

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT\_SELECTION

**Form Version:** 30-Jul-2020 21:29

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

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

**Cohort Selection**

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

1.	Select appropriate response - Protocol version	24 JUL 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** MAIN INFORMED CONSENT

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

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

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/29/2020
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**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** DEMOGRAPHY

**Form Version:** 06-Jul-2020 21:55

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

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[11101164]
2.	Birth Date:	(b) (6)/1986
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

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**Header Text:** c4591001

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

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

**Site No:** 1110

**Subject No:** 11101164

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

**Form:** DATE OF VISIT

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

**Site Name:** (1110) Clinical Research of South Florida

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** c4591001

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

**Form Version:** 30-Jul-2020 21:29

**Site No:** 1110

**Subject No:** 11101164

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

**Form:** INCLUSION/EXCLUSION CRITERIA

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

**Site Name:** (1110) Clinical Research of South Florida

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:49

**Form Comments**

**Inclusion Criteria Not Met**

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

2.	Description of Exclusion Criterion Met	Not Applicable _____
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**Header Text:** c4591001

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

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

**Site No:** 1110

**Subject No:** 11101164

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

**Form:** DISPOSITION - SCREENING

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

**Site Name:** (1110) Clinical Research of South Florida

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

**Disposition - Screening**

1.	Date of Completion/Discontinuation/Death	Aug/29/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** c4591001

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

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

**Site No:** 1110

**Subject No:** 11101164

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

**Form:** GENERAL MEDICAL HISTORY

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

**Site Name:** (1110) Clinical Research of South Florida

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:49

**Form Comments**

**Medical History Details**

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

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**Header Text:** c4591001

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

**Form Version:** 21-Aug-2020 02:51

**Site No:** 1110

**Subject No:** 11101164

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

**Form:** VITAL SIGNS - BASELINE

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

**Site Name:** (1110) Clinical Research of South Florida

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Aug/29/2020
2.	Weight:	[165.8]
3.	Unit:	LB
4.	Height:	[70.8]
5.	Unit:	in
6.	Body Mass Index:	[23.3]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[36.5]
	Unit:	C
	Temperature Location:	FOREHEAD



**Header Text:** c4591001

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

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1110

**Subject No:** 11101164

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

**Site Name:** (1110) Clinical Research of South Florida

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:49

**eCRF Audit Trail History**

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Aug/29/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

**Lab Result**

6.a	Sponsor ID:	[113]
	Test:	Choriogonadotropin Beta_PX113
	Result:	NEGATIVE
	Not Done:	

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**Header Text:** c4591001

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

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

**Site No:** 1110

**Subject No:** 11101164

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

**Form:** RANDOMIZATION

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

**Site Name:** (1110) Clinical Research of South Florida

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Aug/29/2020
2.	Randomization Number:	[73633]
3.	Randomization Group:	[ ]

**Header Text:** c4591001

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/29/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BP3HKF]
5.b	Sample ID	[BP3HKG]
5.c	Sample ID	[BP3HKH]
5.d	Sample ID	[BRWP6C]
5.e	Sample ID	[BRWP6D]

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**Header Text:** c4591001

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

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

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

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

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/29/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BPY0LJ]
-----	-----------	----------

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1110

**Subject No:** 11101164

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

**Form:** VACCINATION

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

**Site Name:** (1110) Clinical Research of South Florida

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:49

**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:	Aug/29/2020 12:16
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

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1110

**Subject No:** 11101164

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

**Form:** REACTOGENICITY DIARY

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

**Site Name:** (1110) Clinical Research of South Florida

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

**Reactogenicity Diary**

1.	Select appropriate response - Reactogenicity diary collection	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT
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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** DATE OF VISIT

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

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

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Sep/18/2020
2.	Erroneous Visit	

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VITAL SIGNS - TEMP

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

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

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Sep/18/2020
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**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[36.2]
	Unit:	C
	Temperature Location:	FOREHEAD



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1110

**Subject No:** 11101164

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

**Site Name:** (1110) Clinical Research of South Florida

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:49

**eCRF Audit Trail History**

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Sep/18/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

**Lab Result**

6.a	Sponsor ID:	[113]
	Test:	Choriogonadotropin Beta_PX113
	Result:	NEGATIVE
	Not Done:	

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/18/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BPY06N]
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090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1110

**Subject No:** 11101164

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

**Form:** VACCINATION

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

**Site Name:** (1110) Clinical Research of South Florida

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:49

**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:	Sep/18/2020 09:59
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

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1110 **Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** c4591001

