

**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:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

[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

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1077

**Subject No:** 10771226

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

**Form:** MAIN INFORMED CONSENT

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

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/11/2020
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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:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[10771226]
2.	Birth Date:	(b) (6)/1952
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1077

**Subject No:** 10771226

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

**Form:** DATE OF VISIT

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

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Sep/11/2020
2.	Erroneous Visit	

**Header Text:** c4591001

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

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

**Site No:** 1077

**Subject No:** 10771226

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

**Form:** INCLUSION/EXCLUSION CRITERIA

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

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

**Form Comments**

**Inclusion Criteria Not Met**

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

**Exclusion Criteria Met**

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

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1077

**Subject No:** 10771226

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

**Form:** DISPOSITION - SCREENING

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

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

**Disposition - Screening**

1.	Date of Completion/Discontinuation/Death	Sep/11/2020
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: 1077

Subject No: 10771226

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1077) Regional Clinical Research, Inc

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[BENIGN PROSTATIC HYPERPLASIA]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[CHRONIC BRONCHITIS]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[TYPE II DIABETES]
	Start Date:	UNK/UNK/2016
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[DIABETIC NEUROPATHY]
	Start Date:	UNK/UNK/2016
	Ongoing:	YES

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**Header Text:** c4591001

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

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

**Site No:** 1077

**Subject No:** 10771226

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

**Form:** GENERAL MEDICAL HISTORY

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

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[HYPERLIPIDEMIA]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[HYPERTENSION]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[OSTEOARTHRITIS]
	Start Date:	UNK/UNK/2005
	Ongoing:	YES
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[VITAMIN D DEFICIENCY]
	Start Date:	UNK/UNK/2017
	Ongoing:	YES
1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[ACNE]
	Start Date:	UNK/UNK/1965
	Ongoing:	YES

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)



**Header Text:** c4591001

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

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

**Site No:** 1077

**Subject No:** 10771226

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

**Form:** VITAL SIGNS - BASELINE

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

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Sep/11/2020
2.	Weight:	[76.5]
3.	Unit:	kg
4.	Height:	[179.0]
5.	Unit:	cm
6.	Body Mass Index:	[23.9]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[36.8]
	Unit:	C
	Temperature Location:	ORAL CAVITY

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**Header Text:** c4591001

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

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

**Site No:** 1077

**Subject No:** 10771226

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

**Form:** RANDOMIZATION

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

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Sep/11/2020
2.	Randomization Number:	[255544]
3.	Randomization Group:	[ ]

**Header Text:** c4591001

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

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

**Site No:** 1077

**Subject No:** 10771226

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Sep/11/2020
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	[BP8HTL]
5.b	Sample ID	[BP8HTM]
5.c	Sample ID	[BP8HVJ]
5.d	Sample ID	[BMNNK1]
5.e	Sample ID	[BMNNK2]

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**Header Text:** c4591001

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

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

**Site No:** 1077

**Subject No:** 10771226

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

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

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

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/11/2020
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	[BP8HV1]
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090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1077

**Subject No:** 10771226

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

**Form:** VACCINATION

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

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

[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/11/2020 08:58
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1077

**Subject No:** 10771226

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

**Form:** REACTOGENICITY DIARY

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

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

[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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090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1077

**Subject No:** 10771226

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

**Form:** DATE OF VISIT

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

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1077

**Subject No:** 10771226

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

**Form:** VITAL SIGNS - TEMP

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

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Oct/2/2020
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**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[36.8]
	Unit:	C
	Temperature Location:	ORAL CAVITY



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1077

**Subject No:** 10771226

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

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

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

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Oct/2/2020
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	[BP1HL6]
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090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1077

**Subject No:** 10771226

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

**Form:** VACCINATION

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

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Oct/2/2020 08:02
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

**Header Text:** c4591001

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

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

**Site No:** 1077

**Subject No:** 10771226

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

**Form:** DATE OF VISIT

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

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Oct/30/2020
2.	Erroneous Visit	

**Header Text:** c4591001

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

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

**Site No:** 1077

**Subject No:** 10771226

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/30/2020
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	[BPZ6X2]
5.b	Sample ID	[BPZ6X3]
5.c	Sample ID	[BPZ6X4]
5.d	Sample ID	[BSJLLT]
5.e	Sample ID	[BSJLLV]

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1077

**Subject No:** 10771226

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1077

**Subject No:** 10771226

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Visit:** V5\_MONTH12\_L

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

**Site No:** 1077

**Subject No:** 10771226

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

**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:** 1077

**Subject No:** 10771226

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Visit:** V6\_MONTH24\_L

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

**Site No:** 1077

**Subject No:** 10771226

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V6\_MONTH24\_L

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

**Site No:** 1077

**Subject No:** 10771226

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET  
on Nov/29/2020

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

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

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

**Date of Visit**

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

**COVID-19 Illness Visit**

3.	COVID-19 Illness Visit:	COVID_A
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090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19  
on Nov/29/2020

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

**Form Status:** Data Complete

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

**Signs and Symptoms**

1.	Date of Assessment:	Nov/29/2020
2.	Date of First Symptom Started:	Nov/29/2020
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Nov/30/2020

**Symptoms**

4.a	Symptoms:	FEVER
	Was symptom present?	YES
4.b	Symptoms:	NEW OR INCREASED COUGH
	Was symptom present?	NO
4.c	Symptoms:	NEW OR INCREASED SHORTNESS OF BREATH
	Was symptom present?	NO
4.d	Symptoms:	CHILLS
	Was symptom present?	NO
4.e	Symptoms:	NEW OR INCREASED MUSCLE PAIN
	Was symptom present?	NO
4.f	Symptoms:	NEW LOSS OF TASTE OR SMELL
	Was symptom present?	NO
4.g	Symptoms:	NEW OR INCREASED SORE THROAT
	Was symptom present?	NO
4.h	Symptoms:	DIARRHEA
	Was symptom present?	NO
4.i	Symptoms:	VOMITING
	Was symptom present?	NO

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/29/2020 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

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

**Form Status:** Data Complete

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

**Symptoms - Other**

5.	Symptoms - Other Text:	[ ]
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** MICROBIOLOGY SPECIMEN

**Form Version:** 06-Jul-2020 21:54

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Nov/29/2020	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** MICROBIOLOGY SPECIMEN  
on Nov/29/2020

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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**Microbiology Specimen**

1.	Actual Date of Collection:	Nov/29/2020
2.	Specimen Type:	SWABBED MATERIAL
3.	Specimen Collection Location:	NASOPHARYNX
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST
6.	Trade Name:	OTHER
7.	Test Result:	NEGATIVE
8.	Comments/Findings/Details:	[ ]
9.	Trade Name Other, Specify:	[NALT UNKNOWN]

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF on Nov/29/2020

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

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

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[NOT REQUIRED. SYMPTOMS RESOLVED LESS THAN FOUR DAYS.]

**Aliquot**

Please enter barcode for each aliquot.

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

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB  
on Nov/29/2020

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

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

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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**Electronic Sample Tracking**

1.	Data Origin	SITE	<a href="#">Comments</a>
2.	Sample Type	NASAL_SWAB	<a href="#">Comments</a>
3.	Sample Collected?	NO	<a href="#">Comments</a>
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[TELHEALH VISIT PERFORMED.]	<a href="#">Comments</a>

**Aliquot**

Please enter barcode for each aliquot.

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

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**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION  
on Nov/29/2020**Form Version:** 10-Dec-2020 02:26**Form Status:** Data Complete**Site No:** 1077**Site Name:** (1077) Regional Clinical Research, Inc**Subject No:** 10771226**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:05[eCRF Audit Trail History](#)**Health Care Utilization**

1.a	Physician or Healthcare Professional:	SPECIALIST
	Occurrence of Visits or Contacts:	NO
1.b	Physician or Healthcare Professional:	EMERGENCY ROOM
	Occurrence of Visits or Contacts:	YES Number of Visits or Contacts: [1]
1.c	Physician or Healthcare Professional:	PRIMARY CARE PHYSICIAN
	Occurrence of Visits or Contacts:	NO
1.d	Physician or Healthcare Professional:	URGENT CARE
	Occurrence of Visits or Contacts:	NO
1.e	Physician or Healthcare Professional:	TELEPHONE CONSULTATION
	Occurrence of Visits or Contacts:	NO
1.f	Physician or Healthcare Professional:	OTHER
	Occurrence of Visits or Contacts:	NO

**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?	NO
----	--	----

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** RESPIRATORY TREATMENT

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

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

#	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Treatment	Start Date	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** RESPIRATORY TREATMENT  
on Nov/29/2020

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

**Form Status:** Data Complete, Frozen

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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**Respiratory Treatment**

