</a>
5.	Specimen Type:	Not Applicable _____	<a href="#">Comments</a>

**Lab Result**

6.a	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Not Applicable _____ Choriogonadotropin Beta_PX113	
	Result:	Not Applicable _____	<a href="#">Comments</a>
	Not Done:	Not Applicable _____	<a href="#">Comments</a>

**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091221

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

**Form:** RANDOMIZATION

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Oct/19/2020
2.	Randomization Number:	[20134]
3.	Randomization Group:	[ ]

**Header Text:** c4591001

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BR9FM9]
5.b	Sample ID	[BR9FM4]
5.c	Sample ID	[BKYCTC]

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**Header Text:** c4591001

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

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

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

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BP9GCC]
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**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091221

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

**Form:** VACCINATION

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Oct/19/2020 13:58
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

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**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091221

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

**Form:** REACTOGENICITY DIARY

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

[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:** 10091221

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

**Form:** DATE OF VISIT

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Nov/7/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Form Version:** 10-Oct-2020 16:03

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

[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?	YES Ongoing? NO Stop Date: Oct/23/2020

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Form Version:** 10-Oct-2020 16:03

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
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

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Form Version:** 10-Oct-2020 16:03

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	YES Ongoing? NO Stop Date: Oct/23/2020

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1009

**Subject No:** 10091221

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

**Form:** VITAL SIGNS - TEMP

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Nov/7/2020
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**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[98.7]
	Unit:	F
	Temperature Location:	ORAL CAVITY

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**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form Version:** 10-Oct-2020 15:58**Site No:** 1009**Subject No:** 10091221**Generated By:** (b) (4)**Form:** LAB URINALYSIS - PREGNANCY TEST**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject Initials:** ---**Generated Time (GMT):** 10-Nov-2021 20:44[Form Comments](#)[eCRF Audit Trail History](#)**Lab Urinalysis**

1.	Lab Panel:	Not Done _____	<a href="#">Comments</a>
2.	Lab Sub-Panel:	Not Done _____	<a href="#">Comments</a>
3.	Collection Date:	Not Done _____ //	<a href="#">Comments</a>
4.	Laboratory Name and Address (Derived)	Not Done _____ [ ]	<a href="#">Comments</a>
5.	Specimen Type:	Not Done _____	<a href="#">Comments</a>

**Lab Result**

6.a	Sponsor ID:	Not Done _____ [ ]	<a href="#">Comments</a>
	Test:	Not Done _____ Choriogonadotropin Beta_PX113	
	Result:	Not Done _____	<a href="#">Comments</a>
	Not Done:	Not Done _____	<a href="#">Comments</a>

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Nov/7/2020
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	[BGGZY1]
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090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION

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

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

[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:	Nov/7/2020 11:10
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

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)



**Header Text:** c4591001

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

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

**Site No:** 1009 **Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject No:** 10091221 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

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

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

**Form Version:** 10-Oct-2020 16:03 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1009 **Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject No:** 10091221 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

[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

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

**Form Version:** 10-Oct-2020 16:03 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1009 **Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject No:** 10091221 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
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 WORSENERD MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENERD JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

**Form Version:** 10-Oct-2020 16:03 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1009 **Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject No:** 10091221 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (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, Locked, Frozen, Verified

**Site No:** 1009 **Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject No:** 10091221 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Dec/10/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BR5BGJ]
5.b	Sample ID	[BR5BGH]
5.c	Sample ID	[BSJ3LJ]

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1009

**Subject No:** 10091221

**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):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

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

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_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:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: May/14/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BTLHCK]
5.b	Sample ID	[BTLHCL]
5.c	Sample ID	[BRTSSY]

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V5\_MONTH12\_L

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

**Site No:** 1009

**Subject No:** 10091221

**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):** 10-Nov-2021 20:44

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	



**Header Text:** c4591001

**Visit:** V5\_MONTH12\_L

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

**Site No:** 1009

**Subject No:** 10091221

**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):** 10-Nov-2021 20:44

**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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090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V6\_MONTH24\_L

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

**Site No:** 1009

**Subject No:** 10091221

**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):** 10-Nov-2021 20:44

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V6\_MONTH24\_L

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Form Status:** Not Started

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

**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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090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Illness Visit		
3.	COVID-19 Illness Visit:	

**Header Text:** c4591001

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

**Form Version:** 30-Apr-2021 01:47

**Site No:** 1009

**Subject No:** 10091221

**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):** 10-Nov-2021 20:44

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

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091221

**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):** 10-Nov-2021 20:44

**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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090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

**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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090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

**Form:** HEALTH CARE UTILIZATION

**Form Version:** 30-Apr-2021 01:37

**Form Status:** Not Started

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

**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?	
----	--	--

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)



**Header Text:** c4591001

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

**Form:** ILLNESS DETAILS

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

**Form Status:** Not Started

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

**Illness Details**

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

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

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

**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY

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

**Form Status:** Not Started

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

**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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090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Repeat Swab		
3.	COVID-19 Repeat Swab:	

**Header Text:** c4591001

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

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

**Site No:** 1009 **Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject No:** 10091221 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

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

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled  
Visit on Oct/20/2020

**Form:** DATE OF VISIT

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

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Oct/20/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled  
Visit on Oct/20/2020

**Form:** UNPLANNED VISIT

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

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Unplanned Assessments**

1.	Assessments	CONTACT OUTCOME
----	-------------	-----------------

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled  
Visit on Oct/20/2020

**Form:** CONTACT OUTCOME - UNPLANNED

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

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Contact Outcome**

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Oct/20/2020  Contact Outcome: VISIT NOT REQUIRED, INVESTIGATOR DECISION
3.	Comments:	[ ]

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)



**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** VITAL SIGNS - TEMP

**Form Version:** 30-Apr-2021 01:41

**Form Status:** Not Started

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

**Vital Signs**

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

**Vital Signs Details**

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

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001**Visit:** Unplanned Vaccination -  
Unscheduled**Form:** LAB URINALYSIS - PREGNANCY TEST**Form Version:** 20-Feb-2021 02:14**Form Status:** Not Started**Site No:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South**Subject No:** 10091221**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 10-Nov-2021 20:44**Lab Urinalysis**

1.	Lab Panel:	
2.	Lab Sub-Panel:	
3.	Collection Date:	//
4.	Laboratory Name and Address (Derived)	[ ]
5.	Specimen Type:	

**Lab Result**

6.	Sponsor ID:	[ ]
	Test:	
	Result:	
	Not Done:	

**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:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

**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?	

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** CONTACT OUTCOME - MONTH 1

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

**Form Status:** Not Started

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** CONTACT OUTCOME - MONTH 6

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

**Form Status:** Not Started

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

**Contact Outcome**

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

**Header Text:** c4591001

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

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

**Site No:** 1009 **Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South

**Subject No:** 10091221 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Apr/9/2021
2.	Erroneous Visit	

**Header Text:** c4591001

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

**Form:** INFORMED CONSENT - ASYMPTOMATIC  
SURVEILLANCE

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

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Informed Consent - Asymptomatic Surveillance**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Apr/9/2021
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**Header Text:** c4591001

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

**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:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Apr/9/2021
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	[BRTSPB]
5.b	Sample ID	[BR9DNK]
5.c	Sample ID	[BR9DNL]

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled**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:** 10091221**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 10-Nov-2021 20:44[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Apr/9/2021
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	[BR9DTR]
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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, Locked, Frozen, Verified

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation /Death :	Dec/10/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	May/13/2021
2.	Erroneous Visit	

**Header Text:** c4591001

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

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Further Vaccination Confirmation**

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is NOT willing to return for Vaccination 3 OR otherwise not eligible
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**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

**Form:** DISPOSITION - FOLLOW-UP

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

**Form Status:** Not Started

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

**Disposition - Follow-Up**

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

**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:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	worsening right ankle pain	Oct/19/2020 17:00	NO End Date Time:  Oct/19/2020 UNK: UNK	<a href="#">Repeating Pages</a>

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

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

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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[Form Audit Trail](#)

**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[worsening right ankle pain]
4.	Start Date Time:	Oct/19/2020 17:00
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/19/2020 UNK:UNK
6.	Toxicity Grade:	3

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1009

**Subject No:** 10091221

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

**Form:** ADVERSE EVENT REPORT

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [dance injury]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

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

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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

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**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:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** MEDICATION ERROR

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

**Form Status:** Not Started

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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**Medication Error**

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

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (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:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Not Started

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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**Concomitant Medications**

1.	What is the medication identifier?	[ ]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	Medication:  Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[ ]
5.	Date:	//

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**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:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**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:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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**Concomitant Medications**

1.	What is the medication identifier?	[ ]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	Medication:  Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[ ]
5.	Dose:	[ ]
6.	Dose Unit:	
7.	Dose Frequency:	
8.	Route:	
9.	Start Date:	//
10.	Ongoing?	