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

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

**Site No:** 1110 **Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BPW9H4]
5.b	Sample ID	[BSGW6M]
5.c	Sample ID	[BSGW6L]

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1110

**Subject No:** 11101164

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1110) Clinical Research of South Florida

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:49

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Form Status:** Not Started

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

**Visit:** V5\_MONTH12\_L

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

**Site No:** 1110

**Subject No:** 11101164

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1110) Clinical Research of South Florida

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:49

**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:** 1110

**Subject No:** 11101164

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1110) Clinical Research of South Florida

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:49

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

**Visit:** V6\_MONTH24\_L

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

**Site No:** 1110

**Subject No:** 11101164

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1110) Clinical Research of South Florida

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:49

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V6\_MONTH24\_L

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Form Status:** Not Started

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

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

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

**Site No:** 1110

**Subject No:** 11101164

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

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

**Form Status:** Not Started

**Site Name:** (1110) Clinical Research of South Florida

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:49

**Signs and Symptoms**

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

**Symptoms**

4.	Symptoms:	
	Was symptom present?	

**Symptoms - Other**

5.	Symptoms - Other Text:	[ ]
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090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1110

**Subject No:** 11101164

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

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

**Form Status:** Not Started

**Site Name:** (1110) Clinical Research of South Florida

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:49

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1110

**Subject No:** 11101164

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

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

**Form Status:** Not Started

**Site Name:** (1110) Clinical Research of South Florida

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:49

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

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

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

**Form:** HEALTH CARE UTILIZATION

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

**Form Status:** Not Started

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

**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?	
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**Header Text:** c4591001

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

**Form:** ILLNESS DETAILS

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

**Form Status:** Not Started

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

**Illness Details**

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

**Header Text:** c4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

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

**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY

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

**Form Status:** Not Started

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

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

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled  
Visit on Oct/12/2020

**Form:** DATE OF VISIT

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

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

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

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

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled  
Visit on Oct/12/2020

**Form:** UNPLANNED VISIT

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

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

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

**Unplanned Assessments**

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

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled  
Visit on Oct/12/2020

**Form:** CONTACT OUTCOME - UNPLANNED

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

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

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

**Contact Outcome**

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Oct/12/2020  Contact Outcome: VISIT NOT REQUIRED, DATA ENTRY ERROR IN E-DIARY
3.	Comments:	[ ]

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

**Disposition - Treatment**

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

**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

**Form:** DISPOSITION - FOLLOW-UP

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

**Form Status:** Not Started

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

**Disposition - Follow-Up**

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



**Header Text:** c4591001

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

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

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Repeat Swab**

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

**Header Text:** c4591001

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

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

**Site No:** 1110 **Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:49

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1110

**Subject No:** 11101164

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Not Started

**Site Name:** (1110) Clinical Research of South Florida

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:49

**Adverse Event Report**

1.	Category:	
2.	AE ID:	[ ]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[ ]
4.	Start Date Time:	//
5.	Is the adverse event still ongoing?	
6.	Toxicity Grade:	
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).	

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

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

**Form Status:** Not Started

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

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.	
9.	Is this event related to study treatment:	
10.	Latest Action Taken with Study Treatment:	
11.	Was a Concomitant Medication given?	
12.	Was a Non-Drug Treatment given?	
13.	What was the outcome of this adverse event?:	
14.	Did the adverse event cause the subject to be discontinued from the study?	
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

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

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** MEDICATION ERROR

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

**Form Status:** Not Started

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

[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	[ ]

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

**Visit:** Logs

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

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

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Not Started

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

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**Concomitant Medications**

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

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)



**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

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

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Form Status:** Not Started

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

[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?	

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

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

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

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

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** RADIATION TREATMENT

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

**Form Status:** Not Started

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

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**Radiation Treatment**

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

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

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

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

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

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** TRANSFUSIONS

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

**Form Status:** Not Started

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** VITAL SIGNS - TEMP

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

**Form Status:** Not Started

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

**Vital Signs**

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

**Vital Signs Details**

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



**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Version:** 20-Feb-2021 02:14

**Form Status:** Not Started

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

**Lab Urinalysis**

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

**Lab Result**

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

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** VACCINATION

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

**Form Status:** Not Started

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

**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?	

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** CONTACT OUTCOME - MONTH 1

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

**Form Status:** Not Started

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

**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:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

**Contact Outcome**

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

**Header Text:** c4591001

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

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

**Site No:** 1110 **Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Feb/19/2021
2.	Erroneous Visit	

**Header Text:** c4591001

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

**Form:** INFORMED CONSENT - ASYMPTOMATIC  
SURVEILLANCE

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

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

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

**Informed Consent - Asymptomatic Surveillance**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Feb/19/2021
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**Header Text:** c4591001

