

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1147

**Subject No:** 11471327

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

**Form:** COHORT\_SELECTION

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

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Cohort Selection**

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

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

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1147

**Subject No:** 11471327

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

**Form:** MAIN INFORMED CONSENT

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

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/5/2021
----	--------------	---

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1147

**Subject No:** 11471327

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

**Form:** DEMOGRAPHY

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

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[11471327]
2.	Birth Date:	(b) (6) 2006
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e196ae30f1\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1147

**Subject No:** 11471327

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

**Form:** DATE OF VISIT

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

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** c4591001

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

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

**Site No:** 1147

**Subject No:** 11471327

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

**Form:** INCLUSION/EXCLUSION CRITERIA

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

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

**Form Comments**

**Inclusion Criteria Not Met**

1.	Description of Inclusion Criterion Not Met	Not Applicable
----	--	----------------

**Exclusion Criteria Met**

2.	Description of Exclusion Criterion Met	Not Applicable
----	--	----------------

**Header Text:** c4591001

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

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

**Site No:** 1147

**Subject No:** 11471327

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

**Form:** DISPOSITION - SCREENING

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

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Disposition - Screening**

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

**Header Text:** c4591001

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

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

**Site No:** 1147

**Subject No:** 11471327

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

**Form:** GENERAL MEDICAL HISTORY

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

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

**Form Comments**

**Medical History Details**

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

090177e196ae30f1\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1147

**Subject No:** 11471327

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

**Form:** HIV STATUS

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

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**HIV Status**

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



**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 10-Dec-2020 02:29**Site No:** 1147**Subject No:** 11471327**Generated By:** (b) (4)**Form:** VITAL SIGNS - BASELINE**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1147) Ochsner Health System**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:56[eCRF Audit Trail History](#)**Vital Signs**

1.	Date:	Jan/5/2021
2.	Weight:	[167.2]
3.	Unit:	LB
4.	Height:	[66.0]
5.	Unit:	in
6.	Body Mass Index:	[27.0]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[98.5]
	Unit:	F
	Temperature Location:	ORAL CAVITY

**Header Text:** c4591001

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

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

**Site No:** 1147

**Subject No:** 11471327

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

**Form:** RANDOMIZATION

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

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Jan/5/2021
2.	Randomization Number:	[25570]
3.	Randomization Group:	[ ]

**Header Text:** c4591001

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

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

**Site No:** 1147

**Subject No:** 11471327

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/5/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BP8HFV]
5.b	Sample ID	[BP8HFW]
5.c	Sample ID	[BSGV0P]

090177e196ae30f1\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1147**Subject No:** 11471327**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1147) Ochsner Health System**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:56**eCRF Audit Trail History****Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/5/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BP8HFG]
-----	-----------	----------

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 10-Dec-2020 02:26**Site No:** 1147**Subject No:** 11471327**Generated By:** (b) (4)**Form:** VACCINATION**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1147) Ochsner Health System**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:56**eCRF Audit Trail History****Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/5/2021 17:10
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

**Header Text:** c4591001

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

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

**Site No:** 1147

**Subject No:** 11471327

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

**Form:** REACTOGENICITY DIARY

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

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Reactogenicity Diary**

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

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1147

**Subject No:** 11471327

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

**Form:** DATE OF VISIT

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

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Jan/27/2021
2.	Erroneous Visit	

090177e196ae30f1\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1147

**Subject No:** 11471327

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

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

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

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vaccination Symptoms Diary - Symptom Resolved Dates**

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

090177e196ae30f1\Final\Final On: 01-Apr-2021 04:20 (GMT)



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1147

**Site Name:** (1147) Ochsner Health System

**Subject No:** 11471327

**Subject Initials:** ---

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

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

2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO	
2.h	Symptom:	NEW OR WORSENERED JOINT PAIN	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO	
3.	Injection Site Location:	DELTOID MUSCLE	
4.	Injection Site Body Side:	LEFT	<a href="#">Comments</a>
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	

090177e196ae30f1\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1147

**Subject No:** 11471327

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

**Form:** VITAL SIGNS - TEMP

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

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Jan/27/2021
----	-------	-------------

**Vital Signs Details**

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

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1147**Subject No:** 11471327**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1147) Ochsner Health System**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:56**eCRF Audit Trail History****Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/27/2021
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	[BR5J0P]
-----	-----------	----------

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form Version:** 10-Dec-2020 02:26**Site No:** 1147**Subject No:** 11471327**Generated By:** (b) (4)**Form:** VACCINATION**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1147) Ochsner Health System**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:56**Form Comments****eCRF Audit Trail History****Vaccination**

1.	Was there a temporary delay of vaccination?	Not Applicable _____	<a href="#">Comments</a>
2.	Treatment Name	Not Applicable _____ [ ]	<a href="#">Comments</a>
3.	Formulation:	Not Applicable _____	<a href="#">Comments</a>
4.	Dose Date Time:	Not Applicable _____ //	<a href="#">Comments</a>
5.	Anatomical Location:	Not Applicable _____	<a href="#">Comments</a>
6.	Body Side:	Not Applicable _____	<a href="#">Comments</a>
7.	Route:	Not Applicable _____	<a href="#">Comments</a>
8.	Actual Dose:	Not Applicable _____ [ ]	<a href="#">Comments</a>
9.	Unit:	Not Applicable _____	<a href="#">Comments</a>
10.	Timeframe Subject Was Observed	Not Applicable _____	<a href="#">Comments</a>
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	Not Applicable _____	<a href="#">Comments</a>

**Header Text:** c4591001

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

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

**Site No:** 1147

**Subject No:** 11471327

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

**Form:** DATE OF VISIT

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

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Feb/25/2021
2.	Erroneous Visit	

090177e196ae30f1\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1147

**Subject No:** 11471327

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

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

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

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

[Form Comments](#)

[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?	Not Applicable	<a href="#">Comments</a>
2.a	Symptom:	FEVER	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Applicable	<a href="#">Comments</a>
2.b	Symptom:	FATIGUE	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Applicable	<a href="#">Comments</a>
2.c	Symptom:	HEADACHE	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Applicable	<a href="#">Comments</a>
2.d	Symptom:	CHILLS	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Applicable	<a href="#">Comments</a>
2.e	Symptom:	VOMITING	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Applicable	<a href="#">Comments</a>
2.f	Symptom:	DIARRHEA	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Applicable	<a href="#">Comments</a>

090177e196ae30f1\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1147

**Site Name:** (1147) Ochsner Health System

**Subject No:** 11471327

**Subject Initials:** ---

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

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

2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Applicable	<a href="#">Comments</a>
2.h	Symptom:	NEW OR WORSENERED JOINT PAIN	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Applicable	<a href="#">Comments</a>
3.	Injection Site Location:	Not Applicable	<a href="#">Comments</a>
4.	Injection Site Body Side:	Not Applicable	<a href="#">Comments</a>
5.a	Injection Site Reaction:	REDNESS	
	Were injection site reactions present on the last day the Subject Diary was completed?	Not Applicable	<a href="#">Comments</a>
5.b	Injection Site Reaction:	SWELLING	
	Were injection site reactions present on the last day the Subject Diary was completed?	Not Applicable	<a href="#">Comments</a>
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE	
	Were injection site reactions present on the last day the Subject Diary was completed?	Not Applicable	<a href="#">Comments</a>

090177e196ae30f1\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1147**Subject No:** 11471327**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1147) Ochsner Health System**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:56**eCRF Audit Trail History****Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Feb/25/2021
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	[BR7X56]
5.b	Sample ID	[BRZXLD]



**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1147

**Subject No:** 11471327

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1147

**Subject No:** 11471327

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001

**Visit:** V5\_MONTH12\_L

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

**Site No:** 1147

**Subject No:** 11471327

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

**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:** 1147

**Subject No:** 11471327

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001

**Visit:** V6\_MONTH24\_L

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

**Site No:** 1147

**Subject No:** 11471327

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V6\_MONTH24\_L

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

**Site No:** 1147

**Subject No:** 11471327

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**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:** 1147