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (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:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** RADIATION TREATMENT

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

**Form Status:** Not Started

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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**Radiation Treatment**

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

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (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:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** TRANSFUSIONS

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

**Form Status:** Not Started

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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

**Header Text:** c4591001

**Visit:** UNPLANNED\_BOOSTER\_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:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:**  
UNPLANNED\_BOOSTER\_CONTACT  
- Unscheduled

**Form:** BOOSTER DOSE TRIGGER FORM

**Form Version:** 13-Apr-2021 01:26

**Form Status:** Not Started

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

**Booster Dose Trigger Form**

1.	Select appropriate response - Will the participant return for consent/eligibility assessment for the booster dose visit?	
----	--	--

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 1 -  
Unscheduled Visit on Apr/18/2021

**Form:** DATE OF VISIT - ASYMPTOMATIC  
SURVEILLANCE

**Form Version:** 14-Jan-2021 02:22

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Apr/18/2021
2.	Erroneous Visit	

**COVID-19 Surveillance Visit**

3.	COVID-19 Surveillance Visit:	SSWAB_WEEK2
----	---------------------------------	-------------

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001**Visit:** V202\_SURVEIL\_SWAB 1 -  
Unscheduled Visit on Apr/18/2021**Form Version:** 10-Oct-2020 15:57**Site No:** 1009**Subject No:** 10091221**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South**Subject Initials:** ---**Generated Time (GMT):** 10-Nov-2021 20:44[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Apr/18/2021
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	[AA45840]
-----	-----------	-----------



**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 2 -  
Unscheduled Visit on Apr/28/2021

**Form:** DATE OF VISIT - ASYMPTOMATIC  
SURVEILLANCE

**Form Version:** 14-Jan-2021 02:22

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Apr/28/2021
2.	Erroneous Visit	

**COVID-19 Surveillance Visit**

3.	COVID-19 Surveillance Visit:	SSWAB_WEEK4
----	---------------------------------	-------------

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001**Visit:** V202\_SURVEIL\_SWAB 2 -  
Unscheduled Visit on Apr/28/2021**Form Version:** 10-Oct-2020 15:57**Site No:** 1009**Subject No:** 10091221**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South**Subject Initials:** ---**Generated Time (GMT):** 10-Nov-2021 20:44[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Apr/28/2021
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	[AA45841]
-----	-----------	-----------

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 3 -  
Unscheduled Visit on May/09/2021

**Form:** DATE OF VISIT - ASYMPTOMATIC  
SURVEILLANCE

**Form Version:** 14-Jan-2021 02:22

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	May/9/2021
2.	Erroneous Visit	

**COVID-19 Surveillance Visit**

3.	COVID-19 Surveillance Visit:	SSWAB_WEEK6
----	---------------------------------	-------------

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001**Visit:** V202\_SURVEIL\_SWAB 3 -  
Unscheduled Visit on May/09/2021**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB**Form Version:** 10-Oct-2020 15:57**Form Status:** Data Complete, Frozen, Verified**Site No:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South**Subject No:** 10091221**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 10-Nov-2021 20:44[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: May/9/2021
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	[AA45844]
-----	-----------	-----------

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** TREATMENT UNBLINDED

**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:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Treatment Unblinded**

1.	Date Treatment Unblinded :	May/13/2021
2.	Primary Reason for Unblinding:	OTHER If other, specify: [parent preference]

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1009

**Subject No:** 10091221

**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):** 10-Nov-2021 20:44

**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:** 10091221

**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):** 10-Nov-2021 20:44

**Death Details**

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

**Cause of Death**

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

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form:** SUBJECT STATUS

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

**Form Status:** Data Complete, Verified

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Subject Status**

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Dec/10/2020



**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

**Form Status:** Data Complete, Verified

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

**Casebook Signature Form**

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

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

**Form Status:** Data Complete, Verified

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

[Audit Trail](#)

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

- CRF\_Sign
- CRF\_Sign\_1

Name	Signature Meaning	Date	Type	Action
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**Header Text:** c4591001

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

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

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

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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Item	Date	User	Comment
Form	Oct-19-2020 15:55:11 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [Redacted] [Redacted]	Not Applicable

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 10-Oct-2020 15:58

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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Item	Date	User	Comment
Form	Oct-19-2020 15:59:29 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [Redacted] [Redacted]	Not Applicable

**Header Text:** c4591001

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

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 10-Oct-2020 15:58

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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Item	Date	User	Comment
1	Oct-19-2020 15:59:29 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [Redacted] [Redacted]	Not Applicable

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 10-Oct-2020 15:58

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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Item	Date	User	Comment
2	Oct-19-2020 15:59:29 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [Redacted] [Redacted]	Not Applicable

**Header Text:** c4591001

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

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 10-Oct-2020 15:58

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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Item	Date	User	Comment
3	Oct-19-2020 15:59:29 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [Redacted] [Redacted]	Not Applicable

**Header Text:** c4591001

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

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 10-Oct-2020 15:58

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
4	Oct-19-2020 15:59:29 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [Redacted] [Redacted]	Not Applicable



**Header Text:** c4591001

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

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 10-Oct-2020 15:58

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
5	Oct-19-2020 15:59:29 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [Redacted] [Redacted]	Not Applicable

**Header Text:** c4591001

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

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 10-Oct-2020 15:58

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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Item	Date	User	Comment
6.a	Oct-19-2020 15:59:29 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [Redacted] [Redacted]	Not Applicable

**Header Text:** c4591001

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

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 10-Oct-2020 15:58

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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Item	Date	User	Comment
6.a	Oct-19-2020 15:59:29 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [Redacted] [Redacted]	Not Applicable

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 10-Oct-2020 15:58

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
6.a	Oct-19-2020 15:59:29 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [Redacted] [Redacted]	Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 10-Oct-2020 15:58

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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Item	Date	User	Comment
Form	Nov-07-2020 11:28:03 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Done

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 10-Oct-2020 15:58

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
1	Nov-07-2020 11:28:03 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 10-Oct-2020 15:58

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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Item	Date	User	Comment
2	Nov-07-2020 11:28:03 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 10-Oct-2020 15:58

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
3	Nov-07-2020 11:28:03 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Done



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 10-Oct-2020 15:58

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
4	Nov-07-2020 11:28:03 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Done

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 10-Oct-2020 15:58

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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Item	Date	User	Comment
5	Nov-07-2020 11:28:03 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 10-Oct-2020 15:58

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
6.a	Nov-07-2020 11:28:03 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 10-Oct-2020 15:58

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
6.a	Nov-07-2020 11:28:03 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 10-Oct-2020 15:58

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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Item	Date	User	Comment
6.a	Nov-07-2020 11:28:03 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [Redacted]	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, Verified

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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

- CRF\_Sign
- CRF\_Sign\_1

Name	Signature Meaning	Date	Type	Action
(b) (6)	N/A	Apr-20-2021 09:30:22 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated