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

**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY

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

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

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Feb/19/2021
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	[BPZX83]
5.b	Sample ID	[BSGVMZ]
5.c	Sample ID	[BSGVN0]

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1110**Site Name:** (1110) Clinical Research of South Florida**Subject No:** 11101164**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:49[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/19/2021
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	[BPZXGM]
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**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 1 -  
Unscheduled Visit on Mar/01/2021

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

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

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

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Mar/1/2021
2.	Erroneous Visit	

**COVID-19 Surveillance Visit**

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

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001**Visit:** V202\_SURVEIL\_SWAB 1 -  
Unscheduled Visit on Mar/01/2021**Form Version:** 10-Oct-2020 15:57**Site No:** 1110**Subject No:** 11101164**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1110) Clinical Research of South Florida**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:49[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Mar/1/2021
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	[BR16B8]
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**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 2 -  
Unscheduled Visit on Mar/11/2021

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Mar/11/2021
2.	Erroneous Visit	

**COVID-19 Surveillance Visit**

3.	COVID-19 Surveillance Visit:	SSWAB_WEEK4
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090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001**Visit:** V202\_SURVEIL\_SWAB 2 -  
Unscheduled Visit on Mar/11/2021**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT  
SWAB**Form Version:** 10-Oct-2020 15:57**Form Status:** Data Complete, Verified**Site No:** 1110**Site Name:** (1110) Clinical Research of South Florida**Subject No:** 11101164**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:49[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Mar/11/2021
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	[BR16GF]
-----	-----------	----------

**Header Text:** c4591001

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

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

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

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Jan/8/2021
2.	Erroneous Visit	

**Header Text:** c4591001

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

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

**Site No:** 1110      **Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164      **Subject Initials:** ---

**Generated By:** (b) (4)      **Generated Time (GMT):** 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

**Further Vaccination Confirmation**

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3  Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2
----	---	---

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** TREATMENT UNBLINDED

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

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

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

**Treatment Unblinded**

1.	Date Treatment Unblinded :	Jan/8/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** WITHDRAWAL OF CONSENT

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

**Form Status:** Not Started

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

**Withdrawal Of Consent**

1.	Withdrawal of Consent Date :	//
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**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** DEATH DETAILS CODED

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

**Form Status:** Not Started

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

**Death Details**

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

**Cause of Death**

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

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form:** SUBJECT STATUS

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

**Form Status:** Data Complete, Verified

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

**Subject Status**

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/19/2020

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

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

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

**Casebook Signature Form**

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

**Visit:** Investigator Signature -  
Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

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

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

[Audit Trail](#)

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
Jeffrey Rosen	Approved	Mar-12-2021 11:37:59 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

**Affidavit:**

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

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

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

**Header Text:** c4591001

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

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

**Form Version:** 30-Jul-2020 21:29

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

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-29-2020 15:42:18 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [Redacted] [Redacted]	Not Applicable

**Header Text:** c4591001

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

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

**Site No:** 1110

**Subject No:** 11101164

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

**Form:** GENERAL MEDICAL HISTORY - Comments

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

**Site Name:** (1110) Clinical Research of South Florida

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:49

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-29-2020 15:43:05 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [Redacted] [Redacted]	Healthy <hr/> Not Applicable

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

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

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

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

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

[Back to Form](#)

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
Jeffrey Rosen	Approved	Mar-12-2021 11:37:59 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

**Affidavit:**

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

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

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

(b) (6)	N/A	Mar-11-2021 11:48:47 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Jeffrey Rosen	Approved	Mar-02-2021 18:51:39 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

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

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

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

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

**Affidavit:**

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

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

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

(b) (6)	N/A	Mar-01-2021 13:56:48 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Jeffrey Rosen	Approved	Feb-23-2021 18:57:07 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**Affidavit:**

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

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

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

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)



**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

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

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

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

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

(b) (6)	N/A	Feb-19-2021 09:14:45 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Jeffrey Rosen	Approved	Jan-25-2021 19:28:55 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**Affidavit:**

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

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

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

(b) (6)	N/A	Jan-22-2021 12:37:56 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Jeffrey Rosen	Approved	Jan-21-2021 10:46:03 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

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

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

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

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

**Affidavit:**

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

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

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

(b) (6)	N/A	Jan-08-2021 11:18:50 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Jeffrey Rosen	Approved	Oct-26-2020 11:26:15 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**Affidavit:**