1.	What is the treatment Identifier?	Not Applicable _____ [ ]	<a href="#">Comments</a>
2.	Concomitant Non-drug Treatment Pre-specified:	Not Applicable _____	<a href="#">Comments</a>
3.	Treatment:	Not Applicable _____	<a href="#">Comments</a>
4.	Treatment:	Not Applicable _____ [ ]	<a href="#">Comments</a>
5.	Start Date:	Not Applicable _____ //	<a href="#">Comments</a>
6.	Ongoing?	Not Applicable _____	<a href="#">Comments</a>

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS  
on Nov/29/2020

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

**Form Status:** Data Complete

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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**Illness Details**

1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	NO
3.	Toxicity Grade:	1

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** ILLNESS DETAILS - SEVERE

**Form Version:** 17-Jul-2020 21:55

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

#	Category of Clinical Event	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** ILLNESS DETAILS - SEVERE  
on Nov/29/2020

**Form Version:** 17-Jul-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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**Illness Details**

1.	Category of Clinical Event:	Not Applicable _____	<a href="#">Comments</a>
2.	Subcategory of Clinical Event:	Not Applicable _____	<a href="#">Comments</a>
3.	Was a diagnosis obtained?	Not Applicable _____	<a href="#">Comments</a>
4.	Toxicity Grade:	Not Applicable _____	<a href="#">Comments</a>

Header Text: c4591001

Visit: POT\_COVID\_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Site No: 1077

Site Name: (1077) Regional Clinical Research, Inc

Subject No: 10771226

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	<b>Sponsor-Defined Identifier</b>	<b>Test:</b>	<b>Result:</b>	<a href="#">Repeating Pages</a>
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY on Nov/29/2020

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1077

Site Name: (1077) Regional Clinical Research, Inc

Subject No: 10771226

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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**Lab Chemistry Details**

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

**Lab Result**

5.a	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	C Reactive Protein_PX329	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
on Nov/29/2020

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

**Form Status:** Data Complete, Frozen

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

5.b	Sponsor ID:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Test:	Alanine Aminotransferase_PX30	
	Result:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Not Applicable _____	<a href="#">Comments</a>	
LNMT	Not Applicable _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		

5.c	Sponsor ID:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Test:	Aspartate Aminotransferase_PX28	
	Result:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Not Applicable _____	<a href="#">Comments</a>	
LNMT	Not Applicable _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
on Nov/29/2020

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

**Form Status:** Data Complete, Frozen

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

5.d	Sponsor ID:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Test:	Alkaline Phosphatase_PX35	
	Result:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Not Applicable _____	<a href="#">Comments</a>	
LNMT	Not Applicable _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		

5.e	Sponsor ID:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Test:	Bilirubin_PX21	
	Result:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Not Applicable _____	<a href="#">Comments</a>	
LNMT	Not Applicable _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
on Nov/29/2020

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

**Form Status:** Data Complete, Frozen

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

5.f	Sponsor ID:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Test:	Blood Urea Nitrogen_PX47	
	Result:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Not Applicable _____	<a href="#">Comments</a>	
LNMT	Not Applicable _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		

5.g	Sponsor ID:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Test:	Creatinine_PX48	
	Result:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Not Applicable _____	<a href="#">Comments</a>	
LNMT	Not Applicable _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Site No: 1077

Site Name: (1077) Regional Clinical Research, Inc

Subject No: 10771226

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

#	Category for Lab Test	Vendor Name ( DERIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	<b>Sponsor-Defined Identifier</b>	<b>Test:</b>	<b>Result:</b>	<a href="#">Repeating Pages</a>
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Nov/29/2020

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

**Form Status:** Data Complete, Frozen

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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**Laboratory Data Hematology**

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

**Lab Result**

5.a	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Hemoglobin_PX1	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** LOCAL LABORATORY DATA - REPEATING Hematology  
on Nov/29/2020

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

**Form Status:** Data Complete, Frozen

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

5.b	Sponsor ID:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Test:	Hematocrit_PX2	
	Result:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Not Applicable _____	<a href="#">Comments</a>	
LNMT	Not Applicable _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		

5.c	Sponsor ID:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Test:	Erythrocytes_PX3	
	Result:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Not Applicable _____	<a href="#">Comments</a>	
LNMT	Not Applicable _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Nov/29/2020

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

**Form Status:** Data Complete, Frozen

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

5.d	Sponsor ID:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Test:	Platelets_PX5	
	Result:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Not Applicable _____	<a href="#">Comments</a>	
LNMT	Not Applicable _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		

5.e	Sponsor ID:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Test:	Leukocytes_PX7	
	Result:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Not Applicable _____	<a href="#">Comments</a>	
LNMT	Not Applicable _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING Hematology on Nov/29/2020

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1077

Site Name: (1077) Regional Clinical Research, Inc

Subject No: 10771226

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

5.f	Sponsor ID:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Test:	Neutrophils_PX608	
	Result:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Not Applicable _____	<a href="#">Comments</a>	
LNMT	Not Applicable _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		

5.g	Sponsor ID:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Test:	Eosinophils_PX609	
	Result:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Not Applicable _____	<a href="#">Comments</a>	
LNMT	Not Applicable _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Nov/29/2020

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

**Form Status:** Data Complete, Frozen

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

5.h	Sponsor ID:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Test:	Monocytes_PX612	
	Result:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Not Applicable _____	<a href="#">Comments</a>	
LNMT	Not Applicable _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		

5.i	Sponsor ID:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Test:	Basophils_PX610	
	Result:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Not Applicable _____	<a href="#">Comments</a>	
LNMT	Not Applicable _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology  
on Nov/29/2020

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

**Form Status:** Data Complete, Frozen

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

5.j	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Lymphocytes_PX611	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** VITAL SIGNS - COVID

**Form Version:** 21-Aug-2020 02:50

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

#	Date:	Vital Signs Details			Form Instance
1.		<b>Record Identifier:</b>	<b>Systolic:</b>	<b>Diastolic:</b>	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** VITAL SIGNS - COVID  
on Nov/29/2020

**Form Version:** 21-Aug-2020 02:50

**Form Status:** Not Started

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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**Vital Signs**

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

**Vital Signs Details**

2.	Record Identifier:	
	Systolic:	[ ]
	Diastolic:	[ ]
	Respiratory Rate in respirations/minute:	[ ]
	Heart Rate in beats/minute:	[ ]

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** VITAL SIGNS - PULSE OX ROOM AIR

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

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

#	Date:	Vital Signs Details		Form Instance
1.	Not Applicable	<b>Record Identifier:</b>	<b>Oxygen Saturation</b>	<a href="#">Repeating Pages</a>
		Not Applicable	Not Applicable	

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR  
on Nov/29/2020

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

**Form Status:** Data Complete, Frozen

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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[Form Comments](#)

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Not Applicable _____ //	<a href="#">Comments</a>
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**Vital Signs Details**

2.a	Record Identifier:	Not Applicable _____ 1	
	SPO2 Pulse Oximetry %	Not Applicable _____ [ ]	<a href="#">Comments</a>

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** OXYGENATION PARAMETERS

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

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	<a href="#">Repeating Pages</a>

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** OXYGENATION PARAMETERS  
on Nov/29/2020

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

**Form Status:** Data Complete, Frozen

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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[Form Comments](#)

[eCRF Audit Trail History](#)

**Oxygenation Parameters**

1.	Date Time of Assessment:	Not Applicable _____ //	<a href="#">Comments</a>
2.	Arterial Blood Gases PaO2 (mmHg):	Not Applicable _____ [ ]	<a href="#">Comments</a>
3.	FiO2 (Fraction of Inhaled Oxygen):	Not Applicable _____ [ ]	<a href="#">Comments</a>

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS

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

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

#	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:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS  
on Nov/29/2020

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

**Form Status:** Not Started

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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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.	Start Date:	//
6.	Ongoing?	

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** IMAGING

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

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.					<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** IMAGING  
on Nov/29/2020

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

**Form Status:** Not Started

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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**Imaging**

1.	Date of Assessment:	//
2.	Location of Assessment:	
3.	Type of Imaging Exam:	
4.	Assessment:	

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)

**Header Text:** c4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

**Header Text:** c4591001

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Form Status:** Not Started

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001

**Visit:** Unplanned - New Unscheduled Visit

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	



**Header Text:** c4591001

**Visit:** Unplanned - New Unscheduled Visit

**Form:** UNPLANNED VISIT

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

**Form Status:** Not Started

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

**Unplanned Assessments**

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

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

**Form Version:** 15-Sep-2020 21:55

**Site No:** 1077

**Subject No:** 10771226

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

**Form:** DISPOSITION - TREATMENT

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

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation/Death :	Oct/30/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

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

**Site No:** 1077

**Subject No:** 10771226

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

**Form:** DISPOSITION - FOLLOW-UP

**Form Status:** Not Started

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

**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 - New  
Unscheduled Visit

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

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

**Form Status:** Not Started

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

**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:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001

**Visit:** Logs

**Form:** ADVERSE EVENT REPORT

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

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	BILATERAL KIDNEY STONES	Nov/29/2020 UNK:UNK	YES	<a href="#">Repeating Pages</a>

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1077

Subject No: 10771226

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1077) Regional Clinical Research, Inc