**Affidavit:**  
N/A

(b) (6)	Approved	Apr-13-2021 17:10:38 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed
---------	----------	---	------	--------

**Affidavit:**

By my dated signature below, I, (b) (6) verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

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

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

(b) (6)	N/A	Apr-09-2021 14:39:55 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated
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090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

**Affidavit:**

N/A

(b) (6)	Approved	Mar-09-2021 21:31:14 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, (b) (6) verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

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

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

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

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

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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*1. Select appropriate response - Protocol version*

Date	Location	User	Value	Reason
Oct-19-2020 15:54:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> 06 OCT 2020	Initial Entry

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

Date	Location	User	Value	Reason
Oct-19-2020 15:54:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)



**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

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

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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*1. Consent Was:*

Date	Location	User	Value	Reason
Oct-19-2020 15:54:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Oct/19/2020	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

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

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Subject ID**

Date	Location	User	Value	Reason
Oct-19-2020 15:54:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> 10091221	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Oct-19-2020 15:54:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> (b) (6) 2006	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Oct-19-2020 15:54:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> FEMALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
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090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

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

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

Oct-19-2020 15:54:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED] [REDACTED]	<b>Data Entry:</b> NOT HISPANIC OR LATIN O(A) OR OF SPANISH ORI GIN	Initial Entry
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**5. Race: (Check X all that apply):**

Date	Location	User	Value	Reason
Oct-19-2020 15:54:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED] [REDACTED]	<b>Data Entry:</b> WHITE	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091221

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

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

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*1. Date of Visit*

Date	Location	User	Value	Reason
Oct-19-2020 15:55:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> Oct/19/2020	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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

Date	Location	User	Value	Reason
Oct-19-2020 15:55:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/19/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Oct-19-2020 15:55:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Oct-19-2020 15:55:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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*1.a*

Date	Location	User	Value	Reason
Oct-19-2020 15:56:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Nu</b> 1 <b>mber:</b> <b>Medical Hist</b> BILATERAL <b>ory Term:</b> KNEE PAIN <b>Start Date:</b> UNK/UNK/20 18 <b>Ongoing:</b> YES	Initial Entry

*1.a Line/MH Number:*

Date	Location	User	Value	Reason
Oct-19-2020 15:56:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	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
Nov-03-2020 17:43:23 (UTC-07:00) Mountain Time (US	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

& Canada)				
Oct-31-2020 11:13:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted]	Query 1: Answered	Changed data per query
Oct-26-2020 08:02:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	Luke Cunliffe (b) (4) [Redacted]	Query 1: Reissued:Opened	All female subjects of childbearing potential should have a UPT included as a pre-vaccination procedure. For adolescents that are not of childbearing potential, 'premenarchal' should be added to medical history. Thank you.
Oct-23-2020 12:04:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted]	Query 1: Answered	not usually captured in medical history as absence of a period is a normal state for children. I will double check

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

Oct-21-2020 19:30:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	ClinQuery: Please confirm if pt is premenarchal if so please could this be added to the Med Hx CRF
Oct-19-2020 15:56:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BILATERAL KNEE PAIN	Initial Entry

***1.a Start Date:***

Date	Location	User	Value	Reason
Oct-19-2020 15:56:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2018	Initial Entry

***1.a Ongoing:***

Date	Location	User	Value	Reason
Oct-19-2020 15:56:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)



**Header Text:** c4591001

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

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

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

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

***1.b***

Date	Location	User	Value	Reason
Oct-19-2020 15:56:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Nu</b> 2 <b>mber:</b> <b>Medical Hist</b> BILATERAL <b>ory Term:</b> ANKLE PAIN <b>Start Date:</b> UNK/UNK/20 18 <b>Ongoing:</b> YES	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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

Date	Location	User	Value	Reason
Oct-19-2020 15:56:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	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
Oct-19-2020 15:56:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> BILATERAL ANKLE PAIN	Initial Entry

**1.b Start Date:**

Date	Location	User	Value	Reason
Oct-19-2020 15:56:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> UNK/UNK/2018	Initial Entry

**1.b Ongoing:**

Date	Location	User	Value	Reason
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090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

Oct-19-2020 15:56:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> YES	Initial Entry
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*I.c*

Date	Location	User	Value	Reason
Oct-19-2020 15:57:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Nu</b> 3 <b>mber:</b> <b>Medical Hist</b> BILATERAL <b>ory Term:</b> HIP PAIN <b>Start Date:</b> UNK/UNK/2 018 <b>Ongoing:</b> YES	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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

Date	Location	User	Value	Reason
Oct-19-2020 15:57:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

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

Date	Location	User	Value	Reason
Oct-19-2020 15:57:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BILATERAL HIP PAIN	Initial Entry

***1.c Start Date:***

Date	Location	User	Value	Reason
Oct-19-2020 15:57:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2018	Initial Entry

***1.c Ongoing:***

Date	Location	User	Value	Reason
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090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

Oct-19-2020 15:57:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> YES	Initial Entry
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*1.d*

Date	Location	User	Value	Reason
Oct-19-2020 15:57:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 4 <b>Medical History Term:</b> TONSILLITIS <b>Start Date:</b> Aug/10/2017 <b>Ongoing:</b> NO End Date:  Apr/UNK /2019	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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

Date	Location	User	Value	Reason
Oct-19-2020 15:57:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> 4	Initial Entry

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

Date	Location	User	Value	Reason
Oct-19-2020 15:57:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> TONSILLITIS	Initial Entry

***1.d Start Date:***

Date	Location	User	Value	Reason
Oct-19-2020 15:57:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/10/2017	Initial Entry

***1.d Ongoing:***

Date	Location	User	Value	Reason
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090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

Oct-19-2020 15:57:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> NO End Date:  Apr/UNK/2019	Initial Entry
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*I.e*

Date	Location	User	Value	Reason
Oct-31-2020 11:13:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 5 <b>Medical History Term:</b> premenarchal <b>Start Date:</b> (b) (6) 2006 <b>Ongoing:</b> YES	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091221

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

Date	Location	User	Value	Reason
Oct-31-2020 11:13:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> 5	Initial Entry

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

Date	Location	User	Value	Reason
Nov-24-2020 09:02:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted]	Query 1: Closed	Response satisfies query
Nov-23-2020 09:38:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted]	Query 1: Answered	Changed data per query
Nov-20-2020 14:08:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted]	Query 1: Opened	Sorry no where else to put this query. Subject reported Facial Acne start date UNK/FEB /2020. Please confirm or clarify.

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091221

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Oct-31-2020 11:13:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> premenarchal	Initial Entry
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*I.e Start Date:*

Date	Location	User	Value	Reason
Oct-31-2020 11:13:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> (b) (6)/2006	Initial Entry

*I.e Ongoing:*

Date	Location	User	Value	Reason
Oct-31-2020 11:13:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

*I.f*

Date	Location	User	Value	Reason
Nov-23-2020 09:38:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Number: 6	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

& Canada)

**Medical History** facial acne

**Term:**

**Start Date:** Feb/UNK/  
2020

**Ongoing:** YES

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091221

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

Date	Location	User	Value	Reason
Nov-23-2020 09:38:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> 6	Initial Entry

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

Date	Location	User	Value	Reason
Nov-23-2020 09:38:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> facial acne	Initial Entry

***1.f Start Date:***

Date	Location	User	Value	Reason
Nov-23-2020 09:38:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/UNK/2020	Initial Entry

***1.f Ongoing:***

Date	Location	User	Value	Reason
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090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

Nov-23-2020 09:38:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry
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090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091221

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

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

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

Date	Location	User	Value	Reason
Oct-19-2020 15:58:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	<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-Oct-2020 16:04

**Site No:** 1009

**Subject No:** 10091221

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

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Date:**

Date	Location	User	Value	Reason
Oct-19-2020 15:59:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> Oct/19/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Oct-19-2020 15:59:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> 105.0	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Oct-19-2020 15:59:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> LB	Initial Entry