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

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

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

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Form Version:** 30-Jul-2020 21:29

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

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

[Back to Form](#)

*1. Select appropriate response - Protocol version*

Date	Location	User	Value	Reason
Aug-29-2020 15:41:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-29-2020 15:41:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> STAGE 3 COHO RTS	Initial Entry

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

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

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

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

[Back to Form](#)

**1. Consent Was:**

Date	Location	User	Value	Reason
Aug-29-2020 15:41:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	<b>Data Entry:</b> OBTAINED Date Written Co nsent Obtained  Aug/29/2020	Initial Entry

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 06-Jul-2020 21:55

**Site No:** 1110

**Subject No:** 11101164

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

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

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

**Site Name:** (1110) Clinical Research of South Florida

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:49

[Back to Form](#)

**1. Subject ID**

Date	Location	User	Value	Reason
Aug-29-2020 15:41:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 11101164	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Aug-29-2020 15:40:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6) 1986	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Aug-29-2020 15:41:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> FEMALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
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090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Form Version:** 06-Jul-2020 21:55

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

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

Aug-29-2020 15:41:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	<b>Data Entry:</b> NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry
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**5. Race: (Check X all that apply):**

Date	Location	User	Value	Reason
Aug-29-2020 15:41:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	<b>Data Entry:</b> WHITE	Initial Entry

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1110

**Subject No:** 11101164

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

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

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

**Site Name:** (1110) Clinical Research of South Florida

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:49

[Back to Form](#)

*1. Date of Visit*

Date	Location	User	Value	Reason
Aug-29-2020 15:42:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> Aug/29/2020	Initial Entry

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1110

**Subject No:** 11101164

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

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

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

**Site Name:** (1110) Clinical Research of South Florida

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:49

[Back to Form](#)

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

Date	Location	User	Value	Reason
Aug-29-2020 15:42:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> Aug/29/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Aug-29-2020 15:42:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Aug-29-2020 15:42:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)



**Header Text:** c4591001

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

**Form Version:** 21-Aug-2020 02:51

**Site No:** 1110

**Subject No:** 11101164

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

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

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

**Site Name:** (1110) Clinical Research of South Florida

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:49

[Back to Form](#)

**1. Date:**

Date	Location	User	Value	Reason
Aug-29-2020 15:44:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> Aug/29/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Aug-29-2020 15:44:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> 165.8	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Aug-29-2020 15:44:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> LB	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
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090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

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

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

**Form Version:** 21-Aug-2020 02:51

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

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

Aug-29-2020 15:44:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 70.8	Initial Entry
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**5. Unit:**

Date	Location	User	Value	Reason
Aug-29-2020 15:44:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> in	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
Aug-29-2020 15:44:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 23.3	Initial Entry

**7.a**

Date	Location	User	Value	Reason
Aug-29-2020 15:44:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record I 1</b> <b>identifier:</b> :	Initial Entry

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

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

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

**Form Version:** 21-Aug-2020 02:51

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

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

			<b>Temperat 36.5 ure:</b> <b>Temperat C ure Unit:</b> <b>Temperat FOR ure Locat EHE ion:: AD</b>	
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**7.a Record Identifier:**

Date	Location	User	Value	Reason
Aug-29-2020 15:44:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> 1	Initial Entry

**7.a Temperature:**

Date	Location	User	Value	Reason
Aug-29-2020 15:44:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> 36.5	Initial Entry

**7.a Unit:**

Date	Location	User	Value	Reason
Aug-29-2020 15:44:03 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> C	Initial Entry

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

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

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

**Form Version:** 21-Aug-2020 02:51

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

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

Eastern Time  
(US & Canada)

**7.a Temperature Location:**

Date	Location	User	Value	Reason
Aug-29-2020 15:44:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> FOREHEAD	Initial Entry

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

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

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:49

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

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Aug-29-2020 15:44:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Aug-29-2020 15:44:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Aug-29-2020 15:44:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> Aug/29/2020	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
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090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

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

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:49

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

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

Aug-29-2020 15:44:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry
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**5. Specimen Type:**

Date	Location	User	Value	Reason
Aug-29-2020 15:44:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

Date	Location	User	Value	Reason
Aug-29-2020 15:44:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-</b> 113 <b>Defined I</b> <b>dentifier:</b> <b>Test::</b> Choriogon adotropin Beta_PX11 3 <b>Result::</b> NEGATIV E <b>Not Done</b> ::	Initial Entry

**6.a Sponsor ID:**

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

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

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:49

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

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

Date	Location	User	Value	Reason
Aug-29-2020 15:44:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