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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[Form Audit Trail](#)

**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[BILATERAL KIDNEY STONES]
4.	Start Date Time:	Nov/29/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	2
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).	YES  Is this serious event associated with congenital anomaly or birth defect? NO  Did this serious event result in death? NO  Did this serious event require or prolong hospitalization? YES  Did this serious event result in persistent or significant disability/incapacity? NO  Is this serious event life threatening? NO  Other medically important serious event NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED  If Not Related to study treatment(s), this event is due to: OTHER  If Other, specify: [NEW MEDICAL EVENT]

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1077

**Subject No:** 10771226

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020487847]



**Header Text:** c4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

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

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1077

**Subject No:** 10771226

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

**Form:** MEDICATION ERROR

**Form Status:** Not Started

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

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**Medication Error**

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

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)

**Header Text:** c4591001

**Visit:** Logs

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

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

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Not Started

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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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:	//

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1077

**Subject No:** 10771226

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

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Status:** Not Started

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

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**Concomitant Medications**

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

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

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

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1077

**Subject No:** 10771226

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

**Form:** RADIATION TREATMENT

**Form Status:** Not Started

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

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**Radiation Treatment**

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



**Header Text:** c4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

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

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1077

**Subject No:** 10771226

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

**Form:** TRANSFUSIONS

**Form Status:** Not Started

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

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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:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

**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:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

**Vital Signs**

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

**Vital Signs Details**

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

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** VACCINATION

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

**Form Status:** Not Started

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

**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?	

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (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:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

**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:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

**Contact Outcome**

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

**Header Text:** c4591001

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

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

**Date of Visit**

1.	Date of Visit	//
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:** Not Started

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

**Informed Consent - Asymptomatic Surveillance**

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

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)

**Header Text:** c4591001

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Form Status:** Not Started

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001

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

**Form:** DATE OF VISIT

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

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

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** c4591001

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

**Form:** FURTHER VACCINATION CONFIRMATION

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

**Form Status:** Data Complete, Frozen

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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

**Site No:** 1077

**Subject No:** 10771226

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

**Form:** TREATMENT UNBLINDED

**Form Status:** Data Complete, Verified

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

**Treatment Unblinded**

1.	Date Treatment Unblinded :	Jan/13/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1077

**Subject No:** 10771226

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

**Form:** WITHDRAWAL OF CONSENT

**Form Status:** Not Started

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

**Withdrawal Of Consent**

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

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1077

**Subject No:** 10771226

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

**Form:** DEATH DETAILS CODED

**Form Status:** Not Started

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

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

**Site No:** 1077

**Subject No:** 10771226

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

**Form:** SUBJECT STATUS

**Form Status:** Data Complete, Verified

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

**Subject Status**

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/30/2020

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

**Site No:** 1077

**Subject No:** 10771226

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

**Form:** CASEBOOK SIGNATURE FORM

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

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

**Casebook Signature Form**

1.	Casebook Signature	<a href="#">Click Here to Enable</a>
----	--------------------	--------------------------------------

**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:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

[Audit Trail](#)

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
Suchet Patel	Approved	Mar-12-2021 16:57:01 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

**Affidavit:**

By my dated signature below, I, SuchetPatel, 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.

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1077

**Subject No:** 10771226

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

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

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

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

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Item	Date	User	Comment
Form	Sep-11-2020 11:21:31 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [Redacted] [Redacted]	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/29/2020

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

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

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

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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Item	Date	User	Comment
Form	Dec-23-2020 13:23:24 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
Form	Dec-22-2020 16:28:41 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done
Form	Dec-21-2020 16:37:31 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

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

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

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

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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Item	Date	User	Comment
1	Dec-23-2020 13:23:24 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
1	Dec-22-2020 16:28:41 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done
1	Dec-21-2020 16:37:31 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

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

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

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

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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Item	Date	User	Comment
2	Dec-23-2020 13:23:24 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
2	Dec-22-2020 16:28:41 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done
2	Dec-21-2020 16:37:31 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

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

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

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

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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Item	Date	User	Comment
3	Dec-23-2020 13:23:24 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
3	Dec-22-2020 16:28:41 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done
3	Dec-21-2020 16:37:31 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

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

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

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

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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Item	Date	User	Comment
4	Dec-23-2020 13:23:24 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
4	Dec-22-2020 16:28:41 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done
4	Dec-21-2020 16:37:31 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments  
on Nov/29/2020

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

**Form Status:** Data Complete, Frozen

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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Item	Date	User	Comment
Form	Dec-18-2020 17:35:02 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments  
on Nov/29/2020

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

**Form Status:** Data Complete, Frozen

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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Item	Date	User	Comment
1	Dec-18-2020 17:35:02 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments  
on Nov/29/2020

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

**Form Status:** Data Complete, Frozen

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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Item	Date	User	Comment
2	Dec-18-2020 17:35:02 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments  
on Nov/29/2020

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

**Form Status:** Data Complete, Frozen

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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Item	Date	User	Comment
3	Dec-18-2020 17:35:02 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments  
on Nov/29/2020

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

**Form Status:** Data Complete, Frozen

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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Item	Date	User	Comment
4	Dec-18-2020 17:35:02 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments  
on Nov/29/2020

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

**Form Status:** Data Complete, Frozen

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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Item	Date	User	Comment
5	Dec-18-2020 17:35:02 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments  
on Nov/29/2020

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

**Form Status:** Data Complete, Frozen

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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Item	Date	User	Comment
6	Dec-18-2020 17:35:02 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** ILLNESS DETAILS - SEVERE - Comments  
on Nov/29/2020

**Form Version:** 17-Jul-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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Item	Date	User	Comment
Form	Dec-18-2020 17:35:50 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments  
on Nov/29/2020

**Form Version:** 17-Jul-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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Item	Date	User	Comment
1	Dec-18-2020 17:35:50 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments  
on Nov/29/2020

**Form Version:** 17-Jul-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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Item	Date	User	Comment
2	Dec-18-2020 17:35:50 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments  
on Nov/29/2020

**Form Version:** 17-Jul-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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Item	Date	User	Comment
3	Dec-18-2020 17:35:50 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments  
on Nov/29/2020

**Form Version:** 17-Jul-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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Item	Date	User	Comment
4	Dec-18-2020 17:35:50 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/29/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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Item	Date	User	Comment
Form	Dec-18-2020 17:36:05 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/29/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

[Back to Form](#)

Item	Date	User	Comment
1	Dec-18-2020 17:36:05 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/29/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

[Back to Form](#)

Item	Date	User	Comment
2	Dec-18-2020 17:36:05 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/29/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1077

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

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Item	Date	User	Comment
3	Dec-18-2020 17:36:05 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/29/2020

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**Site No:** 1077

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Item	Date	User	Comment
4	Dec-18-2020 17:36:05 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/29/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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

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**Site No:** 1077

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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Item	Date	User	Comment
5.a	Dec-18-2020 17:36:05 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/29/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1077

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Item	Date	User	Comment
5.a	Dec-18-2020 17:36:05 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/29/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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**Site No:** 1077

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**Generated Time (GMT):** 29-Mar-2021 10:05

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Item	Date	User	Comment
5.a	Dec-18-2020 17:36:05 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/29/2020

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Item	Date	User	Comment
5.a	Dec-18-2020 17:36:05 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

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**Site No:** 1077

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

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**Form Status:** Data Complete, Frozen

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**Header Text:** c4591001

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**Visit:** Investigator Signature - Unscheduled

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

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

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- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
Suchet Patel	Approved	Mar-12-2021 16:57:01 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

**Affidavit:**

By my dated signature below, I, SuchetPatel, 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	Feb-16-2021 11:19:47 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Suchet Patel	Approved	Jan-27-2021 09:14:44 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, SuchetPatel, 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	Dec-10-2020 10:09:03 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (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:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

Suchet Patel	Approved	Nov-03-2020 10:59:05 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**Affidavit:**

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

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

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

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1077

**Subject No:** 10771226

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

**Form:** COHORT\_SELECTION - eCRF Audit Trail History

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

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

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

Date	Location	User	Value	Reason
Sep-11-2020 11:20:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<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
Sep-11-2020 11:20:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1077

**Subject No:** 10771226

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

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

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

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

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**I. Consent Was:**

Date	Location	User	Value	Reason
Sep-11-2020 11:21:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Sep/11/2020	Initial Entry

Header Text: c4591001

Visit: COHORT\_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1077

Subject No: 10771226

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1077) Regional Clinical Research, Inc

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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**1. Subject ID**

Date	Location	User	Value	Reason
Sep-11-2020 11:20:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 10771226	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Sep-11-2020 11:20:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6)/1952	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Sep-11-2020 11:21:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> MALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Sep-11-2020 11:21:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT HISPANIC OR LATINO(A ) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-11-2020 11:21:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> WHITE	Initial Entry