**4. Height:**

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091221

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Oct-19-2020 15:59:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> 64.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Oct-19-2020 15:59:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Oct-19-2020 15:59:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> 18.0	Initial Entry

7.a

Date	Location	User	Value	Reason
Oct-19-2020 15:59:12 (UTC-07:00)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Record Identifi 1	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

**Form Version:** 10-Oct-2020 16:04

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

Mountain Time (US & Canada)			er:: <b>Temperature:</b> 98.1 <b>Temperature Unit:</b> <b>Temperature Location:</b> ORAL CA VITY	
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**7.a Record Identifier:**

Date	Location	User	Value	Reason
Oct-19-2020 15:59:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**7.a Temperature:**

Date	Location	User	Value	Reason
Oct-19-2020 15:59:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 98.1	Initial Entry

**7.a Unit:**

Date	Location	User	Value	Reason
Oct-19-2020 15:59:12 (UTC-07:00)	ACV0PF EINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> F	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)



**Header Text:** c4591001

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

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

**Form Version:** 10-Oct-2020 16:04

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

Mountain Time (US & Canada)				
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**7.a Temperature Location:**

Date	Location	User	Value	Reason
Oct-19-2020 15:59:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
eCRF Audit Trail History

**Form Version:** 10-Oct-2020 15:58

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Oct-19-2020 15:59:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Oct-19-2020 15:59:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Nov-03-2020 15:05:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	Luke Cunliffe (b) (4)	Query 1: Closed	Response satisfies query
Oct-31-2020 11:13:46	ACV0PF EINFP60	(b) (4), (b) (6) [Redacted]	Query 1: Answered	Changed data per query

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 15:58

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

(UTC-07:00) Mountain Time (US & Canada)	00			
Oct-26-2020 08:01:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	Luke Cunliffe (b) (4)	Query 1: Reissued:Opened	Please add 'premenarchal' to medical history CRF. For adolescents that are not of childbearing potential, 'premenarchal' should be added to medical history and a UPT is not required. Thank you.
Oct-23-2020 12:03:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Answered	patient premenarchal
Oct-22-2020 14:27:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	Clinical review: Please specify why a pregnancy test was not performed. It is not clear from the subject's medical history

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
eCRF Audit Trail History

**Form Version:** 10-Oct-2020 15:58

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

				and age (under 60 years) that they are not of childbearing potential. Please refer to protocol section 10.4.3 WOCBP for guidance.
Oct-22-2020 14:18:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	Luke Cunliffe (b) (4)	Query 1: Candidate	Clinical review: Please specify why a pregnancy test was not performed. It is not clear from the subject's medical history and age (under 60 years) that they are not of childbearing potential. Please refer to protocol section 10.4.3 WOCBP for guidance.
Oct-19-2020 15:59:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091221

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Oct-19-2020 15:59:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Oct-19-2020 15:59:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
Oct-19-2020 15:59:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
eCRF Audit Trail History

**Form Version:** 10-Oct-2020 15:58

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

**6.a Sponsor ID:**

Date	Location	User	Value	Reason
Oct-19-2020 15:59:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> Not Applicable	Initial Entry

**6.a Test:**

Date	Location	User	Value	Reason
Oct-19-2020 15:59:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> Not Applicable	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Oct-19-2020 15:59:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> Not Applicable	Initial Entry

**6.a Not Done:**

Date	Location	User	Value	Reason
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090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
eCRF Audit Trail History

**Form Version:** 10-Oct-2020 15:58

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

Oct-19-2020 15:59:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> Not Applicable	Initial Entry
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090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091221

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

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Oct-19-2020 15:59:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> Oct/19/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Oct-19-2020 15:59:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> 20134	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)



**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091221

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

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Data Origin**

Date	Location	User	Value	Reason
Oct-19-2020 16:03:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-19-2020 16:03:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-19-2020 16:04:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-19-2020 16:03:42	ACV0PF EINFP60	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

(UTC-07:00) Mountain Time (US & Canada)	00			Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-19-2020 16:03:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Oct/19/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-19-2020 16:04:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BR9FM9	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Oct-19-2020 16:04:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BR9FM9	Initial Entry

**5.b**

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Oct-19-2020 16:05:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> <b>Sample ID:</b> BR9FM4	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Oct-19-2020 16:05:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> BR9FM4	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Oct-19-2020 16:05:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> <b>Sample ID:</b> BKYCTC	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

**5.c Sample ID**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Oct-19-2020 16:05:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> BKYCTC	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Data Origin**

Date	Location	User	Value	Reason
Oct-19-2020 16:02:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-19-2020 16:02:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-19-2020 16:02:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-19-2020 16:02:44	ACV0PF EINFP60	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

(UTC-07:00) Mountain Time (US & Canada)	00			Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-19-2020 16:02:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Oct/19/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-19-2020 16:02:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BP9GCC	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Oct-19-2020 16:02:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BP9GCC	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091221

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

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

[Back to Form](#)

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

Date	Location	User	Value	Reason
Oct-19-2020 16:00:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Oct-19-2020 16:00:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Oct-19-2020 16:00:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
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090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

Oct-26-2020 00:23:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	UNPL updated
Oct-23-2020 11:39:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Oct-22-2020 01:15:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Reissued: Opened	PDQ RQ1: Thank you for confirming subject was contacted. Subjects experiencing Grade 3 symptoms/reactions should be contacted. Per CCR, please consider updating UNPLANNED VISIT form and select appropriate Contact Outcome option present on UNPLANNED VISIT.
Oct-21-2020 10:11:15 (UTC-07:00) Mountain Time	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Answered	subject was contacted, no unplanned visit was deemed necessary

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)



**Header Text:** c4591001

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

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

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

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

(US & Canada)				
Oct-21-2020 03:28:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00.InFor mAdapte r.Discrep ancy	PFE SDQ PROD (b) (4)	Query 1: Opened	PDQ: Subject has reported with Severe symptoms/reactions on '2020-10-19'. Per protocol, subjects experiencing Grade 3 local reactions should be contacted. Please confirm if an UNPLANNED CONTACT was made and update the corresponding form as appropriate. (b) (4)
Oct-19-2020 16:00:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/19/2020 13:58	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Oct-19-2020 16:00:26	ACV0PF EINFP60	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

(UTC-07:00) Mountain Time (US & Canada)	00			
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**6. Body Side:**

Date	Location	User	Value	Reason
Oct-19-2020 16:00:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Oct-19-2020 16:00:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Oct-19-2020 16:00:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIE D OBSERVATION PERIOD	Initial Entry

**11. Was the subject observed for at least the protocol specified observation period after**

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091221

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

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

*investigational product administration?*

Date	Location	User	Value	Reason
Oct-19-2020 16:00:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> YES	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1009

**Subject No:** 10091221

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

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

[Back to Form](#)

*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Oct-19-2020 16:00:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> YES - REACTOGENICITY E-DIARY COLLECTED FO R THIS SUBJECT	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1009

**Subject No:** 10091221

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

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

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*1. Date of Visit*

Date	Location	User	Value	Reason
Nov-07-2020 10:59:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/7/2020	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Form Version:** 10-Oct-2020 16:03

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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

Date	Location	User	Value	Reason
Nov-07-2020 11:27:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

*2.a*

Date	Location	User	Value	Reason
Nov-07-2020 11:27:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FE V ER  <b>Were fever or systemic N symptoms present on t O he last day the Subject Diary was completed?:</b>	Initial Entry

*2.a Symptom:*

Date	Location	User	Value	Reason
Nov-07-2020 11:27:23 (UTC-07:00)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Form Version:** 10-Oct-2020 16:03

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

Mountain Time (US  
& Canada)

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

Date	Location	User	Value	Reason
Nov-07-2020 11:27:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.b**

Date	Location	User	Value	Reason
Nov-07-2020 11:27:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FA TI GU E  <b>Were fever or systemic symptoms present on t he last day the Subject Diary was completed?</b> :	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091221