**Site Name:** (1147) Ochsner Health System

**Subject No:** 11471327

**Subject Initials:** ---

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

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

090177e196ae30f1\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1147

**Site Name:** (1147) Ochsner Health System

**Subject No:** 11471327

**Subject Initials:** ---

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

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

**Signs and Symptoms**

1.	Date of Assessment:	//
2.	Date of First Symptom Started:	//
3.	Symptoms Ongoing?	

**Symptoms**

4.	Symptoms:	
	Was symptom present?	

**Symptoms - Other**

5.	Symptoms - Other Text:	[ ]
----	------------------------	-----



**Header Text:** c4591001**Visit:** POT\_COVID\_ILL - New Unscheduled Visit**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1147**Site Name:** (1147) Ochsner Health System**Subject No:** 11471327**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**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:** 1147**Site Name:** (1147) Ochsner Health System**Subject No:** 11471327**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001

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

**Form:** HEALTH CARE UTILIZATION

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

**Form Status:** Not Started

**Site No:** 1147

**Site Name:** (1147) Ochsner Health System

**Subject No:** 11471327

**Subject Initials:** ---

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

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

**Health Care Utilization**

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

**Health Care Utilization Other**

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

**Health Care Utilization**

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

090177e196ae30f1\Final\Final On: 01-Apr-2021 04:20 (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:** 1147

**Site Name:** (1147) Ochsner Health System

**Subject No:** 11471327

**Subject Initials:** ---

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

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

**Illness Details**

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

**Header Text:** c4591001

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

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

**Site No:** 1147

**Subject No:** 11471327

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

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

**Form Status:** Not Started

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

090177e196ae30f1\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_CONVA - New  
Unscheduled Visit**Form Version:** 22-Apr-2020 21:03**Site No:** 1147**Subject No:** 11471327**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Status:** Not Started**Site Name:** (1147) Ochsner Health System**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:56**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1147

**Site Name:** (1147) Ochsner Health System

**Subject No:** 11471327

**Subject Initials:** ---

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

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Repeat Swab**

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

090177e196ae30f1\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_REPEAT\_SWAB - New  
Unscheduled Visit**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB**Form Version:** 10-Oct-2020 15:57**Form Status:** Not Started**Site No:** 1147**Site Name:** (1147) Ochsner Health System**Subject No:** 11471327**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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



**Header Text:** c4591001

**Visit:** Logs

**Form:** ADVERSE EVENT REPORT

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

**Site No:** 1147

**Site Name:** (1147) Ochsner Health System

**Subject No:** 11471327

**Subject Initials:** ---

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

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

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Fever (104.7)	Jan/6/2021 19:30	NO End Date Time:  Jan/8/2021 UNK:UNK	<a href="#">Repeating Pages</a>

090177e196ae30f1\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1147

**Subject No:** 11471327

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

#### Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Fever (104.7)]
4.	Start Date Time:	Jan/6/2021 19:30
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/8/2021 UNK:UNK
6.	Toxicity Grade:	4
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	DRUG WITHDRAWN
11.	Was a Concomitant Medication given?	YES

090177e196ae30f1\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1147

**Subject No:** 11471327

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

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

**Header Text:** c4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

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

**Site No:** 1147

**Site Name:** (1147) Ochsner Health System

**Subject No:** 11471327

**Subject Initials:** ---

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

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

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1147

**Subject No:** 11471327

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

**Form:** MEDICATION ERROR

**Form Status:** Not Started

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

[Back to Form](#)

**Medication Error**

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

090177e196ae30f1\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001

**Visit:** Logs

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

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

**Site No:** 1147

**Site Name:** (1147) Ochsner Health System

**Subject No:** 11471327

**Subject Initials:** ---

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

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

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1147

**Subject No:** 11471327

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

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

**Form Status:** Not Started

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

[Back to Form](#)

**Concomitant Medications**

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

090177e196ae30f1\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Site No:** 1147

**Site Name:** (1147) Ochsner Health System

**Subject No:** 11471327

**Subject Initials:** ---

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

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

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



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1147

**Subject No:** 11471327

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

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Status:** Not Started

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

[Back to Form](#)

**Concomitant Medications**

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

090177e196ae30f1\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

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

**Site No:** 1147

**Site Name:** (1147) Ochsner Health System

**Subject No:** 11471327

**Subject Initials:** ---

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

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

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1147

**Subject No:** 11471327

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

**Form:** RADIATION TREATMENT

**Form Status:** Not Started

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

[Back to Form](#)

**Radiation Treatment**

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

**Header Text:** c4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

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

**Site No:** 1147

**Site Name:** (1147) Ochsner Health System

**Subject No:** 11471327

**Subject Initials:** ---

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

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

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1147

**Subject No:** 11471327

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

**Form:** TRANSFUSIONS

**Form Status:** Not Started

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

[Back to Form](#)

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

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Jan/06/2021

**Form:** DATE OF VISIT

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

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

**Site No:** 1147

**Site Name:** (1147) Ochsner Health System

**Subject No:** 11471327

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Jan/6/2021
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Jan/06/2021

**Form:** UNPLANNED VISIT

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

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

**Site No:** 1147

**Site Name:** (1147) Ochsner Health System

**Subject No:** 11471327

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Unplanned Assessments**

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

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Jan/06/2021

**Form:** CONTACT OUTCOME - UNPLANNED

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

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

**Site No:** 1147

**Site Name:** (1147) Ochsner Health System

**Subject No:** 11471327

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Contact Outcome**

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Jan/6/2021  Contact Outcome: VISIT NOT REQUIRED, INVESTIGATOR DECISION
3.	Comments:	[ ]



**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

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

**Site No:** 1147

**Subject No:** 11471327

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form Version:** 20-Feb-2021 02:16

**Site No:** 1147

**Subject No:** 11471327

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

**Form:** VITAL SIGNS - TEMP

**Form Status:** Not Started

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

**Vital Signs**

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

**Vital Signs Details**

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

**Header Text:** c4591001**Visit:** Unplanned Vaccination - Unscheduled**Form:** VACCINATION**Form Version:** 10-Dec-2020 02:26**Form Status:** Not Started**Site No:** 1147**Site Name:** (1147) Ochsner Health System**Subject No:** 11471327**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56**Vaccination**

1.	Was there a temporary delay of vaccination?	
2.	Treatment Name	[ ]
3.	Formulation:	
4.	Dose Date Time:	//
5.	Anatomical Location:	
6.	Body Side:	
7.	Route:	
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	

**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:** 1147

**Site Name:** (1147) Ochsner Health System

**Subject No:** 11471327

**Subject Initials:** ---

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

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

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** CONTACT OUTCOME - MONTH 6

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

**Form Status:** Not Started

**Site No:** 1147

**Site Name:** (1147) Ochsner Health System

**Subject No:** 11471327

**Subject Initials:** ---

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

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

**Contact Outcome**

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

**Header Text:** c4591001

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

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

**Site No:** 1147

**Subject No:** 11471327

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

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

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

**Site No:** 1147

**Subject No:** 11471327

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

**Form:** INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE

**Form Status:** Not Started

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

**Informed Consent - Asymptomatic Surveillance**

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

090177e196ae30f1\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled**Form Version:** 22-Apr-2020 21:03**Site No:** 1147**Subject No:** 11471327**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Status:** Not Started**Site Name:** (1147) Ochsner Health System**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:56**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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



**Header Text:** c4591001**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled**Form Version:** 22-Apr-2020 21:03**Site No:** 1147**Subject No:** 11471327**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB**Form Status:** Not Started**Site Name:** (1147) Ochsner Health System**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:56**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

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

**Site No:** 1147

**Subject No:** 11471327

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

**Form:** DISPOSITION - TREATMENT

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

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation/Death :	Jan/8/2021
2.	Phase of Disposition:	VACCINATION
3.	Status:	ADVERSE EVENT
4.	Specify Status:	[ ]