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1077

**Subject No:** 10771226

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

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

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

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

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*I. Date of Visit*

Date	Location	User	Value	Reason
Sep-11-2020 11:21:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/11/2020	Initial Entry



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1077

Subject No: 10771226

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1077) Regional Clinical Research, Inc

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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

Date	Location	User	Value	Reason
Sep-11-2020 11:21:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/11/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Sep-11-2020 11:21:43 (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
Sep-11-2020 11:21:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1077

Subject No: 10771226

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1077) Regional Clinical Research, Inc

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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*1.a*

Date	Location	User	Value	Reason
Sep-11-2020 12:00:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH N 1 umber: Medical His BENIGN PROSTAT tory Term: IC HYPERPLASIA Start Date: UNK/UNK/2000 Ongoing: YES	Initial Entry

*1.a Line/MH Number:*

Date	Location	User	Value	Reason
Sep-11-2020 12:00:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

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

Date	Location	User	Value	Reason
Sep-11-2020 12:00:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BENIGN PROSTATIC HYPERP LASIA	Initial Entry

*1.a Start Date:*

Date	Location	User	Value	Reason
Sep-11-2020 12:00:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2000	Initial Entry

*1.a Ongoing:*

Date	Location	User	Value	Reason
Sep-11-2020 12:00:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

*1.b*

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1077

Subject No: 10771226

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1077) Regional Clinical Research, Inc

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

Date	Location	User	Value	Reason
Sep-11-2020 12:07:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Num 2 <b>ber:</b> <b>Medical Histor</b> CHRONIC BRO <b>y Term:</b> NCHITIS <b>Start Date:</b> UNK/UNK/2010 <b>Ongoing:</b> YES	Initial Entry

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

Date	Location	User	Value	Reason
Sep-11-2020 12:07:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

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

Date	Location	User	Value	Reason
Sep-11-2020 12:07:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CHRONIC BRONCHITIS	Initial Entry

**1.b Start Date:**

Date	Location	User	Value	Reason
Sep-11-2020 12:07:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2010	Initial Entry

**1.b Ongoing:**

Date	Location	User	Value	Reason
Sep-11-2020 12:07:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**1.c**

Date	Location	User	Value	Reason
Sep-11-2020 12:09:38 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Numbe 3	Initial Entry

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1077

Subject No: 10771226

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1077) Regional Clinical Research, Inc

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

Time (US & Canada)			<b>r:</b>	
			<b>Medical History</b>	TYPE II DIAB
			<b>Term:</b>	ETES
			<b>Start Date:</b>	UNK/UNK/2016
			<b>Ongoing:</b>	YES

**I.c Line/MH Number:**

Date	Location	User	Value	Reason
Sep-11-2020 12:09:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

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

Date	Location	User	Value	Reason
Sep-11-2020 12:09:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> TYPE II DIABETES	Initial Entry

**I.c Start Date:**

Date	Location	User	Value	Reason
Sep-11-2020 12:09:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2016	Initial Entry

**I.c Ongoing:**

Date	Location	User	Value	Reason
Sep-11-2020 12:09:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**I.d**

Date	Location	User	Value	Reason
Sep-11-2020 12:10:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 4	Initial Entry

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1077

Subject No: 10771226

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1077) Regional Clinical Research, Inc

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

			<b>Medical History Term:</b> DIABETIC NEUROPATHY <b>Start Date:</b> UNK/UNK/2016 <b>Ongoing:</b> YES
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**I.d Line/MH Number:**

Date	Location	User	Value	Reason
Sep-11-2020 12:10:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 4	Initial Entry

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

Date	Location	User	Value	Reason
Sep-11-2020 12:10:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> DIABETIC NEUROPATHY	Initial Entry

**I.d Start Date:**

Date	Location	User	Value	Reason
Sep-11-2020 12:10:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2016	Initial Entry

**I.d Ongoing:**

Date	Location	User	Value	Reason
Sep-11-2020 12:10:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**I.e**

Date	Location	User	Value	Reason
Sep-11-2020 12:10:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 5 <b>Medical History Term:</b> HYPERLIPIDEMIA	Initial Entry

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1077

Subject No: 10771226

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1077) Regional Clinical Research, Inc

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

			<b>Start Date:</b>	UNK/UNK/2010
			<b>Ongoing:</b>	YES

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

Date	Location	User	Value	Reason
Sep-11-2020 12:10:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 5	Initial Entry

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

Date	Location	User	Value	Reason
Sep-11-2020 12:10:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> HYPERLIPIDEMIA	Initial Entry

***1.e Start Date:***

Date	Location	User	Value	Reason
Sep-11-2020 12:10:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2010	Initial Entry

***1.e Ongoing:***

Date	Location	User	Value	Reason
Sep-11-2020 12:10:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

***1.f***

Date	Location	User	Value	Reason
Sep-11-2020 12:10:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number 6</b> : <b>Medical History T HYPERTENS</b> <b>erm:</b> ION <b>Start Date:</b> UNK/UNK/2015	Initial Entry

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1077

Subject No: 10771226

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1077) Regional Clinical Research, Inc

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

			Ongoing:	YES
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**1.f Line/MH Number:**

Date	Location	User	Value	Reason
Sep-11-2020 12:10:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 6	Initial Entry

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

Date	Location	User	Value	Reason
Sep-11-2020 12:10:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> HYPERTENSION	Initial Entry

**1.f Start Date:**

Date	Location	User	Value	Reason
Sep-11-2020 12:10:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2015	Initial Entry

**1.f Ongoing:**

Date	Location	User	Value	Reason
Sep-11-2020 12:10:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**1.g**

Date	Location	User	Value	Reason
Sep-11-2020 12:12:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Number: 7 <b>Medical History Term:</b> OSTEOARTH RITIS <b>Start Date:</b> UNK/UNK/200 5 <b>Ongoing:</b> YES	Initial Entry

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1077

Subject No: 10771226

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1077) Regional Clinical Research, Inc

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

**I.g Line/MH Number:**

Date	Location	User	Value	Reason
Sep-11-2020 12:12:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 7	Initial Entry

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

Date	Location	User	Value	Reason
Sep-11-2020 12:12:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OSTEOARTHRITIS	Initial Entry

**I.g Start Date:**

Date	Location	User	Value	Reason
Sep-11-2020 12:12:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2005	Initial Entry

**I.g Ongoing:**

Date	Location	User	Value	Reason
Sep-11-2020 12:12:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**I.h**

Date	Location	User	Value	Reason
Sep-11-2020 12:13:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 8 <b>Medical History Term:</b> VITAMIN D DEFICIENCY <b>Start Date:</b> UNK/UNK/2017 <b>Ongoing:</b> YES	Initial Entry

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1077

Subject No: 10771226

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1077) Regional Clinical Research, Inc

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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

Date	Location	User	Value	Reason
Sep-11-2020 12:13:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 8	Initial Entry

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

Date	Location	User	Value	Reason
Sep-11-2020 12:13:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> VITAMIN D DEFICIENCY	Initial Entry

**1.h Start Date:**

Date	Location	User	Value	Reason
Sep-11-2020 12:13:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2017	Initial Entry

**1.h Ongoing:**

Date	Location	User	Value	Reason
Sep-11-2020 12:13:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**1.i**

Date	Location	User	Value	Reason
Sep-11-2020 12:13:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 9 <b>Medical History Term:</b> ACNE <b>Start Date:</b> UNK/UNK/1 965 <b>Ongoing:</b> YES	Initial Entry

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1077

Subject No: 10771226

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1077) Regional Clinical Research, Inc

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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

Date	Location	User	Value	Reason
Sep-11-2020 12:13:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 9	Initial Entry

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

Date	Location	User	Value	Reason
Sep-11-2020 12:13:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ACNE	Initial Entry

***1.i Start Date:***

Date	Location	User	Value	Reason
Sep-11-2020 12:13:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1965	Initial Entry

***1.i Ongoing:***

Date	Location	User	Value	Reason
Sep-11-2020 12:13:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:51

Site No: 1077

Subject No: 10771226

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1077) Regional Clinical Research, Inc

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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**1. Date:**

Date	Location	User	Value	Reason
Sep-11-2020 12:14:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/11/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Sep-11-2020 12:14:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 76.5	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Sep-11-2020 12:14:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> kg	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Sep-11-2020 12:14:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 179.0	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Sep-11-2020 12:14:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> cm	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
Sep-11-2020 12:14:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 23.9	Initial Entry

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:51

Site No: 1077

Subject No: 10771226

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1077) Regional Clinical Research, Inc

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

7.a

Date	Location	User	Value	Reason
Sep-11-2020 12:14:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier:</b> 1 : <b>Temperature:</b> 36.8 <b>Temperature Unit</b> C : <b>Temperature Location:</b> ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-11-2020 12:14:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Sep-11-2020 12:14:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 36.8	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-11-2020 12:14:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Sep-11-2020 12:14:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1077

**Subject No:** 10771226

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

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

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

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Sep-11-2020 12:14:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/11/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Sep-11-2020 12:14:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 255544	Initial Entry