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

2.b Symptom:

Date	Location	User	Value	Reason
Nov-07-2020 11:27:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(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
Nov-07-2020 11:27:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Nov-07-2020 11:27:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> HEADACHE	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Form Version:** 10-Oct-2020 16:03

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

			<p><b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b></p> <p>YES</p> <p>Ongoing?</p> <p>NO</p> <p>Stop Date:</p> <p>Oct /23 /20 20</p>	
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090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091221

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

2.c Symptom:

Date	Location	User	Value	Reason
Nov-07-2020 11:27:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(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
Nov-07-2020 11:27:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES Ongoing?  NO  Stop Date:  Oct/23/2020	Initial Entry

2.d

Date	Location	User	Value	Reason
Nov-07-2020 11:27:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b>  C HI LL S	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091221

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

Date	Location	User	Value	Reason
Nov-07-2020 11:27:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Nov-07-2020 11:27:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Nov-07-2020 11:27:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Symptom::</u> VO MI TIN	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091221

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

& Canada)			G Were fever or systemi NO c symptoms present o n the last day the Sub ject Diary was comple ted?:	
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2.e Symptom:

Date	Location	User	Value	Reason
Nov-07-2020 11:27:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(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
Nov-07-2020 11:27:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Nov-07-2020 11:27:23	ACV0PF EINFP60	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> DI	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Form Version:** 10-Oct-2020 16:03

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

(UTC-07:00) Mountain Time (US & Canada)	00	(b) (4), (b) (6)	AR RH EA NO	Were fever or systemic symptoms present on the last day the Subject Diary was completed?:
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**2.f Symptom:**

Date	Location	User	Value	Reason
Nov-07-2020 11:27:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(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
Nov-07-2020 11:27:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.g**

Date	Location	User	Value	Reason
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090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091221

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Nov-07-2020 11:27:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSENERED MUSCLE PAIN  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry
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**2.g Symptom:**

Date	Location	User	Value	Reason
Nov-07-2020 11:27:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSENERED 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
Nov-07-2020 11:27:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Form Version:** 10-Oct-2020 16:03

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

**2.h**

Date	Location	User	Value	Reason
Nov-07-2020 11:27:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<p><b>Data Entry:</b></p> <p><b>Symptom::</b> NEW O R WOR SENED JOINT P AIN</p> <p><b>Were fever or syst NO emic symptoms p resent on the last day the Subject D iary was complete d?:</b></p>	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091221

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

2.h Symptom:

Date	Location	User	Value	Reason
Nov-07-2020 11:27:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSENER JOINT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Nov-07-2020 11:27:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Nov-07-2020 11:27:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091221

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Nov-07-2020 11:27:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry
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5.a

Date	Location	User	Value	Reason
Nov-07-2020 11:27:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction:</b> RES 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
Nov-07-2020 11:27:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(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
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090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Form Version:** 10-Oct-2020 16:03

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

Nov-07-2020 11:27:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry
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**5.b**

Date	Location	User	Value	Reason
Nov-07-2020 11:27:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction:</b> SW ELL ING <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091221

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Nov-07-2020 11:27:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(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
Nov-07-2020 11:27:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-07-2020 11:27:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction:</b> PAIN AT INJECTION SITE	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Form Version:** 10-Oct-2020 16:03

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

			<p><b>Were injection site reactions present on the last day the Subject Diary was completed?:</b></p> <p>YES Ongoing ?</p> <p>NO</p> <p>Stop Date:</p> <p>Oct/23/2020</p>	
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090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Form Version:** 10-Oct-2020 16:03

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

**5.c Injection Site Reaction:**

Date	Location	User	Value	Reason
Nov-07-2020 11:27:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> PAIN AT INJECTION SITE	Initial Entry

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

Date	Location	User	Value	Reason
Nov-07-2020 11:27:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES Ongoing?  NO  Stop Date:  Oct/23/2020	Initial Entry

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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1009

**Subject No:** 10091221

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

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Date:**

Date	Location	User	Value	Reason
Nov-07-2020 11:27:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/7/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Nov-07-2020 11:27:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier:</b> 1 <b>Temperature:</b> 98.7 <b>Temperature Unit:</b> F <b>Temperature Location:</b> ORAL CAVITY	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Nov-07-2020 11:27:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1009

**Subject No:** 10091221

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

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

**2.a Temperature:**

Date	Location	User	Value	Reason
Nov-07-2020 11:27:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> 98.7	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Nov-07-2020 11:27:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> F	Initial Entry

**2.a Temperature Location:**

Date	Location	User	Value	Reason
Nov-07-2020 11:27:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
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**Form Version:** 10-Oct-2020 15:58

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Nov-07-2020 11:28:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Nov-07-2020 11:28:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Nov-07-2020 11:28:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**4. Laboratory Name and Address (Derived)**

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Header Text: c4591001

Visit: V2\_VAX2\_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091221

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Nov-07-2020 11:28:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Nov-07-2020 11:28:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**6.a**

Date	Location	User	Value	Reason
Nov-07-2020 11:28:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Done <b>Test::</b> Not Done <b>Result::</b> Not Done <b>Not Done::</b> Not Done	Initial Entry

**6.a Sponsor ID:**

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: LAB URINALYSIS - PREGNANCY TEST -  
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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091221

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Nov-07-2020 11:28:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

**6.a Test:**

Date	Location	User	Value	Reason
Nov-07-2020 11:28:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Nov-07-2020 11:28:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

**6.a Not Done:**

Date	Location	User	Value	Reason
Nov-07-2020 11:28:03 (UTC-07:00)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
eCRF Audit Trail History

**Form Version:** 10-Oct-2020 15:58

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

Mountain Time (US & Canada)				
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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Data Origin**

Date	Location	User	Value	Reason
Nov-07-2020 11:00:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Nov-07-2020 11:00:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Nov-07-2020 11:00:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-07-2020 11:00:29	ACV0PF EINFP60	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

(UTC-07:00) Mountain Time (US & Canada)	00			Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-07-2020 11:00:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Nov/7/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Nov-07-2020 11:00:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BGGZY1	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Nov-07-2020 11:00:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BGGZY1	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1009

**Subject No:** 10091221

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

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

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

Date	Location	User	Value	Reason
Nov-07-2020 11:31:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Nov-07-2020 11:31:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Nov-07-2020 11:31:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
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090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

Nov-07-2020 11:31:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/7/2020 11:10	Initial Entry
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**5. Anatomical Location:**

Date	Location	User	Value	Reason
Nov-07-2020 11:31:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Nov-07-2020 11:31:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Nov-07-2020 11:31:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Nov-07-2020 11:31:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Nov-07-2020 11:31:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)



**Header Text:** c4591001

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

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

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

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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*1. Date of Visit*

Date	Location	User	Value	Reason
Feb-01-2021 01:13:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-29-2021 14:51:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Jan-27-2021 04:25:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(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.