**6.a Test:**

Date	Location	User	Value	Reason
Aug-29-2020 15:44:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> Choriogonadotro pin Beta_PX113	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Aug-29-2020 15:44:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1110

**Subject No:** 11101164

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

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

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

**Site Name:** (1110) Clinical Research of South Florida

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:49

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Aug-29-2020 15:45:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> Aug/29/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Aug-29-2020 15:45:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> 73633	Initial Entry

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)



**Header Text:** c4591001

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

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

**Site No:** 1110

**Subject No:** 11101164

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

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

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

**Site Name:** (1110) Clinical Research of South Florida

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:49

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**1. Data Origin**

Date	Location	User	Value	Reason
Aug-29-2020 21:35:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-29-2020 21:35:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Aug-29-2020 21:36:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-29-2020 21:35:00 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidat e	'Sample Collected?' is Yes, however

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Aug-29-2020 21:35:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Aug/29/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Aug-29-2020 21:36:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I</b> BP3HK <b>D:</b> F	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Aug-29-2020 21:36:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP3HKF	Initial Entry

**5.b**

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**Header Text:** c4591001

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

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

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

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

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

Date	Location	User	Value	Reason
Aug-29-2020 21:36:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I</b> BP3HK <b>D:</b> G	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Aug-29-2020 21:36:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP3HKG	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Aug-29-2020 21:36:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I</b> BP3HK <b>D:</b> H	Initial Entry

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

**5.c Sample ID**

Date	Location	User	Value	Reason
Aug-29-2020 21:36:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP3HKH	Initial Entry

**5.d**

Date	Location	User	Value	Reason
Aug-29-2020 21:37:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample I BRWP6 D: C	Initial Entry

**5.d Sample ID**

Date	Location	User	Value	Reason
Aug-29-2020 21:37:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRWP6C	Initial Entry

**5.e**

Date	Location	User	Value	Reason
Aug-29-2020 21:37:29	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample I BRWP6	Initial Entry

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	<b>D:</b> D	
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**5.e Sample ID**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Aug-29-2020 21:37:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRWP6D	Initial Entry

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

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**1. Data Origin**

Date	Location	User	Value	Reason
Aug-29-2020 21:34:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-29-2020 21:34:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Aug-29-2020 21:34:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-29-2020 21:34:06 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidat e	'Sample Collected?' is Yes, however

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Aug-29-2020 21:34:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Aug/29/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Aug-29-2020 21:34:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample I BPY0L D: J	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Aug-29-2020 21:34:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPY0LJ	Initial Entry

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1110

**Subject No:** 11101164

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

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

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

**Site Name:** (1110) Clinical Research of South Florida

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:49

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

Date	Location	User	Value	Reason
Aug-29-2020 15:45:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Aug-29-2020 15:45:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Aug-29-2020 15:45:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
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090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)



**Header Text:** c4591001

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

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

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

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

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

Aug-29-2020 15:45:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	<b>Data Entry:</b> Aug/29/2020 12: 16	Initial Entry
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**5. Anatomical Location:**

Date	Location	User	Value	Reason
Aug-29-2020 15:45:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Aug-29-2020 15:45:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Aug-29-2020 15:45:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Aug-29-2020 15:45:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPE CIFIED OBSERVATIO N PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Aug-29-2020 15:45:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

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

Date	Location	User	Value	Reason
Sep-04-2020 08:04:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-03-2020 15:48:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Sep-03-2020 15:48:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT	Changed Information
Sep-03-2020 02:52:40 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	eDiary: REACTOGENICITY E-DIARY COLLECTED FOR

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

(US & Canada)				THIS SUBJECT is 'Yes' however VAX 1 eDiary records are not available for the subject. Please verify and update. Else, confirm in query response appropriately.
Aug-29-2020 15:45:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	<b>Data Entry:</b> YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT	Initial Entry

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1110

**Subject No:** 11101164

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

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

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

**Site Name:** (1110) Clinical Research of South Florida

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:49

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**1. Date of Visit**

Date	Location	User	Value	Reason
Oct-17-2020 06:11:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Closed	Response satisfies query
Oct-16-2020 15:48:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED] [REDACTED]	Query 1: Answered	Updated
Oct-15-2020 12:20:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Opened	Illness ed diary: As per Illness ed diary records, subject reported "Yes" for the question "Have you experienced any of the following?" for the COVID-19 symptoms or diagnosis on 10OCT2020. But corresponding COVID Illness visit not