**Header Text:** c4591001

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

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

**Site No:** 1147

**Subject No:** 11471327

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001**Visit:** Potential ReVax Initial Contact -  
Unscheduled**Form Version:** 10-Dec-2020 02:25**Site No:** 1147**Subject No:** 11471327**Generated By:** (b) (4)**Form:** FURTHER VACCINATION CONFIRMATION**Form Status:** Not Started**Site Name:** (1147) Ochsner Health System**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:56**Further Vaccination Confirmation**

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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1147

**Subject No:** 11471327

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

**Form:** TREATMENT UNBLINDED

**Form Status:** Not Started

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

**Treatment Unblinded**

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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1147

**Subject No:** 11471327

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

**Form:** WITHDRAWAL OF CONSENT

**Form Status:** Not Started

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

**Withdrawal Of Consent**

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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1147

**Subject No:** 11471327

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

**Form:** DEATH DETAILS CODED

**Form Status:** Not Started

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

**Death Details**

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

**Cause of Death**

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

**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

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

**Site No:** 1147

**Subject No:** 11471327

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

**Form:** DISPOSITION - FOLLOW-UP

**Form Status:** Not Started

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

**Disposition - Follow-Up**

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



**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1147

**Subject No:** 11471327

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

**Form:** SUBJECT STATUS

**Form Status:** Data Complete, Verified

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Subject Status**

1.	Subject Status	DISCONTINUED
2.	Subject Status Date	Jan/8/2021

090177e196ae30f1\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

**Site No:** 1147

**Subject No:** 11471327

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

**Form:** CASEBOOK SIGNATURE FORM

**Form Status:** Not Started

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

**Casebook Signature Form**

1.	Casebook Signature	
----	--------------------	--

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

**Form Status:** Not Started

**Site No:** 1147

**Site Name:** (1147) Ochsner Health System

**Subject No:** 11471327

**Subject Initials:** ---

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

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

[Audit Trail](#)

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

- CRF\_Sign
- CRF\_Sign\_1

Name	Signature Meaning	Date	Type	Action
------	----------------------	------	------	--------

**Header Text:** c4591001

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

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

**Site No:** 1147

**Subject No:** 11471327

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

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

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

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-06-2021 16:41:22 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	not applicable
			Not Applicable

**Header Text:** c4591001

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

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

**Site No:** 1147

**Subject No:** 11471327

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

**Form:** GENERAL MEDICAL HISTORY - Comments

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

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-06-2021 16:42:20 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	not applicable
			Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1147

**Subject No:** 11471327

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

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

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

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
4	Mar-02-2021 14:43:57 (UTC-06:00) Central Time (US & Canada)	James McMullen (b) (4)	
4	Jan-28-2021 00:20:22 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) (b) (6)	n/a <hr/> Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1147

**Subject No:** 11471327

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

**Form:** VACCINATION - Comments

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

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-28-2021 00:17:40 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	n/a
			Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1147

**Subject No:** 11471327

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

**Form:** VACCINATION - Comments

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

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
1	Jan-28-2021 00:17:40 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	n/a
			Not Applicable



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1147

**Subject No:** 11471327

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

**Form:** VACCINATION - Comments

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

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
2	Jan-28-2021 00:17:40 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	n/a
			Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1147

**Subject No:** 11471327

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

**Form:** VACCINATION - Comments

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

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
3	Jan-28-2021 00:17:40 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	n/a
			Not Applicable

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form Version:** 10-Dec-2020 02:26**Site No:** 1147**Subject No:** 11471327**Generated By:** (b) (4)**Form:** VACCINATION - Comments**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1147) Ochsner Health System**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:56[Back to Form](#)

Item	Date	User	Comment
4	Jan-28-2021 00:17:40 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	n/a
			Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1147

**Subject No:** 11471327

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

**Form:** VACCINATION - Comments

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

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
5	Jan-28-2021 00:17:40 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	n/a
			Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1147

**Subject No:** 11471327

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

**Form:** VACCINATION - Comments

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

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
6	Jan-28-2021 00:17:40 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	n/a
			Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1147

**Subject No:** 11471327

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

**Form:** VACCINATION - Comments

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

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
7	Jan-28-2021 00:17:40 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	n/a
			Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1147

**Subject No:** 11471327

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

**Form:** VACCINATION - Comments

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

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
8	Jan-28-2021 00:17:40 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	n/a
			Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1147

**Subject No:** 11471327

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

**Form:** VACCINATION - Comments

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

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
9	Jan-28-2021 00:17:40 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	n/a
			Not Applicable



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1147

**Subject No:** 11471327

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

**Form:** VACCINATION - Comments

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

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
10	Jan-28-2021 00:17:40 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	n/a
			Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1147

**Subject No:** 11471327

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

**Form:** VACCINATION - Comments

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

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
11	Jan-28-2021 00:17:40 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	n/a
			Not Applicable

**Header Text:** c4591001

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

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

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

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

**Site No:** 1147

**Site Name:** (1147) Ochsner Health System

**Subject No:** 11471327

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
Form	Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	James McMullen (b) (4)	Subject discontinued from study treatment. Did not receive Vaccination 2 Not Applicable

**Header Text:** c4591001

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

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

**Site No:** 1147

**Subject No:** 11471327

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

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

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

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
1	Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	James McMullen (b) (4)	Subject discontinued from study treatment. Did not receive Vaccination 2
			Not Applicable

**Header Text:** c4591001

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

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

**Site No:** 1147

**Subject No:** 11471327

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

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

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

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
2.a	Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	James McMullen (b) (4)	Subject discontinued from study treatment. Did not receive Vaccination 2
			Not Applicable

**Header Text:** c4591001

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

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

**Site No:** 1147

**Subject No:** 11471327

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

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

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

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
2.b	Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	James McMullen (b) (4)	Subject discontinued from study treatment. Did not receive Vaccination 2
			Not Applicable

**Header Text:** c4591001

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

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

**Site No:** 1147

**Subject No:** 11471327

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

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

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

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
2.c	Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	James McMullen (b) (4)	Subject discontinued from study treatment. Did not receive Vaccination 2
			Not Applicable

**Header Text:** c4591001

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

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

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

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

**Site No:** 1147

**Site Name:** (1147) Ochsner Health System

**Subject No:** 11471327

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
2.d	Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	James McMullen (b) (4)	Subject discontinued from study treatment. Did not receive Vaccination 2
			Not Applicable



**Header Text:** c4591001

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

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

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

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

**Site No:** 1147

**Site Name:** (1147) Ochsner Health System

**Subject No:** 11471327

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
2.e	Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	James McMullen (b) (4)	Subject discontinued from study treatment. Did not receive Vaccination 2
			Not Applicable

**Header Text:** c4591001

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

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

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

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

**Site No:** 1147

**Site Name:** (1147) Ochsner Health System

**Subject No:** 11471327

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
2.f	Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	James McMullen (b) (4)	Subject discontinued from study treatment. Did not receive Vaccination 2
			Not Applicable

**Header Text:** c4591001

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

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

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

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

**Site No:** 1147

**Site Name:** (1147) Ochsner Health System

**Subject No:** 11471327

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
2.g	Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	James McMullen (b) (4)	Subject discontinued from study treatment. Did not receive Vaccination 2
			Not Applicable

**Header Text:** c4591001

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

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

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

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

**Site No:** 1147

**Site Name:** (1147) Ochsner Health System

**Subject No:** 11471327

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
2.h	Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	James McMullen (b) (4)	Subject discontinued from study treatment. Did not receive Vaccination 2
			Not Applicable

**Header Text:** c4591001

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

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

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

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

**Site No:** 1147

**Site Name:** (1147) Ochsner Health System

**Subject No:** 11471327

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
3	Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	James McMullen (b) (4)	Subject discontinued from study treatment. Did not receive Vaccination 2
			Not Applicable