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1009 **Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject No:** 10091221 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

Jan-25-2021 13:05:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Dec/10/2020	Transcription Error
Jan-25-2021 13:04:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Jan/25/2021	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 16:03

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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

Date	Location	User	Value	Reason
Jan-25-2021 13:05:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

*2.a*

Date	Location	User	Value	Reason
Jan-25-2021 13:05:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FE V ER  <b>Were fever or systemic N symptoms present on t O he last day the Subject Diary was completed?:</b>	Initial Entry

*2.a Symptom:*

Date	Location	User	Value	Reason
Jan-25-2021 13:05:05 (UTC-07:00)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009 Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091221 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

Mountain Time (US & Canada)				
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2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-25-2021 13:05:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Jan-25-2021 13:05:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FA TI GU E  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?</b> NO : :	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 16:03 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1009 **Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject No:** 10091221 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

**2.b Symptom:**

Date	Location	User	Value	Reason
Jan-25-2021 13:05:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(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
Jan-25-2021 13:05:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.c**

Date	Location	User	Value	Reason
Jan-25-2021 13:05:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> HE AD AC HE	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009 Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091221 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

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

Date	Location	User	Value	Reason
Jan-25-2021 13:05:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Jan-25-2021 13:05:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Jan-25-2021 13:05:05 (UTC-07:00)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: C HI	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 16:03 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1009 **Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject No:** 10091221 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

Mountain Time (US & Canada)			LL S N O	
<b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b>				

**2.d Symptom:**

Date	Location	User	Value	Reason
Jan-25-2021 13:05:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(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
Jan-25-2021 13:05:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.e**

Date	Location	User	Value	Reason
Jan-25-2021 13:05:05	ACV0PF EINFP60	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> VO	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009 Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091221 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

(UTC-07:00) Mountain Time (US & Canada)	00	(b) (4), (b) (6)	MI TIN G  Were fever or systemi c symptoms present o n the last day the Sub ject Diary was comple ted?:	
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2.e Symptom:

Date	Location	User	Value	Reason
Jan-25-2021 13:05:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> 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-25-2021 13:05:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.f

Date	Location	User	Value	Reason
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090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)



Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009 Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091221 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

Jan-25-2021 13:05:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> DI AR RH EA  <b>Were fever or systemi c symptoms present o n the last day the Subj ect Diary was complet ed?:</b> NO	Initial Entry
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2.f Symptom:

Date	Location	User	Value	Reason
Jan-25-2021 13:05:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(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
Jan-25-2021 13:05:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.g

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 16:03 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1009 **Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject No:** 10091221 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Jan-25-2021 13:05:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW O R WOR SENED MUSCL E PAIN  <b>Were fever or sys temic symptoms present on the las t day the Subject Diary was comple ted?:</b> NO	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 16:03 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1009 **Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject No:** 10091221 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

**2.g Symptom:**

Date	Location	User	Value	Reason
Jan-25-2021 13:05:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSENERED MU SCLE 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-25-2021 13:05:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.h**

Date	Location	User	Value	Reason
Jan-25-2021 13:05:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW O R WOR SENERED JOINT P AIN	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 16:03 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1009 **Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject No:** 10091221 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

			Were fever or syst NO emic symptoms p resent on the last day the Subject D iary was complete d?:	
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**2.h Symptom:**

Date	Location	User	Value	Reason
Jan-25-2021 13:05:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSENE D JOINT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Jan-25-2021 13:05:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**3. Injection Site Location:**

Date	Location	User	Value	Reason
Jan-25-2021 13:05:05 (UTC-07:00)	ACV0PF EINFP60	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009 Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091221 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

Mountain Time (US & Canada)	00			
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4. Injection Site Body Side:

Date	Location	User	Value	Reason
Jan-25-2021 13:05:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-25-2021 13:05:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<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-25-2021 13:05:05	ACV0PF EINFP60	(b) (4), (b) (6)	<b>Data Entry:</b> REDNESS	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 16:03 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1009 **Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject No:** 10091221 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

(UTC-07:00) Mountain Time (US & Canada)	00	(b) (4), (b) (6)		
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**5.a Were injection site reactions present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Jan-25-2021 13:05:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Jan-25-2021 13:05:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction:</b> SW ELL ING <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 16:03 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1009 **Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject No:** 10091221 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

**5.b Injection Site Reaction:**

Date	Location	User	Value	Reason
Jan-25-2021 13:05:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(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
Jan-25-2021 13:05:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Jan-25-2021 13:05:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> PAIN AT INJ ECTI ON SI TE	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009 Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091221 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

			Were injection site reactions present on the last day the Subject Diary was completed?:	
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5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Jan-25-2021 13:05:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> PAIN AT INJECTION SITE	Initial Entry

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

Date	Location	User	Value	Reason
Jan-25-2021 13:05:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)



**Header Text:** c4591001

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

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

**Site No:** 1009 **Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject No:** 10091221 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Data Origin**

Date	Location	User	Value	Reason
Jan-25-2021 13:05:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-25-2021 13:05:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-25-2021 13:06:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Jan-25-2021 13:06:07 (UTC-07:00) Mountain Time (US	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Closed	Close Auto Query

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

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

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

Site No: 1009 Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091221 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

& Canada)				
Jan-25-2021 13:06:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Dec/10/2020	Transcription Error
Jan-25-2021 13:05:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 2: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-25-2021 13:05:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Opened	Date of Assessment is a future date relative to when it was entered. Please correct.
Jan-25-2021 13:05:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Dec/10/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
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090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1009 **Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject No:** 10091221 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

Jan-25-2021 13:06:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BR5BGJ	Initial Entry
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**5.a Sample ID**

Date	Location	User	Value	Reason
Jan-25-2021 13:06:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BR5BGJ	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Jan-25-2021 13:09:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BR5BGH	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

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

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

Site No: 1009 Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091221 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

**5.b Sample ID**

Date	Location	User	Value	Reason
Jan-25-2021 13:09:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BR5BGH	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Jan-25-2021 13:09:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BSJ3LJ	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Jan-25-2021 13:09:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BSJ3LJ	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1009

**Subject No:** 10091221

**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):** 10-Nov-2021 20:44

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*1. Date of Visit*

Date	Location	User	Value	Reason
May-14-2021 15:31:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> May/14/2021	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1009

**Subject No:** 10091221

**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):** 10-Nov-2021 20:44

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**1. Data Origin**

Date	Location	User	Value	Reason
May-14-2021 15:31:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
May-14-2021 15:31:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
May-14-2021 15:31:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
May-14-2021 15:31:33	ACV0PF EINFP60	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_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:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

(UTC-07:00) Mountain Time (US & Canada)	00			Yes, however no barcodes are entered. Please review and correct as appropriate.
May-14-2021 15:31:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  May/14/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
May-14-2021 15:31:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BTLHCK	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
May-14-2021 15:31:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BTLHCK	Initial Entry

**5.b**

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_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:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

Date	Location	User	Value	Reason
May-14-2021 15:32:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BTLHCL	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
May-14-2021 15:32:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BTLHCL	Initial Entry

**5.c**

Date	Location	User	Value	Reason
May-14-2021 15:32:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BRTSSY	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)



**Header Text:** c4591001

**Visit:** V4\_MONTH6\_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:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

**5.c Sample ID**

Date	Location	User	Value	Reason
May-14-2021 15:32:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BRTSSY	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled  
Visit on Oct/20/2020

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

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

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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*1. Date of Visit*

Date	Location	User	Value	Reason
Nov-24-2020 09:02:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED] [REDACTED]	Query 1: Closed	Response satisfies query
Nov-23-2020 09:39:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Answered	Transcription Error
Nov-23-2020 09:39:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Oct/20/2020	Transcription Error
Nov-20-2020 14:10:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED] [REDACTED]	Query 1: Opened	Per source documents date of visit is 20/OCT/2020. Please confirm or clarify.
Oct-23-2020 11:36:57 (UTC-07:00)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Oct/21/2020	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled  
Visit on Oct/20/2020

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

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

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

Mountain Time (US & Canada)				
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**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on Oct/20/2020

**Form:** UNPLANNED VISIT - eCRF Audit Trail History

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

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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*1. Assessments*

Date	Location	User	Value	Reason
Oct-23-2020 11:38:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-23-2020 11:38:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Oct-23-2020 11:38:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> CONTACT OUTCOME	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled  
Visit on Oct/20/2020

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

**Site No:** 1009

**Subject No:** 10091221

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

**Form:** CONTACT OUTCOME - UNPLANNED - eCRF  
Audit Trail History

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Contact Type:**

Date	Location	User	Value	Reason
Oct-23-2020 11:38:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> TELEPHONE VISIT	Initial Entry

**2. Was contact made?**

Date	Location	User	Value	Reason
Nov-25-2020 02:54:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Date of Contact is updated as Date of Visit 20/Oct/2020.
Nov-24-2020 10:27:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Answered	Answer Auto Query
Nov-24-2020 10:27:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Contact:  Oct/20/2020  Contact Outcome:	Transcription Error

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on Oct/20/2020

**Form:** CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History

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

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

			VISIT NOT REQUIRED, INVESTIGATOR DECISION	
Nov-23-2020 21:48:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM : Form is unfrozen now. Date of Contact 21/Oct/2020 is not equal to the Date of Visit 20/Oct/2020 within same unplanned visit. Please review and update as appropriate.
Nov-23-2020 09:41:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Answered	please unfreeze and I will update to 10/20/20
Nov-23-2020 09:39:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Opened	Date of Contact 21/Oct/2020 is not equal to the Date of Visit 20/Oct/2020 within same unplanned visit. Please review and update as appropriate.