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1110

**Subject No:** 11101164

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

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

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

**Site Name:** (1110) Clinical Research of South Florida

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:49

				reported. Please clarify.
Sep-18-2020 14:21:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/18/2020	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1110

**Subject No:** 11101164

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

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

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

**Site Name:** (1110) Clinical Research of South Florida

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:49

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**1. Date:**

Date	Location	User	Value	Reason
Sep-18-2020 14:23:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/18/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-18-2020 14:23:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> <b>Temperature:</b> <b>Temperature Unit:</b> <b>Temperature Fore</b> <b>Location:</b> <b>Head:</b>	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Sep-18-2020 14:23:52 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

& Canada)

**2.a Temperature:**

Date	Location	User	Value	Reason
Sep-18-2020 14:23:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 36.2	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Sep-18-2020 14:23:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> C	Initial Entry

**2.a Temperature Location:**

Date	Location	User	Value	Reason
Sep-18-2020 14:23:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FOREHEAD	Initial Entry

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:49

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

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Sep-18-2020 14:23:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Sep-18-2020 14:23:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Sep-18-2020 14:23:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/18/2020	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
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090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:49

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

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

Sep-18-2020 14:23:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry
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**5. Specimen Type:**

Date	Location	User	Value	Reason
Sep-18-2020 14:23:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

Date	Location	User	Value	Reason
Sep-18-2020 14:23:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-</b> 113 <b>Defined Identifier:</b> <b>Test::</b> Choriogon adotropin Beta_PX11 3 <b>Result::</b> NEGATIV E <b>Not Done</b> <b>::</b>	Initial Entry

**6.a Sponsor ID:**

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:49

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

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

Date	Location	User	Value	Reason
Sep-18-2020 14:23:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

**6.a Test:**

Date	Location	User	Value	Reason
Sep-18-2020 14:23:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Sep-18-2020 14:23:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

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**1. Data Origin**

Date	Location	User	Value	Reason
Sep-18-2020 19:56:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-18-2020 19:56:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-18-2020 19:56:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-18-2020 19:56:30 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidat e	'Sample Collected?' is Yes, however

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Sep-18-2020 19:56:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Sep/18/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-18-2020 19:56:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I</b> BPY06 <b>D:</b> N	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Sep-18-2020 19:56:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPY06N	Initial Entry

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1110

**Subject No:** 11101164

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

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

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

**Site Name:** (1110) Clinical Research of South Florida

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:49

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

Date	Location	User	Value	Reason
Sep-18-2020 14:24:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Sep-18-2020 14:24:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Sep-18-2020 14:24:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
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090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1110

Site Name: (1110) Clinical Research of South Florida

Subject No: 11101164

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Sep-18-2020 14:24:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/18/2020 09:59	Initial Entry
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**5. Anatomical Location:**

Date	Location	User	Value	Reason
Sep-18-2020 14:24:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Sep-18-2020 14:24:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Sep-18-2020 14:24:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Sep-18-2020 14:24:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPE CIFIED OBSERVATIO N PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-18-2020 14:24:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)



**Header Text:** c4591001

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

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

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

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

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

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*1. Date of Visit*

Date	Location	User	Value	Reason
Oct-19-2020 18:15:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/19/2020	Initial Entry

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1110 **Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:49

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**1. Data Origin**

Date	Location	User	Value	Reason
Oct-19-2020 18:53:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-19-2020 18:53:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-19-2020 18:53:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-19-2020 18:53:05 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidat e	'Sample Collected?' is Yes, however

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

Header Text: c4591001

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

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

Site No: 1110 Site Name: (1110) Clinical Research of South Florida

Subject No: 11101164 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 29-Mar-2021 10:49

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Oct-19-2020 18:53:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Oct/19/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-19-2020 18:53:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I</b> BPW9 <b>D:</b> H4	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-19-2020 18:53:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPW9H4	Initial Entry

5.b

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1110 **Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:49

Date	Location	User	Value	Reason
Oct-19-2020 18:53:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I</b> BSGW6 <b>D:</b> M	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Oct-19-2020 18:53:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BSGW6M	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Oct-19-2020 18:53:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample I</b> BSGW6 <b>D:</b> L	Initial Entry

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1110 **Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:49

*5.c Sample ID*

Date	Location	User	Value	Reason
Oct-19-2020 18:53:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BSGW6L	Initial Entry

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled  
Visit on Oct/12/2020

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

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

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

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

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*1. Date of Visit*

Date	Location	User	Value	Reason
Oct-16-2020 15:46:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted] [Redacted]	<b>Data Entry:</b> Oct/12/2020	Initial Entry