**Header Text:** c4591001

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

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

**Site No:** 1147

**Subject No:** 11471327

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

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

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

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
4	Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	James McMullen (b) (4)	Subject discontinued from study treatment. Did not receive Vaccination 2
			Not Applicable

**Header Text:** c4591001

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

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

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

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

**Site No:** 1147

**Site Name:** (1147) Ochsner Health System

**Subject No:** 11471327

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
5.a	Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	James McMullen (b) (4)	Subject discontinued from study treatment. Did not receive Vaccination 2
			Not Applicable

**Header Text:** c4591001

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

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

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

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

**Site No:** 1147

**Site Name:** (1147) Ochsner Health System

**Subject No:** 11471327

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
5.b	Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	James McMullen (b) (4)	Subject discontinued from study treatment. Did not receive Vaccination 2
			Not Applicable



**Header Text:** c4591001

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

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

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

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

**Site No:** 1147

**Site Name:** (1147) Ochsner Health System

**Subject No:** 11471327

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
5.c	Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	James McMullen (b) (4)	Subject discontinued from study treatment. Did not receive Vaccination 2
			Not Applicable

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

**Site No:** 1147

**Subject No:** 11471327

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

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

**Form Status:** Not Started

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

[Back to Form](#)

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

- CRF\_Sign
- CRF\_Sign\_1

Name	Signature Meaning	Date	Type	Action
------	----------------------	------	------	--------

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1147

**Subject No:** 11471327

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

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

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

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Jan-06-2021 16:39:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 01 DEC 2020	Initial Entry

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

Date	Location	User	Value	Reason
Jan-06-2021 16:39:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1147

**Subject No:** 11471327

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

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

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

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

[Back to Form](#)

**I. Consent Was:**

Date	Location	User	Value	Reason
Jan-06-2021 16:39:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Jan/5/2021	Initial Entry

Header Text: c4591001

Visit: COHORT\_SELECTION

Form Version: 10-Dec-2020 02:26

Site No: 1147

Subject No: 11471327

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

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

[Back to Form](#)

**1. Subject ID**

Date	Location	User	Value	Reason
Jan-06-2021 16:38:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 11471327	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Jan-06-2021 16:35:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6) 2006	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Jan-06-2021 16:40:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> MALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Jan-07-2021 08:21:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT HISPANIC OR LATINO( A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Jan-07-2021 08:21:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> WHITE	Initial Entry

**6. Racial Designation:**

Date	Location	User	Value	Reason
Jan-27-2021 01:17:52	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Clo	Response satisfies query

090177e196ae30f1\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001**Visit:** COHORT\_SELECTION**Form Version:** 10-Dec-2020 02:26**Site No:** 1147**Subject No:** 11471327**Generated By:** (b) (4)**Form:** DEMOGRAPHY - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1147) Ochsner Health System**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:56

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	sed	
Jan-26-2021 20:27:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Clo sed	Auto closed by Validation Check: VC_DM001_09
Jan-26-2021 13:49:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: An swere d	Changed Information
Jan-26-2021 13:49:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: An swere d	Changed Information
Jan-26-2021 13:49:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> :	Changed Information
Jan-21-2021 10:57:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Op ened	DMW6938178;Racial Designation is updated, however Race is not ASIAN. Please review and update appropriately or clarify.
Jan-21-2021 09:49:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Op ened	DMW6938178;Racial Designation is updated, however Race is not ASIAN. Please review and update appropriately or clarify.

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1147

**Subject No:** 11471327

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

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

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

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

Jan-06-2021 16:40:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : OTH ER	Initial Entry
--	-----------------	------------------	---	---------------

**Header Text:** c4591001

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

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

**Site No:** 1147

**Subject No:** 11471327

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

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

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

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

[Back to Form](#)

***1. Date of Visit***

Date	Location	User	Value	Reason
Jan-06-2021 16:40:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b><u>Data Entry:</u></b> Jan/5/2021	Initial Entry



**Header Text:** c4591001

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

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

**Site No:** 1147

**Subject No:** 11471327

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

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

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

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Jan-06-2021 16:41:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/5/2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Jan-06-2021 16:41:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Jan-06-2021 16:41:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae30f1\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1147

**Subject No:** 11471327

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

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

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

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Jan-06-2021 16:43:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> The subject is NOT known to be HIV POSITIVE	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1147

**Subject No:** 11471327

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

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

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

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

[Back to Form](#)

**1. Date:**

Date	Location	User	Value	Reason
Jan-06-2021 16:47:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/5/2021	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Jan-06-2021 16:47:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 167.2	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Jan-06-2021 16:47:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LB	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Jan-06-2021 16:47:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 66.0	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Jan-06-2021 16:47:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> in	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
Jan-06-2021 16:47:10 (UTC-06:00) Central	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 27.0	Initial Entry

090177e196ae30f1\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1147

**Subject No:** 11471327

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

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

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

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

Time (US & Canada)

**7.a**

Date	Location	User	Value	Reason
Jan-06-2021 16:47:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier</b> 1 : <b>Temperature:</b> 98.5 <b>Temperature Unit:</b> F <b>Temperature Location:</b> ORAL CAVITY	Initial Entry

**7.a Record Identifier:**

Date	Location	User	Value	Reason
Jan-06-2021 16:47:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**7.a Temperature:**

Date	Location	User	Value	Reason
Jan-06-2021 16:47:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 98.5	Initial Entry

**7.a Unit:**

Date	Location	User	Value	Reason
Jan-06-2021 16:47:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> F	Initial Entry

**7.a Temperature Location:**

Date	Location	User	Value	Reason
Jan-06-2021 16:47:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae30f1\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1147

**Subject No:** 11471327

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

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

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

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

[Back to Form](#)

**1. Randomization Date :**

Date	Location	User	Value	Reason
Jan-06-2021 16:44:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/5/2021	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Jan-06-2021 16:44:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 25570	Initial Entry

090177e196ae30f1\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1147

**Subject No:** 11471327

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

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

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

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

[Back to Form](#)

**1. Data Origin**

Date	Location	User	Value	Reason
Jan-06-2021 16:45:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-06-2021 16:45:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-07-2021 05:22:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-06-2021 16:45:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-06-2021 16:45:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Jan/5/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jan-07-2021 05:22:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BP8HFV	Initial Entry

090177e196ae30f1\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1147

**Subject No:** 11471327

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

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

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

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

**5.a Sample ID**

Date	Location	User	Value	Reason
Jan-07-2021 05:22:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> BP8HFV	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Jan-07-2021 05:23:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> <b>Sample ID:</b> BP8HFW	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Jan-07-2021 05:23:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> BP8HFW	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Jan-07-2021 05:47:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> <b>Sample ID:</b> BSGV0P	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Jan-07-2021 05:47:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> BSGV0P	Initial Entry

090177e196ae30f1\Final\Final On: 01-Apr-2021 04:20 (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, Frozen, Verified**Site No:** 1147**Site Name:** (1147) Ochsner Health System**Subject No:** 11471327**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Jan-06-2021 16:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-06-2021 16:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-07-2021 06:10:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-06-2021 16:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-06-2021 16:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Jan/5/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jan-07-2021 06:10:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BP8HFG	Initial Entry



**Header Text:** c4591001

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

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

**Site No:** 1147

**Subject No:** 11471327

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

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

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

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

**5.a Sample ID**

Date	Location	User	Value	Reason
Jan-07-2021 06:10:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> BP8HFG	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1147

**Subject No:** 11471327

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

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

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

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Jan-06-2021 16:44:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Jan-06-2021 16:44:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Jan-06-2021 16:44:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Jan-06-2021 16:44:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/5/2021 17:10	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Jan-06-2021 16:44:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Jan-06-2021 16:44:18 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae30f1\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1147

**Subject No:** 11471327

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

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

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

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

Time (US & Canada)