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (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: 1077

Site Name: (1077) Regional Clinical Research, Inc

Subject No: 10771226

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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**1. Data Origin**

Date	Location	User	Value	Reason
Sep-11-2020 11:25:28 (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-11-2020 11:25:28 (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
Sep-11-2020 11:25:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-11-2020 11:25:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-11-2020 11:25:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Sep/11/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-11-2020 11:25:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BP8HTL	Initial Entry

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (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: 1077

Site Name: (1077) Regional Clinical Research, Inc

Subject No: 10771226

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

5.a Sample ID

Date	Location	User	Value	Reason
Sep-11-2020 11:25:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP8HTL	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-11-2020 11:25:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BP8HTM	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-11-2020 11:25:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP8HTM	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-11-2020 11:25:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BP8HVJ	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-11-2020 11:25:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP8HVJ	Initial Entry

5.d

Date	Location	User	Value	Reason
Sep-11-2020 11:26:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BMNNK1	Initial Entry

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (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:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

**5.d Sample ID**

Date	Location	User	Value	Reason
Sep-11-2020 11:26:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BMNNK1	Initial Entry

**5.e**

Date	Location	User	Value	Reason
Sep-11-2020 11:26:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BMNNK2	Initial Entry

**5.e Sample ID**

Date	Location	User	Value	Reason
Sep-11-2020 11:26:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BMNNK2	Initial Entry

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (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:** 1077**Site Name:** (1077) Regional Clinical Research, Inc**Subject No:** 10771226**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:05[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Sep-11-2020 11:26:26 (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-11-2020 11:26:26 (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-11-2020 11:26:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-11-2020 11:26:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-11-2020 11:26:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Sep/11/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-11-2020 11:26:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BP8HV1	Initial Entry

**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:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

**5.a Sample ID**

Date	Location	User	Value	Reason
Sep-11-2020 11:26:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP8HV1	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1077

Subject No: 10771226

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1077) Regional Clinical Research, Inc

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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

Date	Location	User	Value	Reason
Sep-11-2020 12:15:06 (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-11-2020 12:15:06 (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-11-2020 12:15:06 (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
Sep-11-2020 12:15:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/11/2020 08:58	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Sep-11-2020 12:15:06 (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-11-2020 12:15:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1077

Subject No: 10771226

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1077) Regional Clinical Research, Inc

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

7. Route:

Date	Location	User	Value	Reason
Sep-11-2020 12:15:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-11-2020 12:15:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OB SERVATION 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-11-2020 12:15:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1077

**Subject No:** 10771226

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

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

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

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

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*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Sep-11-2020 12:15:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO - REACTOGENICITY E-DI ARY NOT COLLECTED FOR T HIS SUBJECT	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1077

**Subject No:** 10771226

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

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

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

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

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*I. Date of Visit*

Date	Location	User	Value	Reason
Oct-02-2020 09:16:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/2/2020	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 15-Sep-2020 21:54

Site No: 1077

Subject No: 10771226

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1077) Regional Clinical Research, Inc

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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1. Date:

Date	Location	User	Value	Reason
Oct-02-2020 09:16:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/2/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-02-2020 09:16:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier:</b> 1 : <b>Temperature:</b> 36.8 <b>Temperature Unit C</b> : <b>Temperature Location:</b> ORAL CAV ITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Oct-02-2020 09:16:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Oct-02-2020 09:16:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 36.8	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Oct-02-2020 09:16:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> C	Initial Entry

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1077

**Subject No:** 10771226

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

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

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

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

**2.a Temperature Location:**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Oct-02-2020 09:16:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry



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: 1077

Site Name: (1077) Regional Clinical Research, Inc

Subject No: 10771226

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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**1. Data Origin**

Date	Location	User	Value	Reason
Oct-02-2020 13:31:57 (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-02-2020 13:31:57 (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
Oct-02-2020 13:32:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-02-2020 13:31:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-02-2020 13:31:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Oct/2/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-02-2020 13:32:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BP1HL6	Initial Entry

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (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:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

**5.a Sample ID**

Date	Location	User	Value	Reason
Oct-02-2020 13:32:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP1HL6	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1077

Subject No: 10771226

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1077) Regional Clinical Research, Inc

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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

Date	Location	User	Value	Reason
Oct-02-2020 09:17:04 (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
Oct-02-2020 09:17:04 (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
Oct-02-2020 09:17:04 (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
Oct-02-2020 09:17:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/2/2020 08:02	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Oct-02-2020 09:17:04 (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
Oct-02-2020 09:17:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1077

Subject No: 10771226

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1077) Regional Clinical Research, Inc

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

7. Route:

Date	Location	User	Value	Reason
Oct-02-2020 09:17:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Oct-02-2020 09:17:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OB SERVATION 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
Oct-02-2020 09:17:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1077

**Subject No:** 10771226

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

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

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

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

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*I. Date of Visit*

Date	Location	User	Value	Reason
Oct-30-2020 11:57:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/30/2020	Initial Entry

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: 1077

Site Name: (1077) Regional Clinical Research, Inc

Subject No: 10771226

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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**1. Data Origin**

Date	Location	User	Value	Reason
Oct-30-2020 11:57:48 (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-30-2020 11:57:48 (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-30-2020 11:57:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-30-2020 11:57:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-30-2020 11:57:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Oct/30/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-30-2020 11:57:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BPZ6X2	Initial Entry

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (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: 1077

Site Name: (1077) Regional Clinical Research, Inc

Subject No: 10771226

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

5.a Sample ID

Date	Location	User	Value	Reason
Oct-30-2020 11:57:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BPZ6X2	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-30-2020 11:58:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BPZ6X3	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-30-2020 11:58:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BPZ6X3	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-30-2020 11:58:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BPZ6X4	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-30-2020 11:58:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BPZ6X4	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-30-2020 11:58:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BSJLLT	Initial Entry

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (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:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

**5.d Sample ID**

Date	Location	User	Value	Reason
Oct-30-2020 11:58:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BSJLLT	Initial Entry

**5.e**

Date	Location	User	Value	Reason
Oct-30-2020 11:58:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BSJLLV	Initial Entry

**5.e Sample ID**

Date	Location	User	Value	Reason
Oct-30-2020 11:58:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BSJLLV	Initial Entry

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/29/2020

Form: DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1077

Site Name: (1077) Regional Clinical Research, Inc

Subject No: 10771226

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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**I. Date of Visit**

Date	Location	User	Value	Reason
Dec-24-2020 01:13:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Deleted	Sample not collected Nasal Swab Self and Nasal Swab
Dec-23-2020 13:24:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Dec-22-2020 01:33:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Dec-22-2020 00:30:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-21-2020 16:45:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	INFORMATION ADDED
Dec-21-2020 16:37:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	INFORMATION UPDATED.
Dec-21-2020 06:23:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	DM: Kindly review and complete 'Microbiology Specimen form' at this visit. Thank you.
Dec-21-2020 03:48:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Date of Visit is completed but Date of Collection in Nasal Swab is missing. Please review and update as appropriate.

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Nov/29/2020

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

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

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

Dec-18-2020 17:33:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Dec-18-2020 17:32:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Dec-18-2020 17:32:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Dec-18-2020 17:32:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/29/2020	Initial Entry

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

Date	Location	User	Value	Reason
Dec-18-2020 17:32:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> COVID_A	Initial Entry

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit  
on Nov/29/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF  
Audit Trail History**Form Version:** 10-Dec-2020 02:29**Form Status:** Data Complete**Site No:** 1077**Site Name:** (1077) Regional Clinical Research, Inc**Subject No:** 10771226**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:05[Back to Form](#)**1. Date of Assessment:**

Date	Location	User	Value	Reason
Dec-18-2020 17:33:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/29/2020	Initial Entry

**2. Date of First Symptom Started:**

Date	Location	User	Value	Reason
Dec-18-2020 17:33:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/29/2020	Initial Entry

**3. Symptoms Ongoing?**

Date	Location	User	Value	Reason
Dec-18-2020 17:33:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO Date of Last Symptom Resolved: Nov/30/2020	Initial Entry

**4.a**

Date	Location	User	Value	Reason
Dec-18-2020 17:33:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> FEVER <b>Symptom Present:</b> YES	Initial Entry

**4.a Symptoms:**

Date	Location	User	Value	Reason
Dec-18-2020 17:33:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry

**4.a Was symptom present?**

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/29/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1077

Site Name: (1077) Regional Clinical Research, Inc

Subject No: 10771226

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

Dec-18-2020 17:33:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry
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4.b

Date	Location	User	Value	Reason
Dec-18-2020 17:33:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED COUGH <b>Symptom P NO</b> <b>resent:</b>	Initial Entry

4.b Symptoms:

Date	Location	User	Value	Reason
Dec-18-2020 17:33:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Dec-18-2020 17:33:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.c

Date	Location	User	Value	Reason
Dec-18-2020 17:33:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED SHORTNESS OF BREATH <b>Symptom Present:</b> NO	Initial Entry