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on Oct/12/2020

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

**Site No:** 1110

**Subject No:** 11101164

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

**Form:** UNPLANNED VISIT - eCRF Audit Trail History

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

**Site Name:** (1110) Clinical Research of South Florida

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:49

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***1. Assessments***

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Oct-16-2020 15:47:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-16-2020 15:46:10 (UTC-05:00) Eastern 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.
Oct-16-2020 15:46:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CONTACT OUTCOME	Initial Entry

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on Oct/12/2020

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

**Site No:** 1110

**Subject No:** 11101164

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

**Form:** CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History

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

**Site Name:** (1110) Clinical Research of South Florida

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:49

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**1. Contact Type:**

Date	Location	User	Value	Reason
Oct-16-2020 15:46:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> TELEPHONE VISIT	Initial Entry

**2. Was contact made?**

Date	Location	User	Value	Reason
Oct-16-2020 15:47:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-16-2020 15:47:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Contact: Oct/12/2020  Contact Outcome:  VISIT NOT REQUIRED, DATA ENTRY ERROR IN E-DIA	Transcription Error

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)



**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled  
Visit on Oct/12/2020

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

**Site No:** 1110

**Subject No:** 11101164

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

**Form:** CONTACT OUTCOME - UNPLANNED - eCRF  
Audit Trail History

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

**Site Name:** (1110) Clinical Research of South Florida

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:49

			RY	
Oct-16-2020 15:46:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Response to "Date of Contact" is missing.
Oct-16-2020 15:46:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Contact Outcom e:  VISIT NOT RE QUIRED, DAT A ENTRY ER ROR IN E-DIA RY	Initial Entry

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

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

**Site No:** 1110 **Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:49

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

Date	Location	User	Value	Reason
Oct-19-2020 18:15:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/19/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Oct-19-2020 18:15:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Oct-19-2020 18:15:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT - **Form:** DATE OF VISIT - eCRF Audit Trail History  
Unscheduled

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

**Site No:** 1110 **Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:49

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*1. Date of Visit*

Date	Location	User	Value	Reason
Feb-19-2021 09:14:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/19/2021	Initial Entry

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

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

**Form:** INFORMED CONSENT - ASYMPTOMATIC  
SURVEILLANCE - eCRF Audit Trail History

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

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

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

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**1. Consent Was:**

Date	Location	User	Value	Reason
Feb-19-2021 09:15:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consen t Obtained  Feb/19/2021	Initial Entry

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

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**1. Data Origin**

Date	Location	User	Value	Reason
Feb-19-2021 14:09:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Feb-19-2021 14:09:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Feb-19-2021 14:09:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-19-2021 14:09:05 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Feb-19-2021 14:09:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Feb/19/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Feb-19-2021 14:09:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BPZX83</b>	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Feb-19-2021 14:09:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPZX83	Initial Entry

**5.b**

Date	Location	User	Value	Reason
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090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT - **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History  
Unscheduled

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

**Site No:** 1110 **Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:49

Feb-19-2021 14:10:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID</b> BSGVM : Z	Initial Entry
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**5.b Sample ID**

Date	Location	User	Value	Reason
Feb-19-2021 14:10:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BSGVMZ	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Feb-19-2021 14:10:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID</b> BSGVN : 0	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Feb-19-2021 14:10:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BSGVN0	Initial Entry

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

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**1. Data Origin**

Date	Location	User	Value	Reason
Feb-19-2021 14:11:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Feb-19-2021 14:11:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Feb-19-2021 14:11:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-19-2021 14:11:11 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)



**Header Text:** c4591001

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

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

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

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

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Feb-19-2021 14:11:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Feb/19/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Feb-19-2021 14:11:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID BPZXG : M	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Feb-19-2021 14:11:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPZXGM	Initial Entry

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 1 -  
Unscheduled Visit on Mar/01/2021

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

**Site No:** 1110

**Subject No:** 11101164

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

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

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

**Site Name:** (1110) Clinical Research of South Florida

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:49

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**1. Date of Visit**

Date	Location	User	Value	Reason
Mar-01-2021 13:56:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/1/2021	Initial Entry

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

Date	Location	User	Value	Reason
Mar-01-2021 13:56:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SSWAB_WEEK2	Initial Entry

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 1 -  
Unscheduled Visit on Mar/01/2021