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled  
Visit on Oct/20/2020

**Form Version:** 22-Apr-2020 21:04  
**Site No:** 1009

**Subject No:** 10091221

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

**Form:** CONTACT OUTCOME - UNPLANNED - eCRF  
Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified  
**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South

**Subject Initials:** ---

**Generated Time (GMT):** 10-Nov-2021 20:44

Oct-23-2020 11:38:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> YES Date of Contact:  Oct/21/2020  Contact Outcome:  VISIT NOT REQUIRE D, INVESTIGATOR D ECISION	Initial Entry
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090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT - **Form:** DATE OF VISIT - eCRF Audit Trail History  
Unscheduled

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

**Site No:** 1009 **Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South

**Subject No:** 10091221 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

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*1. Date of Visit*

Date	Location	User	Value	Reason
Apr-09-2021 14:39:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Apr/9/2021	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)



**Header Text:** c4591001

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

**Form:** INFORMED CONSENT - ASYMPTOMATIC  
SURVEILLANCE - eCRF Audit Trail History

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

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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*1. Consent Was:*

Date	Location	User	Value	Reason
Apr-09-2021 14:40:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Apr/9/2021	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT - **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History  
Unscheduled

**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:** 10091221 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Data Origin**

Date	Location	User	Value	Reason
Apr-09-2021 14:40:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Apr-09-2021 14:40:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Apr-09-2021 14:56:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Apr-09-2021 14:40:23	ACV0PF EINFP60	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

**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:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

(UTC-07:00) Mountain Time (US & Canada)	00			Yes, however no barcodes are entered. Please review and correct as appropriate.
Apr-09-2021 14:40:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Apr/9/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Apr-09-2021 14:56:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BRTSPB	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Apr-09-2021 14:56:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BRTSPB	Initial Entry

**5.b**

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT - **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History  
Unscheduled

**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:** 10091221 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Apr-09-2021 14:56:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BR9DNK	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Apr-09-2021 14:56:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BR9DNK	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Apr-09-2021 14:56:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BR9DNL	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

**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:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

**5.c Sample ID**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Apr-09-2021 14:56:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BR9DNL	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

**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:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Data Origin**

Date	Location	User	Value	Reason
Apr-09-2021 14:40:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Apr-09-2021 14:40:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Apr-09-2021 14:56:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Apr-09-2021 14:40:35	ACV0PF EINFP60	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

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

**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:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

(UTC-07:00) Mountain Time (US & Canada)	00			Yes, however no barcodes are entered. Please review and correct as appropriate.
Apr-09-2021 14:40:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Apr/9/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Apr-09-2021 14:56:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BR9DTR	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Apr-09-2021 14:56:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> BR9DTR	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (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, Locked, Frozen, Verified

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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

Date	Location	User	Value	Reason
Jan-29-2021 14:51:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/10/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Jan-29-2021 14:51:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Jan-29-2021 14:51:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)



**Header Text:** c4591001

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

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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*1. Date of Visit*

Date	Location	User	Value	Reason
May-14-2021 08:43:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> May/13/2021	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION -  
Unscheduled eCRF Audit Trail History

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

**Site No:** 1009 **Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South

**Subject No:** 10091221 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

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

Date	Location	User	Value	Reason
May-14-2021 08:43:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Participant is NOT willing t o return for Vaccination 3 O R otherwise not eligible	Initial Entry

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:**

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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Date	Location	User	Value	Reason
Nov-11-2020 11:52:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Category:**

Date	Location	User	Value	Reason
Nov-11-2020 11:52:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Nov-11-2020 11:52:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	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
Nov-25-2020 22:52:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-25-2020 09:00:08	ACV0PF EINFP60	auto query (autoquery)	Query 1: Answered	Changed Information

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

(UTC-07:00) Mountain Time (US & Canada)	00			
Nov-25-2020 09:00:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> worsening right ankle pain	Changed Information
Nov-25-2020 07:53:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00.InFor mAdapte r.Discrep ancy	PFE SDQ PROD (b) (4)	Query 1: Opened	The AE right ankle pain was reported but is also listed in Medical History. Please clarify if this is a worsening of the baseline condition, and if so, please consider adding "worsening" to the AE term. AE as baseline conditions should only be reported as AEs if they worsen. (b) (4)
Nov-11-2020 11:52:36	ACV0PF EINFP60	(b) (4), (b) (6)	<b>Data Entry:</b> right ankle pain	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

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

**Site No:** 1009

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

**Subject No:** 10091221

**Subject Initials:** ---

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

**Generated Time (GMT):** 10-Nov-2021 20:44

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

00

**4. Start Date Time:**

Date	Location	User	Value	Reason
Nov-11-2020 11:52:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/19/2020 17:00	Initial Entry

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

Date	Location	User	Value	Reason
Nov-11-2020 11:53:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-11-2020 11:53:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Oct/19/2020 UNK:UNK	Transcription Error
Nov-11-2020 11:52:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Opened	For right ankle pain End Date 19/Nov/2020, is a future date relative to when

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1009

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

Subject No: 10091221

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

				it was entered on 11/Nov/2020. Please correct.
Nov-11-2020 11:52:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Nov/19/2020 UNK:UNK	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Nov-11-2020 11:52:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> 3	Initial Entry

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

***If Yes, NOTIFY PFIZER IMMEDIATELY.***

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

Date	Location	User	Value	Reason
Nov-11-2020 11:52:36 (UTC-07:00)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Locked, Frozen

**Site No:** 1009

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject No:** 10091221

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

Mountain Time (US & Canada)

**8. Is this adverse event the result of a study Medication Error?**

*If Yes, record the type of medication error on the Medication Error Log.*

Date	Location	User	Value	Reason
Nov-11-2020 11:52:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Nov-11-2020 11:52:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(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>  dance injury	Initial Entry

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
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090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Locked, Frozen

**Site No:** 1009

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject No:** 10091221

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

Nov-11-2020 11:52:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry
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**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Nov-11-2020 11:52:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Nov-11-2020 11:52:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**13. What was the outcome of this adverse event?:**

Date	Location	User	Value	Reason
Nov-11-2020 11:52:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Locked, Frozen

**Site No:** 1009

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject No:** 10091221

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

& Canada)

**14. Did the adverse event cause the subject to be discontinued from the study?**

Date	Location	User	Value	Reason
Nov-11-2020 11:52:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 1 -  
Unscheduled Visit on Apr/18/2021

**Form:** DATE OF VISIT - ASYMPTOMATIC  
SURVEILLANCE - eCRF Audit Trail History

**Form Version:** 14-Jan-2021 02:22

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1009

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South

**Subject No:** 10091221

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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*1. Date of Visit*

Date	Location	User	Value	Reason
May-03-2021 03:51:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	As per site confirmation - updated PD tracker
Apr-30-2021 09:27:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Answered	confirmed
Apr-30-2021 05:08:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	PDQ: DOV at this visit is out of window (-1 day) from DOV (09/Apr/2021) at SURV CONS. Please reconcile and update accordingly, else confirm date is correct as is.
Apr-20-2021 09:34:19 (UTC-07:00) Mountain Time (US	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Apr/18/2021	Transcription Error