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/29/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1077

Site Name: (1077) Regional Clinical Research, Inc

Subject No: 10771226

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

4.c Symptoms:

Date	Location	User	Value	Reason
Dec-18-2020 17:33:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Dec-18-2020 17:33:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Dec-18-2020 17:33:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> CHILLS <b>Symptom Present:</b> NO	Initial Entry

4.d Symptoms:

Date	Location	User	Value	Reason
Dec-18-2020 17:33:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Dec-18-2020 17:33:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Dec-18-2020 17:33:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom s:</b> NEW OR INCREASED MUSCLE PAIN	Initial Entry

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/29/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

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Form Status: Data Complete

Site No: 1077

Site Name: (1077) Regional Clinical Research, Inc

Subject No: 10771226

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

			Symptom NO Present:	
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4.e Symptoms:

Date	Location	User	Value	Reason
Dec-18-2020 17:33:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Dec-18-2020 17:33:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Dec-18-2020 17:33:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptoms NEW LOSS OF TASTE OR SMELL Symptom NO Present:	Initial Entry

4.f Symptoms:

Date	Location	User	Value	Reason
Dec-18-2020 17:33:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Dec-18-2020 17:33:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.g

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090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/29/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

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Form Status: Data Complete

Site No: 1077

Site Name: (1077) Regional Clinical Research, Inc

Subject No: 10771226

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

Date	Location	User	Value	Reason
Dec-18-2020 17:33:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom</b> NEW OR INCREASED SORE THROAT <b>Symptom Present:</b> NO	Initial Entry

4.g Symptoms:

Date	Location	User	Value	Reason
Dec-18-2020 17:33:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED SORE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Dec-18-2020 17:33:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.h

Date	Location	User	Value	Reason
Dec-18-2020 17:33:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> DIARRHEA <b>Symptom Present:</b> NO	Initial Entry

4.h Symptoms:

Date	Location	User	Value	Reason
Dec-18-2020 17:33:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Dec-18-2020 17:33:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit  
on Nov/29/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF  
Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1077

Site Name: (1077) Regional Clinical Research, Inc

Subject No: 10771226

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

4.i

Date	Location	User	Value	Reason
Dec-18-2020 17:33:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> VOMITING <b>Symptom Present:</b> NO	Initial Entry

4.i Symptoms:

Date	Location	User	Value	Reason
Dec-18-2020 17:33:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Dec-18-2020 17:33:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Audit Trail  
on Nov/29/2020

**Form Version:** 06-Jul-2020 21:54

**Form Status:**

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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Date	Location	User	Value	Reason
Dec-21-2020 16:44:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Nov/29/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1077

Site Name: (1077) Regional Clinical Research, Inc

Subject No: 10771226

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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**1. Actual Date of Collection:**

Date	Location	User	Value	Reason
Dec-21-2020 16:44:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/29/2020	Initial Entry

**2. Specimen Type:**

Date	Location	User	Value	Reason
Dec-21-2020 16:44:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SWABBED MATERIAL	Initial Entry

**3. Specimen Collection Location:**

Date	Location	User	Value	Reason
Dec-21-2020 16:44:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NASOPHARYNX	Initial Entry

**4. Assay Code and Description:**

Date	Location	User	Value	Reason
Dec-21-2020 16:44:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SEVERE ACUTE RESP SYNDRO ME CORONAVIRUS 2	Initial Entry

**5. Device Type:**

Date	Location	User	Value	Reason
Dec-21-2020 16:44:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SARS-COV-2 DIAGNOSTIC TES T	Initial Entry

**6. Trade Name:**

Date	Location	User	Value	Reason
Dec-21-2020 16:44:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OTHER	Initial Entry

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History  
on Nov/29/2020

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

**7. Test Result:**

Date	Location	User	Value	Reason
Dec-21-2020 16:44:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

**9. Trade Name Other, Specify:**

Date	Location	User	Value	Reason
Dec-21-2020 16:44:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NALT UNKNOWN	Initial Entry

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1077

Site Name: (1077) Regional Clinical Research, Inc

Subject No: 10771226

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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**1. Data Origin**

Date	Location	User	Value	Reason
Dec-18-2020 17:41:49 (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
Dec-18-2020 17:41:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB_SELF	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Dec-18-2020 17:41:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4. If no sample was collected or sample was not collected according to protocol, please provide reason:**

Date	Location	User	Value	Reason
Dec-18-2020 17:41:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT REQUIRED. SYMPTOMS RESOLVED LESS THAN FOUR DAYS.	Initial Entry

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/29/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1077**Subject No:** 10771226**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1077) Regional Clinical Research, Inc**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:05[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Dec-23-2020 13:24:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry
Dec-23-2020 13:23:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Dec-22-2020 16:28:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry
Dec-21-2020 16:37:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Dec-23-2020 13:24:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry
Dec-23-2020 13:23:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Dec-22-2020 16:28:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry
Dec-21-2020 16:37:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Dec-23-2020 21:32:56	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Clo	Auto closed by Validation Check:

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/29/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1077**Subject No:** 10771226**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1077) Regional Clinical Research, Inc**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:05

(UTC-05:00) Eastern Time (US & Canada)			sed	VC_BEETRK001_07
Dec-23-2020 13:24:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Ans wered	Initial Entry
Dec-23-2020 13:24:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry</b> : NO	Initial Entry
Dec-23-2020 13:23:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry</b> :	Initial Entry
Dec-23-2020 01:49:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4) [REDACTED]	Query 2: Ope ned	DMW6593916;Sample Collected is not expected to be marked Not Done. Please complete. If the sample was not obtained, Sample Collected = No. Sample Comments box should be entered with reason sample not collected. Please consider update.
Dec-22-2020 21:32:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4) [REDACTED]	Query 1: Clo sed	Auto closed by Validation Check: VC_BEETRK001_05

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/29/2020

**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:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

Dec-22-2020 16:29:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Dec-22-2020 16:28:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : Not Done	Initial Entry
Dec-21-2020 22:45:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW6555774;Sample Collected is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Dec-21-2020 16:37:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : Not Applicable	Initial Entry

**4. If no sample was collected or sample was not collected according to protocol, please provide reason:**

Date	Location	User	Value	Reason
Dec-23-2020 13:24:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> TELHEALTH VISIT PERFORMED.	Initial Entry
Dec-23-2020 13:23:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Dec-22-2020 16:28:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry
Dec-21-2020 16:37:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Nov/29/2020

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete

Site No: 1077

Site Name: (1077) Regional Clinical Research, Inc

Subject No: 10771226

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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**1.a**

Date	Location	User	Value	Reason
Dec-18-2020 17:34:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> SPECIALIST <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

**1.a Physician or Healthcare Professional:**

Date	Location	User	Value	Reason
Dec-18-2020 17:34:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SPECIALIST	Initial Entry

**1.a Occurrence of Visits or Contacts:**

Date	Location	User	Value	Reason
Dec-18-2020 17:34:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**1.b**

Date	Location	User	Value	Reason
Dec-18-2020 17:34:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> EMERGENCY ROOM <b>Occurrence of Visits or Contacts:</b> YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Nov/29/2020

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete

Site No: 1077

Site Name: (1077) Regional Clinical Research, Inc

Subject No: 10771226

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

**1.b Physician or Healthcare Professional:**

Date	Location	User	Value	Reason
Dec-18-2020 17:34:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EMERGENCY ROOM	Initial Entry

**1.b Occurrence of Visits or Contacts:**

Date	Location	User	Value	Reason
Dec-18-2020 17:34:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Number of Visits or Contacts:</i>  1	Initial Entry

**1.c**

Date	Location	User	Value	Reason
Dec-18-2020 17:34:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> PRIMARY CARE PHYSICIAN  <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

**1.c Physician or Healthcare Professional:**

Date	Location	User	Value	Reason
Dec-18-2020 17:34:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PRIMARY CARE PHYSICIAN	Initial Entry

**1.c Occurrence of Visits or Contacts:**

Date	Location	User	Value	Reason
Dec-18-2020 17:34:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**1.d**

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Nov/29/2020

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete

Site No: 1077

Site Name: (1077) Regional Clinical Research, Inc

Subject No: 10771226

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

Date	Location	User	Value	Reason
Dec-18-2020 17:34:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> URGENT CARE <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

*1.d Physician or Healthcare Professional:*

Date	Location	User	Value	Reason
Dec-18-2020 17:34:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> URGENT CARE	Initial Entry

*1.d Occurrence of Visits or Contacts:*

Date	Location	User	Value	Reason
Dec-18-2020 17:34:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

*1.e*

Date	Location	User	Value	Reason
Dec-18-2020 17:34:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> TELEPHONE CONSULTATION <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History  
on Nov/29/2020**Form Version:** 10-Dec-2020 02:26**Form Status:** Data Complete**Site No:** 1077**Site Name:** (1077) Regional Clinical Research, Inc**Subject No:** 10771226**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:05***1.e Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Dec-18-2020 17:34:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> TELEPHONE CONSULTATION	Initial Entry

***1.e Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Dec-18-2020 17:34:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***1.f***

Date	Location	User	Value	Reason
Dec-18-2020 17:34:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> OTHER <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

***1.f Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Dec-18-2020 17:34:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OTHER	Initial Entry

***1.f Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Dec-18-2020 17:34:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Dec-18-2020 17:34:40 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History  
on Nov/29/2020

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

**Form Status:** Data Complete

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

Time (US & Canada)	(b) (4), (b) (6)
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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: RESPIRATORY TREATMENT - eCRF Audit Trail History on Nov/29/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1077

Site Name: (1077) Regional Clinical Research, Inc

Subject No: 10771226

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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1. What is the treatment Identifier?