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

**7. Route:**

Date	Location	User	Value	Reason
Jan-06-2021 16:44:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Jan-06-2021 16:44:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED O BSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Jan-06-2021 16:44:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae30f1\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1147

**Subject No:** 11471327

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

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

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

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Jan-06-2021 16:44:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b><u>Data Entry:</u></b> YES - REACTOGENICITY E- DIARY COLLECTED FOR TH IS SUBJECT	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1147

**Subject No:** 11471327

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

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

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

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

[Back to Form](#)

***1. Date of Visit***

Date	Location	User	Value	Reason
Jan-28-2021 00:13:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/27/2021	Initial Entry

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form Version:** 10-Dec-2020 02:30**Site No:** 1147**Subject No:** 11471327**Generated By:** (b) (4)**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1147) Ochsner Health System**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:56[Back to Form](#)**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Jan-28-2021 00:20:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Jan-28-2021 00:20:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FE VE R  <b>Were fever or systemic sy N</b> <b>mptoms present on the las O</b> <b>t day the Subject Diary w</b> <b>as completed?:</b>	Initial Entry

**2.a Symptom:**

Date	Location	User	Value	Reason
Jan-28-2021 00:20:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry

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

Date	Location	User	Value	Reason
Jan-28-2021 00:20:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.b**

Date	Location	User	Value	Reason
Jan-28-2021 00:20:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FA TI	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 10-Dec-2020 02:30

Site No: 1147

Subject No: 11471327

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

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

			GU E Were fever or systemic sy NO mptoms present on the la st day the Subject Diary was completed?:	
--	--	--	--	--

**2.b Symptom:**

Date	Location	User	Value	Reason
Jan-28-2021 00:20:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Jan-28-2021 00:20:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

**2.c**

Date	Location	User	Value	Reason
Jan-28-2021 00:20:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: HE AD AC HE Were fever or systemic s NO ymptoms present on the last day the Subject Diar y was completed?:	Initial Entry

090177e196ae30f1\Final\Final On: 01-Apr-2021 04:20 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 10-Dec-2020 02:30

Site No: 1147

Subject No: 11471327

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

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

**2.c Symptom:**

Date	Location	User	Value	Reason
Jan-28-2021 00:20:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Jan-28-2021 00:20:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

**2.d**

Date	Location	User	Value	Reason
Jan-28-2021 00:20:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: CH IL LS  Were fever or systemic sy NO mptoms present on the las t day the Subject Diary w as completed?:	Initial Entry

**2.d Symptom:**

Date	Location	User	Value	Reason
Jan-28-2021 00:20:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Jan-28-2021 00:20:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

**2.e**

090177e196ae30f1\Final\Final On: 01-Apr-2021 04:20 (GMT)



Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 10-Dec-2020 02:30

Site No: 1147

Subject No: 11471327

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

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

Date	Location	User	Value	Reason
Jan-28-2021 00:20:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> VO MIT ING  <b>Were fever or systemic s NO ymptoms present on the last day the Subject Diar y was completed?:</b>	Initial Entry

**2.e Symptom:**

Date	Location	User	Value	Reason
Jan-28-2021 00:20:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> VOMITING	Initial Entry

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

Date	Location	User	Value	Reason
Jan-28-2021 00:20:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.f**

Date	Location	User	Value	Reason
Jan-28-2021 00:20:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> DIA RR HE A  <b>Were fever or systemic s NO ymptoms present on the last day the Subject Diar y was completed?:</b>	Initial Entry

090177e196ae30f1\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Frozen, Verified**Site No:** 1147**Site Name:** (1147) Ochsner Health System**Subject No:** 11471327**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56**2.f Symptom:**

Date	Location	User	Value	Reason
Jan-28-2021 00:20:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Jan-28-2021 00:20:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.g**

Date	Location	User	Value	Reason
Jan-28-2021 00:20:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSE NED MU SCLE PA IN  <b>Were fever or syste</b> NO <b>mic symptoms pres</b> <b>ent on the last day t</b> <b>he Subject Diary w</b> <b>as completed?:</b>	Initial Entry

**2.g Symptom:**

Date	Location	User	Value	Reason
Jan-28-2021 00:20:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSE NED MUSC LE PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Jan-28-2021 00:20:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 10-Dec-2020 02:30

Site No: 1147

Subject No: 11471327

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

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

## 2.h

Date	Location	User	Value	Reason
Jan-28-2021 00:20:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW O R WORS ENED J OINT PA IN  <b>Were fever or syste NO mic symptoms prese nt on the last day th e Subject Diary was completed?:</b>	Initial Entry

## 2.h Symptom:

Date	Location	User	Value	Reason
Jan-28-2021 00:20:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSENERD 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-28-2021 00:20:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

## 3. Injection Site Location:

Date	Location	User	Value	Reason
Jan-28-2021 00:20:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

## 4. Injection Site Body Side:

Date	Location	User	Value	Reason
Mar-02-2021 23:12:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

090177e196ae30f1\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Frozen, Verified**Site No:** 1147**Site Name:** (1147) Ochsner Health System**Subject No:** 11471327**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56

Mar-02-2021 14:44:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Mar-02-2021 14:44:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<b>Data Entry:</b> LEFT	Initial Entry
Mar-02-2021 14:43:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<b>Data Entry:</b>	Initial Entry
Mar-02-2021 14:33:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Subject received Vax 1 so NOT APPLICABLE is not an acceptable response for INJECTION SITE BODY SIDE in this CRF. Please update INJECTION SITE BODY SIDE in this CRF (based on Vax 1 injection site laterality) as data point is required.
Jan-28-2021 00:20:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jan-28-2021 00:20:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> RE DN ESS  <b>Were injection site reacti NO</b> <b>ons present on the last da</b> <b>y the Subject Diary was c</b> <b>ompleted?:</b>	Initial Entry

**5.a Injection Site Reaction:**

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Frozen, Verified**Site No:** 1147**Site Name:** (1147) Ochsner Health System**Subject No:** 11471327**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56

Date	Location	User	Value	Reason
Jan-28-2021 00:20:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Jan-28-2021 00:20:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Jan-28-2021 00:20:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> SW ELL ING  <b>Were injection site react NO</b> <b>ions present on the last d</b> <b>ay the Subject Diary wa</b> <b>s completed?:</b>	Initial Entry

**5.b Injection Site Reaction:**

Date	Location	User	Value	Reason
Jan-28-2021 00:20:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Jan-28-2021 00:20:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**5.c**

Date	Location	User	Value	Reason
------	----------	------	-------	--------

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1147

**Site Name:** (1147) Ochsner Health System

**Subject No:** 11471327

**Subject Initials:** ---

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

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

Jan-28-2021 00:20:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction:</b> PAIN AT INJECTION SITE  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO	Initial Entry
---	-----------------	---------------------	---	---------------

**5.c Injection Site Reaction:**

Date	Location	User	Value	Reason
Jan-28-2021 00:20:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PAIN AT INJECTION SITE	Initial Entry

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

Date	Location	User	Value	Reason
Jan-28-2021 00:20:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae30f1\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form Version:** 14-Jan-2021 02:22**Site No:** 1147**Subject No:** 11471327**Generated By:** (b) (4)**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1147) Ochsner Health System**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:56[Back to Form](#)**1. Date:**

Date	Location	User	Value	Reason
Jan-28-2021 00:14:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/27/2021	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Jan-28-2021 00:14:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier</b> 1 :: <b>Temperature:</b> 98.6 <b>Temperature Uni</b> F <b>t:</b> <b>Temperature Loc</b> ORAL CAV <b>ation::</b> ITY	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Jan-28-2021 00:14:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a Temperature:**

Date	Location	User	Value	Reason
Jan-28-2021 00:14:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 98.6	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Jan-28-2021 00:14:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> F	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1147

**Subject No:** 11471327

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

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

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

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

**2.a Temperature Location:**

Date	Location	User	Value	Reason
Jan-28-2021 00:14:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> ORAL CAVITY	Initial Entry