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 1 -  
Unscheduled Visit on Apr/18/2021

**Form Version:** 14-Jan-2021 02:22

**Site No:** 1009

**Subject No:** 10091221

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - ASYMPTOMATIC  
SURVEILLANCE - 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):** 10-Nov-2021 20:44

& Canada)				
Apr-20-2021 09:31:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> Apr/20/2021	Transcription Error
Apr-20-2021 09:30:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> Apr/18/2021	Initial Entry

**3. COVID-19 Surveillance Visit:**

Date	Location	User	Value	Reason
Apr-20-2021 09:30:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> SSWAB_WEEK2	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 1 -  
Unscheduled Visit on Apr/18/2021

**Form Version:** 10-Oct-2020 15:57

**Site No:** 1009

**Subject No:** 10091221

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
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):** 10-Nov-2021 20:44

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**1. Data Origin**

Date	Location	User	Value	Reason
Apr-20-2021 09:30:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Apr-20-2021 09:30:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> NASAL_SWAB_SELF	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Apr-20-2021 09:34:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Apr-20-2021 09:34:19	ACV0PF EINFP60	auto query (autoquery)	Query 2: Closed	Close Auto Query

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001**Visit:** V202\_SURVEIL\_SWAB 1 -  
Unscheduled Visit on Apr/18/2021**Form Version:** 10-Oct-2020 15:57**Site No:** 1009**Subject No:** 10091221**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
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):** 10-Nov-2021 20:44

(UTC-07:00) Mountain Time (US & Canada)	00			
Apr-20-2021 09:31:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 2: Opened	Date of Collection is different from Date of Visit. Please review and update as appropriate, else clarify.
Apr-20-2021 09:30:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Apr-20-2021 09:30:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED] [REDACTED]	<b>Data Entry:</b> YES Date of Collection:  Apr/18/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Apr-20-2021 09:34:52 (UTC-07:00)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED] [REDACTED]	<b>Data Entry:</b> Sample ID: AA45840	Initial Entry

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 1 -  
Unscheduled Visit on Apr/18/2021

**Form Version:** 10-Oct-2020 15:57

**Site No:** 1009

**Subject No:** 10091221

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
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):** 10-Nov-2021 20:44

Mountain Time (US & Canada)				
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**5.a Sample ID**

Date	Location	User	Value	Reason
Apr-20-2021 09:34:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> AA45840	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 2 -  
Unscheduled Visit on Apr/28/2021

**Form Version:** 14-Jan-2021 02:22

**Site No:** 1009

**Subject No:** 10091221

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - ASYMPTOMATIC  
SURVEILLANCE - 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):** 10-Nov-2021 20:44

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**1. Date of Visit**

Date	Location	User	Value	Reason
Apr-30-2021 09:27:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Apr/28/2021	Initial Entry

**3. COVID-19 Surveillance Visit:**

Date	Location	User	Value	Reason
Apr-30-2021 09:27:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> SSWAB_WEEK4	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)



**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 2 -  
Unscheduled Visit on Apr/28/2021

**Form Version:** 10-Oct-2020 15:57

**Site No:** 1009

**Subject No:** 10091221

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
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):** 10-Nov-2021 20:44

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**1. Data Origin**

Date	Location	User	Value	Reason
Apr-30-2021 09:28:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Apr-30-2021 09:28:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> NASAL_SWAB_SELF	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Apr-30-2021 09:28:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Apr-30-2021 09:28:05	ACV0PF EINFP60	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 2 -  
Unscheduled Visit on Apr/28/2021

**Form Version:** 10-Oct-2020 15:57

**Site No:** 1009

**Subject No:** 10091221

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
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):** 10-Nov-2021 20:44

(UTC-07:00) Mountain Time (US & Canada)	00			Yes, however no barcodes are entered. Please review and correct as appropriate.
Apr-30-2021 09:28:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Apr/28/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Apr-30-2021 09:28:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> AA45841	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Apr-30-2021 09:28:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> AA45841	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 3 -  
Unscheduled Visit on May/09/2021

**Form:** DATE OF VISIT - ASYMPTOMATIC  
SURVEILLANCE - eCRF Audit Trail History

**Form Version:** 14-Jan-2021 02:22

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1009

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South

**Subject No:** 10091221

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Date of Visit**

Date	Location	User	Value	Reason
May-12-2021 08:40:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> May/9/2021	Initial Entry

**3. COVID-19 Surveillance Visit:**

Date	Location	User	Value	Reason
May-12-2021 08:40:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> SSWAB_WEEK6	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 3 -  
Unscheduled Visit on May/09/2021

**Form Version:** 10-Oct-2020 15:57

**Site No:** 1009

**Subject No:** 10091221

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
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):** 10-Nov-2021 20:44

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**1. Data Origin**

Date	Location	User	Value	Reason
May-12-2021 08:41:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
May-12-2021 08:41:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> NASAL_SWAB_SELF	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
May-12-2021 08:41:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
May-12-2021 08:41:19	ACV0PF EINFP60	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 3 -  
Unscheduled Visit on May/09/2021

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 15:57

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1009

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family  
Clinic South

**Subject No:** 10091221

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

(UTC-07:00) Mountain Time (US & Canada)	00			Yes, however no barcodes are entered. Please review and correct as appropriate.
May-12-2021 08:41:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> YES Date of Collection:  May/9/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
May-12-2021 08:41:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> <b>Sample ID:</b> AA45844	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
May-12-2021 08:41:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> AA45844	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1009

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject No:** 10091221

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
May-14-2021 08:46:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> May/13/2021	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
May-26-2021 09:56:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
May-22-2021 00:04:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00.InFor mAdapte r.Discrep ancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_DS001_35
May-21-2021 07:28:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 2: Answer ed	Transcription Error

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1009

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject No:** 10091221

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

May-21-2021 07:28:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> OTHER <i>If other, specify</i> :  parent preference	Transcription Error
May-21-2021 07:27:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Query 1: Answered	Original value is correct
May-20-2021 12:48:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Query 2: Opened	Per source documents primary reason for unblinding is Other: parent request. Please confirm or clarify. As subject did not want to return for vaccination 3 unblinding is not done to assess eligibility for additional vaccination.
May-14-2021 14:49:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00.InFormAdapted.Discrepancy	DMW QUERY (b) (4) [REDACTED]	Query 1: Opened	DMW9401082;Primary Reason for Unblinding is "ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION", but "Participant is willing to return for Vaccination 3" is not

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1009

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject No:** 10091221

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

				selected in the Further Vaccination Confirmation CRF. Please review and update as appropriate.
May-14-2021 08:46:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> ASSESS ELIGI BILITY FOR A DDITIONAL V ACCINATION	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)



**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form:** SUBJECT STATUS - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Verified

**Site No:** 1009

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject No:** 10091221

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

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**1. Subject Status**

Date	Location	User	Value	Reason
Jan-29-2021 14:51:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Oct-19-2020 15:59:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Oct-19-2020 15:55:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

**2. Subject Status Date**

Date	Location	User	Value	Reason
Jan-29-2021 14:51:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> Dec/10/2020	Initial Entry
Oct-19-2020 15:59:53 (UTC-07:00)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> Oct/19/2020	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form:** SUBJECT STATUS - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Verified

**Site No:** 1009

**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

**Subject No:** 10091221

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 10-Nov-2021 20:44

Mountain Time (US & Canada)				
Oct-19-2020 15:55:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	<b>Data Entry:</b> Oct/19/2020	Initial Entry

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1009

**Subject No:** 10091221

**Generated By:** (b) (4)

**Form:** CASEBOOK SIGNATURE FORM - 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):** 10-Nov-2021 20:44

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*1. Casebook Signature*

Date	Location	User	Value	Reason
Mar-09-2021 17:15:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<b>Data Entry:</b> Click Here to Enable	Initial Entry

090177e19891a03e\Final\Final On: 11-Nov-2021 01:20 (GMT)