Date	Location	User	Value	Reason
Dec-18-2020 17:35:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

2. Concomitant Non-drug Treatment Pre-specified:

Date	Location	User	Value	Reason
Dec-18-2020 17:35:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

3. Treatment:

Date	Location	User	Value	Reason
Dec-18-2020 17:35:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

4. Treatment:

Date	Location	User	Value	Reason
Dec-18-2020 17:35:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Dec-18-2020 17:35:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Dec-18-2020 17:35:02 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - eCRF Audit Trail History  
on Nov/29/2020

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

**Form Status:** Data Complete, Frozen

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

Time (US & Canada)	(b) (4), (b) (6)
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - eCRF Audit Trail History  
on Nov/29/2020

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

**Form Status:** Data Complete

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Dec-18-2020 17:35:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> POTENTIAL COVID-19 ILLNESS	Initial Entry

**2. Was a diagnosis obtained for Potential COVID-19 Illness?**

Date	Location	User	Value	Reason
Dec-18-2020 17:35:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**3. Toxicity Grade:**

Date	Location	User	Value	Reason
Dec-18-2020 17:35:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: ILLNESS DETAILS - SEVERE - eCRF Audit Trail History on Nov/29/2020

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1077

Site Name: (1077) Regional Clinical Research, Inc

Subject No: 10771226

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Dec-18-2020 17:35:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Subcategory of Clinical Event:**

Date	Location	User	Value	Reason
Dec-18-2020 17:35:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Was a diagnosis obtained?**

Date	Location	User	Value	Reason
Dec-18-2020 17:35:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Toxicity Grade:**

Date	Location	User	Value	Reason
Dec-18-2020 17:35:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/29/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1077

Site Name: (1077) Regional Clinical Research, Inc

Subject No: 10771226

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Dec-18-2020 17:36:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Laboratory Name and Address**

Date	Location	User	Value	Reason
Dec-18-2020 17:36:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Dec-18-2020 17:36:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Specimen Type:**

Date	Location	User	Value	Reason
Dec-18-2020 17:36:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Dec-18-2020 17:36:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable	Initial Entry

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/29/2020

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Generated Time (GMT): 29-Mar-2021 10:05

			<b>Not Done::</b>	Not Applicable
			<b>Lab Normal Range:</b>	Not Applicable

5.a Sponsor ID:

Date	Location	User	Value	Reason
Dec-18-2020 17:36:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

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Date	Location	User	Value	Reason
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Date	Location	User	Value	Reason
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5.a Not Done:

Date	Location	User	Value	Reason
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5.a LNMT

Date	Location	User	Value	Reason
Dec-18-2020 17:36:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.b

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)

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Date	Location	User	Value	Reason
Dec-18-2020 17:36:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable	Initial Entry

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5.b Sponsor ID:

Date	Location	User	Value	Reason
Dec-18-2020 17:36:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
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5.b Result:

Date	Location	User	Value	Reason
Dec-18-2020 17:36:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Dec-18-2020 17:36:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

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Date	Location	User	Value	Reason
Dec-18-2020 17:36:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.c

Date	Location	User	Value	Reason
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5.c Result:

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5.c Not Done:

Date	Location	User	Value	Reason
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5.d

Date	Location	User	Value	Reason
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			<b>Not Done::</b>	Not Applicable	
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5.d Result:

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5.d Not Done:

Date	Location	User	Value	Reason
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Date	Location	User	Value	Reason
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5.e

Date	Location	User	Value	Reason
Dec-18-2020 17:36:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable	Initial Entry

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			<b>Test::</b>	Not Applicable	
			<b>Result::</b>	Not Applicable	
			<b>Not Done::</b>	Not Applicable	
			<b>Lab Normal Range:</b>	Not Applicable	

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Date	Location	User	Value	Reason
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5.e Not Done:

Date	Location	User	Value	Reason
Dec-18-2020 17:36:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Dec-18-2020 17:36:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.f

Date	Location	User	Value	Reason
Dec-18-2020 17:36:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable	Initial Entry

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**Generated Time (GMT):** 29-Mar-2021 10:05

			<b>Test::</b>	Not Applicable	
			<b>Result::</b>	Not Applicable	
			<b>Not Done::</b>	Not Applicable	
			<b>Lab Normal Range:</b>	Not Applicable	

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Date	Location	User	Value	Reason
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5.g

Date	Location	User	Value	Reason
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Date	Location	User	Value	Reason
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Date	Location	User	Value	Reason
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Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/29/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

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Subject Initials: ---

Generated By: (b) (4)

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**1. Lab Panel:**

Date	Location	User	Value	Reason
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**2. Laboratory Name and Address**

Date	Location	User	Value	Reason
Dec-18-2020 17:36:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Dec-18-2020 17:36:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Specimen Type:**

Date	Location	User	Value	Reason
Dec-18-2020 17:36:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Dec-18-2020 17:36:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable	Initial Entry

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			<b>Not Done::</b> Not Applicable	
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Dec-18-2020 17:36:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/29/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1077

Site Name: (1077) Regional Clinical Research, Inc

Subject No: 10771226

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

**5.b Sponsor ID:**

Date	Location	User	Value	Reason
Dec-18-2020 17:36:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.b Test:**

Date	Location	User	Value	Reason
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**5.b Result:**

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**5.b LNMT**

Date	Location	User	Value	Reason
Dec-18-2020 17:36:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.c**

Date	Location	User	Value	Reason
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090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/29/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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Header Text: c4591001

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

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**Generated Time (GMT):** 29-Mar-2021 10:05

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

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**Site No:** 1077

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**Subject No:** 10771226

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**Generated Time (GMT):** 29-Mar-2021 10:05

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Date	Location	User	Value	Reason
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**Subject No:** 10771226

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**Generated Time (GMT):** 29-Mar-2021 10:05

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Header Text: c4591001

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5.f Test:

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Date	Location	User	Value	Reason
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5.g

Date	Location	User	Value	Reason
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**Generated Time (GMT):** 29-Mar-2021 10:05

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5.h LNMT

Date	Location	User	Value	Reason
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Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/29/2020

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1. Date:

Date	Location	User	Value	Reason
Dec-18-2020 17:37:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

2.a

Date	Location	User	Value	Reason
Dec-18-2020 17:37:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier:</b> Not Applicable : le <b>Oxygen Saturation:</b> Not Applicable le	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Dec-18-2020 17:37:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

2.a SPO2 Pulse Oximetry %

Date	Location	User	Value	Reason
Dec-18-2020 17:37:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - eCRF Audit Trail History on Nov/29/2020

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

**Form Status:** Data Complete, Frozen

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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**1. Date Time of Assessment:**

Date	Location	User	Value	Reason
Dec-18-2020 17:36:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Arterial Blood Gases PaO2 (mmHg):**

Date	Location	User	Value	Reason
Dec-18-2020 17:36:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. FiO2 (Fraction of Inhaled Oxygen):**

Date	Location	User	Value	Reason
Dec-18-2020 17:36:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (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:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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

Date	Location	User	Value	Reason
Oct-30-2020 11:58:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/30/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Oct-30-2020 11:58:45 (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-30-2020 11:58:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1077

**Subject No:** 10771226

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

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

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Date	Location	User	Value	Reason
Dec-10-2020 10:09:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1077

Subject No: 10771226

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1077) Regional Clinical Research, Inc

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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**1. Category:**

Date	Location	User	Value	Reason
Dec-10-2020 10:09:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Dec-10-2020 10:09:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Dec-20-2020 19:05:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 4: Closed	Response satisfies query
Dec-20-2020 19:05:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 5: Closed	Response satisfies query
Dec-20-2020 19:05:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 3: Closed	Response satisfies query
Dec-18-2020 17:43:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Answered	INFORMATION ADDED
Dec-18-2020 17:39:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	INFORMATION ADDED
Dec-18-2020 17:37:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	FORM SUBMITTED AS REQUESTED.
Dec-18-2020 15:41:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 5: Opened	Clin: Please the data should still be captured on the

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1077

Subject No: 10771226

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1077) Regional Clinical Research, Inc