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

**Site No:** 1110

**Subject No:** 11101164

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

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

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

**Site Name:** (1110) Clinical Research of South Florida

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:49

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**1. Data Origin**

Date	Location	User	Value	Reason
Mar-01-2021 13:57:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Mar-01-2021 13:57:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Mar-01-2021 13:57:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-01-2021 13:57:03 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 1 -  
Unscheduled Visit on Mar/01/2021

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

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

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

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Mar-01-2021 13:57:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Mar/1/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Mar-01-2021 13:57:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BR16B8	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Mar-01-2021 13:57:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR16B8	Initial Entry

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 2 -  
Unscheduled Visit on Mar/11/2021

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

**Site No:** 1110

**Subject No:** 11101164

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

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

**Form Status:** Data Complete, Verified

**Site Name:** (1110) Clinical Research of South Florida

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:49

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**1. Date of Visit**

Date	Location	User	Value	Reason
Mar-11-2021 11:48:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/11/2021	Initial Entry

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

Date	Location	User	Value	Reason
Mar-11-2021 11:48:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SSWAB_WEEK4	Initial Entry

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 2 -  
Unscheduled Visit on Mar/11/2021

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

**Site No:** 1110

**Subject No:** 11101164

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

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

**Form Status:** Data Complete, Verified

**Site Name:** (1110) Clinical Research of South Florida

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:49

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**1. Data Origin**

Date	Location	User	Value	Reason
Mar-11-2021 11:49:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Mar-11-2021 11:49:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Mar-11-2021 11:49:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-11-2021 11:49:02 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

**Visit:** V202\_SURVEIL\_SWAB 2 -  
Unscheduled Visit on Mar/11/2021

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

**Site No:** 1110

**Subject No:** 11101164

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

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

**Form Status:** Data Complete, Verified

**Site Name:** (1110) Clinical Research of South Florida

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:49

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Mar-11-2021 11:49:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Mar/11/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Mar-11-2021 11:49:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID BR16G : F	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Mar-11-2021 11:49:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR16GF	Initial Entry

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact - **Form:** DATE OF VISIT - eCRF Audit Trail History  
Unscheduled

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

**Site No:** 1110      **Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164      **Subject Initials:** ---

**Generated By:** (b) (4)      **Generated Time (GMT):** 29-Mar-2021 10:49

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*1. Date of Visit*

Date	Location	User	Value	Reason
Jan-08-2021 11:18:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted] [Redacted]	<b>Data Entry:</b> Jan/8/2021	Initial Entry

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)



**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION -  
Unscheduled eCRF Audit Trail History

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

**Site No:** 1110 **Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:49

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

Date	Location	User	Value	Reason
Jan-30-2021 11:54:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Closed	Response satisfies query
Jan-27-2021 15:11:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED] [REDACTED]	Query 1: Answered	updated, will be upload to Florence
Jan-25-2021 22:52:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Opened	Pls document in source how subject met eligibility for unblinding
Jan-22-2021 12:37:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED] [REDACTED]	<b>Data Entry:</b> Participant is willing to return for Vaccination 3 Participant is:  eligible and NOT confirmed to have received only placebo at Vaccination 1/2	Transcription Error

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION -  
Unscheduled eCRF Audit Trail History

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

**Site No:** 1110 **Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:49

Jan-08-2021 11:19:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted] [Redacted]	<b>Data Entry:</b> Participant is NOT willing to return fo r Vaccination 3 O R otherwise not eli gible	Initial Entry
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**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

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

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

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

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**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Jan-08-2021 11:19:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/8/2021	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Jan-08-2021 11:19:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ASSESS ELIGIBIL ITY FOR ADDITIO NAL VACCINATIO N	Initial Entry

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

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**1. Subject Status**

Date	Location	User	Value	Reason
Oct-19-2020 18:15:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Aug-29-2020 15:45:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Aug-29-2020 15:42:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

**2. Subject Status Date**

Date	Location	User	Value	Reason
Oct-19-2020 18:15:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/19/2020	Initial Entry
Aug-29-2020 15:45:05	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/29/2020	Initial Entry

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1110

**Site Name:** (1110) Clinical Research of South Florida

**Subject No:** 11101164

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:49

(UTC-05:00) Eastern Time (US & Canada)				
Aug-29-2020 15:42:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/29/2020	Initial Entry

090177e196ae3d9d\Final\Final On: 01-Apr-2021 04:39 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

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

**Site No:** 1110

**Subject No:** 11101164

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

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit  
Trail History

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

**Site Name:** (1110) Clinical Research of South Florida

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:49

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*1. Casebook Signature*

Date	Location	User	Value	Reason
Sep-15-2020 11:50:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Click Here to Enabl e	Initial Entry