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1147

**Subject No:** 11471327

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

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

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

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

[Back to Form](#)

**1. Data Origin**

Date	Location	User	Value	Reason
Jan-28-2021 00:15:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-28-2021 00:15:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-28-2021 07:55:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-28-2021 03:12:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-28-2021 00:15:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-28-2021 00:15:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Jan/27/2021	Initial Entry

090177e196ae30f1\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1147

**Subject No:** 11471327

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

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

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

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

**5.a**

Date	Location	User	Value	Reason
Jan-28-2021 07:55:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> <b>Sample ID:</b> BR5J0P	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Jan-28-2021 07:55:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> BR5J0P	Initial Entry

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form Version:** 10-Dec-2020 02:26**Site No:** 1147**Subject No:** 11471327**Generated By:** (b) (4)**Form:** VACCINATION - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1147) Ochsner Health System**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:56[Back to Form](#)**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Feb-01-2021 00:03:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Clo sed	Response satisfies query
Jan-29-2021 11:27:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Ans wered	subject discontinued
Jan-29-2021 02:20:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Ope ned	DMW7042935;Temp Delay is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Jan-28-2021 00:17:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : Not A pplica ble	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Jan-28-2021 00:17:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
------	----------	------	-------	--------

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form Version:** 10-Dec-2020 02:26**Site No:** 1147**Subject No:** 11471327**Generated By:** (b) (4)**Form:** VACCINATION - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1147) Ochsner Health System**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:56

Jan-28-2021 00:17:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
---	-----------------	---------------------	--------------------------------------	---------------

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Feb-01-2021 05:06:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Clos ed	Confirmed As-Is
Jan-29-2021 11:27:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Ans wered	Subject discontinued
Jan-29-2021 02:22:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Ope ned	DMW7042957;Dose Date is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Jan-28-2021 00:17:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not A pplicab le	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Jan-28-2021 00:17:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
------	----------	------	-------	--------

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1147

**Subject No:** 11471327

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

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

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

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

Jan-28-2021 00:17:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
---	-----------------	---------------------	--------------------------------------	---------------

**7. Route:**

Date	Location	User	Value	Reason
Jan-28-2021 00:17:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**8. Actual Dose:**

Date	Location	User	Value	Reason
Jan-28-2021 00:17:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**9. Unit:**

Date	Location	User	Value	Reason
Jan-28-2021 00:17:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Jan-28-2021 00:17:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

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

Date	Location	User	Value	Reason
Jan-28-2021 00:17:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae30f1\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1147

**Subject No:** 11471327

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

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

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

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

[Back to Form](#)

***1. Date of Visit***

Date	Location	User	Value	Reason
Feb-26-2021 17:21:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/25/2021	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1147

**Subject No:** 11471327

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

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

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

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry
Mar-01-2021 12:20:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<b>Data Entry:</b>	Changed Information
Feb-26-2021 17:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> FEV ER <b>Were fever or systemic symptoms present on t he last day the Subject Diary was completed?:</b> e	Initial Entry
Mar-01-2021 12:20:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> FE VE R <b>Were fever or systemic s ymptoms present on the l ast day the Subject Diary was completed?:</b>	Changed Information
Feb-26-2021 17:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FE VE R	Initial Entry

**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Frozen, Verified**Site No:** 1147**Site Name:** (1147) Ochsner Health System**Subject No:** 11471327**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56

			Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	
--	--	--	---	--

**2.a Symptom:**

Date	Location	User	Value	Reason
Feb-26-2021 17:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry

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

Date	Location	User	Value	Reason
Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry
Mar-01-2021 12:20:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<b>Data Entry:</b>	Changed Information
Feb-26-2021 17:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.b**

Date	Location	User	Value	Reason
Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> FAT IGU E <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> Not Appl icabl e	Initial Entry
Mar-01-2021 12:20:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> FA TI GU	Changed Information



**Header Text:** c4591001

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

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

**Site No:** 1147

**Subject No:** 11471327

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

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

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

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

			E Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	
Feb-26-2021 17:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FA TI GU E  Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

**2.b Symptom:**

Date	Location	User	Value	Reason
Feb-26-2021 17:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry
Mar-01-2021 12:20:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<b>Data Entry:</b>	Changed Information
Feb-26-2021 17:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.c**

Date	Location	User	Value	Reason
Mar-01-2021 12:22:25 (UTC-06:00) Central	ACV0PFEINFP6000	James McMullen	<b>Data Entry:</b> <b>Symptom::</b> HE	Initial Entry

**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form Version:** 10-Dec-2020 02:30**Site No:** 1147**Subject No:** 11471327**Generated By:** (b) (4)**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1147) Ochsner Health System**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:56

Time (US & Canada)		(b) (4)	AD AC HE  Were fever or systemic symptoms present on the last day the Subject Diary was completed?: Not Applicable	
Mar-01-2021 12:21:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<u>Data Entry:</u> Symptom:: HE AD AC HE  Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Changed Information
Feb-26-2021 17:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: HE AD AC HE NO  Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry

**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Frozen, Verified**Site No:** 1147**Site Name:** (1147) Ochsner Health System**Subject No:** 11471327**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56**2.c Symptom:**

Date	Location	User	Value	Reason
Feb-26-2021 17:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry
Mar-01-2021 12:21:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<b>Data Entry:</b>	Changed Information
Feb-26-2021 17:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.d**

Date	Location	User	Value	Reason
Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> CHI LLS <b>Were fever or systemic symptoms present on t he last day the Subject Diary was completed?:</b> Not Appl icabl e	Initial Entry
Mar-01-2021 12:21:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> CH IL LS <b>Were fever or systemic s ymptoms present on the last day the Subject Diar y was completed?:</b>	Changed Information
Feb-26-2021 17:23:22 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Frozen, Verified**Site No:** 1147**Site Name:** (1147) Ochsner Health System**Subject No:** 11471327**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56

Time (US & Canada)		(b) (4), (b) (6)	<b>Symptom::</b> CH IL LS  <b>Were fever or systemic s</b> N <b>ymptoms present on the</b> O <b>last day the Subject Diar</b> <b>y was completed?:</b>	
--------------------	--	------------------	--	--

**2.d Symptom:**

Date	Location	User	Value	Reason
Feb-26-2021 17:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry
Mar-01-2021 12:21:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<b>Data Entry:</b>	Changed Information
Feb-26-2021 17:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.e**

Date	Location	User	Value	Reason
Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> VO MIT ING  <b>Were fever or systemic</b> Not <b>symptoms present on t</b> Appl <b>he last day the Subject</b> icabl <b>Diary was completed?:</b> e	Initial Entry
Mar-01-2021 12:21:15	ACV0PFEINFP6000	James	<b>Data Entry:</b>	Changed

**Header Text:** c4591001

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

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

**Site No:** 1147

**Subject No:** 11471327

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

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

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

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

(UTC-06:00) Central Time (US & Canada)		McMullen (b) (4)	<b>Symptom::</b> VO MIT ING  <b>Were fever or systemic symptoms present on th e last day the Subject D iary was completed?:</b>	Information
Feb-26-2021 17:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> VO MIT ING  <b>Were fever or systemic symptoms present on th e last day the Subject D iary was completed?:</b> NO	Initial Entry

**2.e Symptom:**

Date	Location	User	Value	Reason
Feb-26-2021 17:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> VOMITING	Initial Entry

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

Date	Location	User	Value	Reason
Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry
Mar-01-2021 12:21:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<b>Data Entry:</b>	Changed Information
Feb-26-2021 17:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.f**

Date	Location	User	Value	Reason
Mar-01-2021 12:22:25	ACV0PFEINFP6000	James	<b>Data Entry:</b>	Initial Entry

**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form Version:** 10-Dec-2020 02:30**Site No:** 1147**Subject No:** 11471327**Generated By:** (b) (4)**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1147) Ochsner Health System**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:56