Subject Initials: ---

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				appropriate CRF pages (as for any late data, we will still capture it and not ignore it) but a swab will not be required if symptoms have resolved >4d
Dec-18-2020 15:41:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 4: Opened	Clin: Despite telehealth visit was not done, please complete the potential COVID-19 Illness Visit CRF forms with all information available. Should be captured on the SOD CRF form and a NASAL SWAB will not be collected
Dec-18-2020 15:37:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 3: Opened	Clin: It was stated in the SAE report #2020498020 that the subject experienced FEVER a COVID-19 listed symptom that should have please triggered a potential COVID Illness Visit irrespective of perceived etiology or clinical significance
Dec-15-2020 21:53:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-15-2020 14:47:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	MEDICAL RECORDS HAVE REQUESTED BUT ARE STILL PENDING RECEIPT. FOLLOW UP WILL BE

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1077

Subject No: 10771226

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1077) Regional Clinical Research, Inc

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

				SUBMITTED UPON RECEIPT.
Dec-15-2020 13:43:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Query closed; will follow for SAE update with the requested fever information
Dec-15-2020 13:41:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	CLINICAL Thank you. No SAE update has been received after original on 09Dec20; please check and submit updated SAE term as a SAE safety update
Dec-11-2020 12:35:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Updated SAE form faxed. Still awaiting medical records.
Dec-11-2020 12:35:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Updated SAE form faxed. Still awaiting medical records.
Dec-11-2020 09:42:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINICAL - Please submit a SAE safety update with information on the maximum fever experienced
Dec-11-2020 09:41:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINICAL Event term is 'bilat Kidney Stones'; however, SAE term is 'Kidney Stone in his Left Kidney & a smaller stone in his Right Kidney'. Note; stone size is not required in term. Please harmonize reporting, & update where applicable.
Dec-10-2020 15:05:36 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BILATERAL KIDNEY STONE	Changed Information

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete

Site No: 1077

Site Name: (1077) Regional Clinical Research, Inc

Subject No: 10771226

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

Time (US & Canada)		(b) (4), (b) (6)	S	
Dec-10-2020 10:09:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> KIDNEY STONES	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Dec-10-2020 10:09:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/29/2020 UNK:UNK	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Jan-05-2021 05:15:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Closed	Response satisfies query
Jan-04-2021 16:53:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	THIS EVENT REMAINS ONGOING.
Jan-04-2021 05:56:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Opened	CLINQUERY: Please review if this event remains ongoing. Else, update for end date and outcome.
Dec-10-2020 10:09:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Dec-15-2020 11:22:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-14-2020 16:35:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct

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Header Text: c4591001

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Form Status: Data Complete

Site No: 1077

Site Name: (1077) Regional Clinical Research, Inc

Subject No: 10771226

Subject Initials: ---

Generated By: (b) (4)

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Dec-14-2020 12:25:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	GPD CLINQUERY: Please confirm that toxicity grade is considered grade 2, given reported as a serious adverse event (SAE).
Dec-10-2020 10:09:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2	Initial Entry

**7. Is the adverse event serious?**

**If Yes, NOTIFY PFIZER IMMEDIATELY.**

*Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).*

Date	Location	User	Value	Reason
Dec-22-2020 16:41:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Dec-18-2020 17:42:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	INFORMATION ADDED
Dec-18-2020 12:23:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	CLINICAL - If subject had a COVID test during the Hospitalization (is this the negative test mentioned when queried about a Covid illness visit); please submit COVID test date, result and test manufacturer if known, in a SAE update.
Dec-15-2020 13:40:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Query closed; will follow for SAE update with the requested COVID

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**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1077**Subject No:** 10771226**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1077) Regional Clinical Research, Inc**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:05

				test info
Dec-11-2020 12:35:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Updated SAE form faxed. Still awaiting medical records.
Dec-11-2020 09:44:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clinical COVID test status (yes/no) during Hosp was not reported in the SAE. Please submit a follow-up SAE form [#2020487847] to document if COVID testing was performed (YES/NO or info not available) and if yes, the date and results.
Dec-11-2020 08:02:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-10-2020 15:05:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE BILATERAL KIDNEY STONES: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Dec-10-2020 10:09:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE KIDNEY STONES: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Dec-10-2020 10:09:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Is this serious event associat ed with congenital anomaly or birth defect?  NO	Initial Entry

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Site No: 1077

Subject No: 10771226

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1077) Regional Clinical Research, Inc

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

			<p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>NO</p>	
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**8. Is this adverse event the result of a study Medication Error?**

*If Yes, record the type of medication error on the Medication Error Log.*

Date	Location	User	Value	Reason
Dec-10-2020 10:09:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Dec-10-2020 10:09:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1077

Subject No: 10771226

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1077) Regional Clinical Research, Inc

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

			NEW MEDICAL EVENT	
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-10-2020 10:09:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Dec-10-2020 10:09:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Dec-10-2020 10:09:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Dec-22-2020 07:39:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-18-2020 18:35:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	UPDATED FORM SUBMITTED AS REQUESTED
Dec-18-2020 07:38:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Op ened	SAE RECON 1: Please confirm if a follow up AEM form was sent to update outcome to NOT RECOVERED/NOT RESOLVED in Safety database.

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1077

**Subject No:** 10771226

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

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

Dec-17-2020 18:14:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Confirmed to be not recovered/not resolved.
Dec-17-2020 05:49:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER2020487847,outcome was reported as RECOVERING/RESOLVING to Safety DB however, recorded as NOT RECOVERED/NOT RESOLVED on AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form.

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1077

Subject No: 10771226

Generated By: (b) (4)

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Form Status: Data Complete

Site Name: (1077) Regional Clinical Research, Inc

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Dec-10-2020 10:09:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RECOVERED/NOT RESO LVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Dec-10-2020 10:09:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Dec-11-2020 08:02:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2020487847	Initial Entry

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**Header Text:** c4591001

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

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

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

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

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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*1. Date of Visit*

Date	Location	User	Value	Reason
Feb-16-2021 11:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/13/2021	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1077

**Subject No:** 10771226

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

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

**Form Status:** Data Complete, Frozen

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

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

Date	Location	User	Value	Reason
Feb-22-2021 20:15:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Participant is willing to return fo r Vaccination 3 Participant is:  eligible and NOT confirmed t o have received only placebo at Vaccination 1/2	Transcription Error
Feb-16-2021 11:19:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Participant is NOT willing to ret urn for Vaccination 3 OR otherw ise not eligible	Initial Entry

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Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1077

Subject No: 10771226

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1077) Regional Clinical Research, Inc

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Feb-18-2021 16:27:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/13/2021	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Feb-23-2021 02:51:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Query closed as site has updated the data on REVAX per query.
Feb-22-2021 20:15:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Further Vaccination Confirmation CRF updated
Feb-22-2021 03:29:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW7348802;Primary Reason for Unblinding is "ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION", but "Participant is willing to return for Vaccination 3" is not selected in the Further Vaccination Confirmation CRF. Please review and update as appropriate.
Feb-18-2021 16:27:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ASSESS EL	Initial Entry

090177e196ae30d3\Final\Final On: 01-Apr-2021 04:18 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1077

**Subject No:** 10771226

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

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

**Form Status:** Data Complete, Verified

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:05

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Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1077

Subject No: 10771226

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1077) Regional Clinical Research, Inc

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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**I. Subject Status**

Date	Location	User	Value	Reason
Oct-30-2020 11:58:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Sep-11-2020 12:14:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Sep-11-2020 11:21:43 (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
Dec-18-2020 12:15:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Dec-17-2020 18:11:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Fever was related to kidney stones and not potential COVID. Subject was tested and proven to be negative for COVID-19 at that time.
Dec-15-2020 22:02:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	CLINICAL As per protocol section 8.13, any COVID illness symptom including temperature must be reported in a COVID illness visit, irrespective of perceived etiology
Dec-15-2020 21:51:40 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

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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: 1077

Site Name: (1077) Regional Clinical Research, Inc

Subject No: 10771226

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

Time (US & Canada)		(b) (4), (b) (6)		
Dec-10-2020 15:06:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Fever was a symptom of SAE, NOT a Covid Illness.
Dec-10-2020 15:06:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Added Bilateral. It was one event.
Dec-10-2020 10:12:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINICAL - SAE report (#2020487847) includes symptom of FEVER; however, no temperature value is reported in the SAE lab section; please update. Consider if FEVER is a symptom for a COVID Illness Visit.
Dec-10-2020 10:10:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINICAL SAE of Lt kidney stone and Rt kidney stone submitted; however no event is reported on AE CRF. Please report each side separately and individually evaluate for Serious criteria.
Oct-30-2020 11:58:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/30/2020	Initial Entry
Sep-11-2020 12:14:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/11/2020	Initial Entry
Sep-11-2020 11:21:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/11/2020	Initial Entry

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**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

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

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

**Site No:** 1077

**Site Name:** (1077) Regional Clinical Research, Inc

**Subject No:** 10771226

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:05

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*I. Casebook Signature*

Date	Location	User	Value	Reason
Nov-03-2020 10:33:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Click Here to Enable	Initial Entry