(UTC-06:00) Central Time (US & Canada)		McMullen (b) (4)	<b>Symptom::</b> DIA RR HE A  <b>Were fever or systemic symptoms present on t he last day the Subject Diary was completed?:</b> Not Appl icabl e	
Mar-01-2021 12:21:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> DIA RR HE A  <b>Were fever or systemic symptoms present on th e last day the Subject Di ary was completed?:</b>	Changed Information
Feb-26-2021 17:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> DIA RR HE A  <b>Were fever or systemic symptoms present on th e last day the Subject Di ary was completed?:</b> NO	Initial Entry

**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Frozen, Verified**Site No:** 1147**Site Name:** (1147) Ochsner Health System**Subject No:** 11471327**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56**2.f Symptom:**

Date	Location	User	Value	Reason
Feb-26-2021 17:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry
Mar-01-2021 12:21:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<b>Data Entry:</b>	Changed Information
Feb-26-2021 17:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.g**

Date	Location	User	Value	Reason
Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSE NED MU SCLE PA IN  <b>Were fever or syste Not Appl mic symptoms pres icable ent on the last day the Subject Diary was completed?:</b>	Initial Entry
Mar-01-2021 12:21:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSE NED MU SCLE PA IN	Changed Information

**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form Version:** 10-Dec-2020 02:30**Site No:** 1147**Subject No:** 11471327**Generated By:** (b) (4)**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1147) Ochsner Health System**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:56

			<b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b>	
Feb-26-2021 17:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSE NED MU SCLE PA IN  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

**2.g Symptom:**

Date	Location	User	Value	Reason
Feb-26-2021 17:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSE NED MUSC LE PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry
Mar-01-2021 12:21:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<b>Data Entry:</b>	Changed Information
Feb-26-2021 17:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.h**

Date	Location	User	Value	Reason
------	----------	------	-------	--------



**Header Text:** c4591001

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

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

**Site No:** 1147

**Subject No:** 11471327

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

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

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

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> NEW O R WOR SENED JOINT P AIN  <b>Were fever or syste</b> Not Appl <b>mic symptoms pres</b> icable <b>ent on the last day t</b> <b>he Subject Diary w</b> <b>as completed?:</b>	Initial Entry
---	-----------------	------------------------------	--	---------------

**Header Text:** c4591001

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

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

**Site No:** 1147

**Subject No:** 11471327

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

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

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

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

[Back to Form](#)

**2.h**

Date	Location	User	Value	Reason
Mar-01-2021 12:21:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> NEW O R WOR SENED JOINT P AIN  <b>Were fever or syste mic symptoms pres ent on the last day the Subject Diary was completed?:</b>	Changed Information
Feb-26-2021 17:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW O R WOR SENED JOINT P AIN  <b>Were fever or syste NO mic symptoms pres ent on the last day the Subject Diary was completed?:</b>	Initial Entry

090177e196ae30f1\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1147

**Subject No:** 11471327

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

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

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

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

**2.h Symptom:**

Date	Location	User	Value	Reason
Feb-26-2021 17:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSENERD 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
Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry
Mar-01-2021 12:21:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<b>Data Entry:</b>	Changed Information
Feb-26-2021 17:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**3. Injection Site Location:**

Date	Location	User	Value	Reason
Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Not Applicable	Initial Entry
Mar-01-2021 12:20:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Changed Information
Feb-26-2021 17:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**4. Injection Site Body Side:**

Date	Location	User	Value	Reason
Mar-02-2021 05:04:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

090177e196ae30f1\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Frozen, Verified**Site No:** 1147**Site Name:** (1147) Ochsner Health System**Subject No:** 11471327**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56

Mar-01-2021 12:22:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	Query 1: Answered	Subject discontinued from study treatment
Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry
Mar-01-2021 02:26:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Please complete this item. Thank you.

**5.a**

Date	Location	User	Value	Reason
Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<b>Data Entry:</b> <b>Injection Site Reaction</b> RED :: NES S  <b>Were injection site rea</b> Not <b>ctions present on the la</b> Appl <b>st day the Subject Diar</b> icabl <b>y was completed?:</b> e	Initial Entry
Mar-01-2021 12:21:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<b>Data Entry:</b> <b>Injection Site Reaction:</b> RE : DN ES S  <b>Were injection site reac</b> <b>tions present on the last</b> <b>day the Subject Diary w</b> <b>as completed?:</b>	Changed Information
Feb-26-2021 17:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction:</b> RE : DN ES S  <b>Were injection site reac</b> NO <b>tions present on the last</b> <b>day the Subject Diary w</b> <b>as completed?:</b>	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1147

**Subject No:** 11471327

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

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

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

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

**5.a Injection Site Reaction:**

Date	Location	User	Value	Reason
Feb-26-2021 17:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry
Mar-01-2021 12:21:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<b>Data Entry:</b>	Changed Information
Feb-26-2021 17:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<b>Data Entry:</b> <b>Injection Site Reaction SWE</b> :: LLI NG  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> Not Applicable	Initial Entry
Mar-01-2021 12:21:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<b>Data Entry:</b> <b>Injection Site Reaction SW</b> :: ELL ING  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b>	Changed Information

**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Frozen, Verified**Site No:** 1147**Site Name:** (1147) Ochsner Health System**Subject No:** 11471327**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56

Feb-26-2021 17:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction</b> SW :: ELL ING  <b>Were injection site reac NO</b> <b>tions present on the las</b> <b>t day the Subject Diary</b> <b>was completed?:</b>	Initial Entry
---	-----------------	---------------------	---	---------------

**5.b Injection Site Reaction:**

Date	Location	User	Value	Reason
Feb-26-2021 17:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry
Mar-01-2021 12:21:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<b>Data Entry:</b>	Changed Information
Feb-26-2021 17:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<b>Data Entry:</b> <b>Injection Site Reacti PAIN</b> <b>on:: AT INJ</b> <b>ECTIO</b> <b>N SITE</b>	Initial Entry

**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:30**Form Status:** Data Complete, Frozen, Verified**Site No:** 1147**Site Name:** (1147) Ochsner Health System**Subject No:** 11471327**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56

			Were injection site reactions present on the last day the Subject Diary was completed?:	
Mar-01-2021 12:22:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<b>Data Entry:</b> <b>Injection Site Reaction:</b> PAIN AT INJECTION SITE  Were injection site reactions present on the last day the Subject Diary was completed?:	Changed Information
Feb-26-2021 17:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction:</b> PAIN AT INJECTION SITE  Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1147

**Subject No:** 11471327

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

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

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

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

**5.c Injection Site Reaction:**

Date	Location	User	Value	Reason
Feb-26-2021 17:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PAIN AT INJECTION SITE	Initial Entry

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

Date	Location	User	Value	Reason
Mar-01-2021 12:22:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry
Mar-01-2021 12:22:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<b>Data Entry:</b>	Changed Information
Feb-26-2021 17:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae30f1\Final\Final On: 01-Apr-2021 04:20 (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, Frozen, Verified**Site No:** 1147**Site Name:** (1147) Ochsner Health System**Subject No:** 11471327**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Feb-26-2021 07:59:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Feb-26-2021 07:59:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Feb-26-2021 08:00:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-26-2021 07:59:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-26-2021 07:59:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Feb/25/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Feb-26-2021 08:00:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BR7X56	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1147

**Subject No:** 11471327

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

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

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

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

**5.a Sample ID**

Date	Location	User	Value	Reason
Feb-26-2021 08:00:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> BR7X56	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Feb-26-2021 08:28:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> <b>Sample ID:</b> BRZXLD	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Feb-26-2021 08:28:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> BRZXLD	Initial Entry

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1147

**Subject No:** 11471327

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

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

**Form Status:**

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

[Back to Form](#)

Date	Location	User	Value	Reason
Mar-03-2021 12:56:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	Form Created	

090177e196ae30f1\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1147

**Subject No:** 11471327

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

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

**Form Status:** Data Complete, Frozen

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

[Back to Form](#)

**1. Category:**

Date	Location	User	Value	Reason
Mar-03-2021 12:56:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Mar-03-2021 12:56:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Mar-03-2021 12:56:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<b>Data Entry:</b> Fever (104.7)	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Mar-03-2021 12:56:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<b>Data Entry:</b> Jan/6/2021 19:30	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Mar-03-2021 12:56:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<b>Data Entry:</b> NO End Date Time:  Jan/8/2021 UNK:UNK	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae30f1\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1147**Subject No:** 11471327**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1147) Ochsner Health System**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:56

Mar-11-2021 13:35:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-11-2021 07:41:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	Query 1: Answered	Per Table 3, a fever >104.0F is a grade 4.
Mar-11-2021 07:21:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	GPD Clin: Fever alone may not typically be considered life threatening AE. Please review and confirm if toxicity grade assignment appropriate and provide rationale in query response.
Mar-03-2021 12:56:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<b>Data Entry:</b> 4	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
Mar-03-2021 12:56:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**8. Is this adverse event the result of a study Medication Error?****If Yes, record the type of medication error on the Medication Error Log.**

Date	Location	User	Value	Reason
Mar-03-2021 12:56:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<b>Data Entry:</b> NO	Initial Entry

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1147

**Subject No:** 11471327

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

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

**Form Status:** Data Complete, Frozen

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

Date	Location	User	Value	Reason
Mar-03-2021 12:56:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<b>Data Entry:</b> RELATED	Initial Entry

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

Date	Location	User	Value	Reason
Mar-03-2021 12:56:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<b>Data Entry:</b> DRUG WITHDRAWN	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Mar-03-2021 12:56:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<b>Data Entry:</b> YES	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Mar-03-2021 12:56:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Mar-03-2021 12:56:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Mar-03-2021 12:56:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae30f1\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Jan/06/2021

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

**Site No:** 1147

**Subject No:** 11471327

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

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

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

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

[Back to Form](#)

*1. Date of Visit*

Date	Location	User	Value	Reason
Jan-07-2021 10:30:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<b>Data Entry:</b> Jan/6/2021	Initial Entry

090177e196ae30f1\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001**Visit:** Unplanned 1 - Unscheduled Visit on  
Jan/06/2021**Form:** UNPLANNED VISIT - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:04**Form Status:** Data Complete, Frozen, Verified**Site No:** 1147**Site Name:** (1147) Ochsner Health System**Subject No:** 11471327**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56[Back to Form](#)***I. Assessments***

Date	Location	User	Value	Reason
Jan-07-2021 10:31:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-07-2021 10:30:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Jan-07-2021 10:30:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<b><u>Data Entry:</u></b> CONTACT OUTCOME	Initial Entry



**Header Text:** c4591001**Visit:** Unplanned 1 - Unscheduled Visit on Jan/06/2021**Form Version:** 22-Apr-2020 21:04**Site No:** 1147**Subject No:** 11471327**Generated By:** (b) (4)**Form:** CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1147) Ochsner Health System**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:56[Back to Form](#)**1. Contact Type:**

Date	Location	User	Value	Reason
Jan-07-2021 10:30:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> TELEPHONE VISIT	Initial Entry

**2. Was contact made?**

Date	Location	User	Value	Reason
Jan-07-2021 10:31:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-07-2021 10:31:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<b>Data Entry:</b> YES Date of Contact:  Jan/6/2021  Contact Outcome:  VISIT NOT REQUIRED, I NVESTIGATOR DECISIO N	Changed Information
Jan-07-2021 10:30:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Response to "Date of Contact" is missing.
Jan-07-2021 10:30:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<b>Data Entry:</b> YES Contact Outcome:  VISIT NOT REQUIRED, I NVESTIGATOR DECISIO N	Initial Entry

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

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

**Site No:** 1147

**Subject No:** 11471327

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

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

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

**Site Name:** (1147) Ochsner Health System

**Subject Initials:** ---

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Mar-03-2021 11:18:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<b>Data Entry:</b> Jan/8/2021	Changed Information
Jan-28-2021 08:47:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<b>Data Entry:</b> Jan/9/2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Jan-28-2021 08:47:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Mar-04-2021 09:18:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Closed	Response satisfies query
Mar-03-2021 15:56:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Mar-03-2021 15:55:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Response to "Status" is ADVERSE EVENT but "Specify Status" is Provided.
Mar-03-2021 15:55:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Mar-03-2021 15:55:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<b>Data Entry:</b> ADVERSE EVENT	Changed Information

**Header Text:** c4591001**Visit:** End of Treatment - Unscheduled**Form Version:** 10-Dec-2020 02:29**Site No:** 1147**Subject No:** 11471327**Generated By:** (b) (4)**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1147) Ochsner Health System**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:56

Mar-03-2021 15:25:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Reissued:Opened	CLINQUERY: Comment and AE log reports 'fever' as event leading to treatment discontinuation. Please match status selection to this event (status ADVERSE EVENT)
Mar-03-2021 11:19:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	Query 1: Answered	Reason updated. Please unfreeze DOV for visit 2
Mar-03-2021 00:59:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: EOT date and status should match to reason why Vax 2 was not given. Please review and update. Current entry is inadequate for reporting end of treatment
Mar-02-2021 07:55:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Candidate	CLINQUERY: EOT date and status should match to reason why Vax 2 was not given. Please review and update. Current entry is inadequate for reporting end of treatment
Jan-28-2021 08:47:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<b>Data Entry:</b> OTHER	Initial Entry

**4. Specify Status:**

Date	Location	User	Value	Reason
Mar-03-2021 15:56:14 (UTC-06:00) Central	ACV0PFEINFP6000	James McMullen	<b>Data Entry:</b>	Changed Information

**Header Text:** c4591001**Visit:** End of Treatment - Unscheduled**Form Version:** 10-Dec-2020 02:29**Site No:** 1147**Subject No:** 11471327**Generated By:** (b) (4)**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1147) Ochsner Health System**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:56

Time (US & Canada)		(b) (4)		
Mar-03-2021 15:26:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Closed	Response satisfies query
Mar-03-2021 12:57:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	Query 1: Answered	AE leading to treatment discontinuation captured in AE log
Mar-03-2021 12:33:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Opened	CLINQUERY: Fever is reported leading to treatment discontinuation. However, an AE entry has not been reported. Please review - any event leading to discontinuation should be reported even if captured in ediary
Mar-03-2021 11:19:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<b>Data Entry:</b> Treatment discontinued due to fever of 104.7	Changed Information
Mar-03-2021 11:16:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<b>Data Entry:</b> Treatment discontinued due to COVID Illness	Changed Information
Jan-28-2021 08:47:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	James McMullen (b) (4)	<b>Data Entry:</b> Treatment discontinued	Initial Entry

**Header Text:** c4591001**Visit:** Subject Status - Unscheduled**Form Version:** 22-Apr-2020 21:03**Site No:** 1147**Subject No:** 11471327**Generated By:** (b) (4)**Form:** SUBJECT STATUS - eCRF Audit Trail History**Form Status:** Data Complete, Verified**Site Name:** (1147) Ochsner Health System**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:56[Back to Form](#)**1. Subject Status**

Date	Location	User	Value	Reason
Mar-03-2021 15:55:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DISCONTINUED	Changed Information
Jan-28-2021 08:47:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DISCONTINUED	Initial Entry
Jan-06-2021 16:44:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Jan-06-2021 16:41:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

**2. Subject Status Date**

Date	Location	User	Value	Reason
Mar-03-2021 15:55:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Jan/8/2021	Changed Information
Mar-03-2021 11:18:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Jan/8/2021	Changed Information
Jan-28-2021 08:47:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Jan/9/2021	Initial Entry
Jan-06-2021 16:44:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Jan/5/2021	Initial Entry
Jan-06-2021 16:41:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Jan/5/2021	Initial Entry