

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1054

**Subject No:** 10541186

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

**Form:** COHORT\_SELECTION

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Cohort Selection**

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

1.	Select appropriate response - Protocol version	08 SEP 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:** 1054

**Subject No:** 10541186

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

**Form:** MAIN INFORMED CONSENT

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/23/2020
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**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** DEMOGRAPHY

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

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

**Site No:** 1054

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject No:** 10541186

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[10541186]
2.	Birth Date:	(b) (6)/1949
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	BLACK OR AFRICAN AMERICAN
6.	Racial Designation:	

**Header Text:** c4591001

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

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

**Site No:** 1054

**Subject No:** 10541186

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

**Form:** DATE OF VISIT

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Sep/23/2020
2.	Erroneous Visit	

**Header Text:** c4591001

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

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

**Site No:** 1054

**Subject No:** 10541186

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

**Form:** INCLUSION/EXCLUSION CRITERIA

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[Form Comments](#)

**Inclusion Criteria Not Met**

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

**Exclusion Criteria Met**

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

**Header Text:** c4591001

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

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

**Site No:** 1054

**Subject No:** 10541186

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

**Form:** DISPOSITION - SCREENING

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Disposition - Screening**

1.	Date of Completion/Discontinuation /Death	Sep/23/2020
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: 1054

Subject No: 10541186

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[appendicitis]
	Start Date:	Feb/14/2017
	Ongoing:	NO End Date: Feb/14/2017
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[appendectomy]
	Start Date:	Feb/14/2017
	Ongoing:	NO End Date: Feb/14/2017
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[lactose intolerance]
	Start Date:	UNK/UNK/2016
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[cyst, R axilla]
	Start Date:	UNK/UNK/2019
	Ongoing:	YES

090177e196ae30d5\Final\Final On: 01-Apr-2021 04:18 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1054

**Subject No:** 10541186

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

**Form:** HIV STATUS

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**HIV Status**

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



**Header Text:** c4591001

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

**Form Version:** 15-Sep-2020 21:56

**Site No:** 1054

**Subject No:** 10541186

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

**Form:** VITAL SIGNS - BASELINE

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Sep/23/2020
2.	Weight:	[84.35]
3.	Unit:	kg
4.	Height:	[172.72]
5.	Unit:	cm
6.	Body Mass Index:	[28.3]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[97.7]
	Unit:	F
	Temperature Location:	ORAL CAVITY

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**Header Text:** c4591001

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

**Form Version:** 15-Sep-2020 21:51

**Site No:** 1054

**Subject No:** 10541186

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[Form Comments](#)

[eCRF Audit Trail History](#)

**Lab Urinalysis**

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

**Lab Result**

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

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**Header Text:** c4591001

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

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

**Site No:** 1054

**Subject No:** 10541186

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

**Form:** RANDOMIZATION

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Sep/23/2020
2.	Randomization Number:	[264594]
3.	Randomization Group:	[ ]

**Header Text:** c4591001

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

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

**Site No:** 1054

**Subject No:** 10541186

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Sep/23/2020
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	[BPYWXM]
5.b	Sample ID	[BPYWXN]

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**Header Text:** c4591001

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

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

**Site No:** 1054

**Subject No:** 10541186

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

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

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/23/2020
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	[BPYWXP]
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090177e196ae30d5\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:** 1054

**Subject No:** 10541186

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

**Form:** VACCINATION

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/23/2020 12:32
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

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**Header Text:** c4591001

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

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

**Site No:** 1054

**Subject No:** 10541186

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

**Form:** REACTOGENICITY DIARY

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Reactogenicity Diary**

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

**Visit:** V2\_VAX2\_L

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

**Site No:** 1054

**Subject No:** 10541186

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

**Form:** DATE OF VISIT

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Date of Visit**

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



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1054

**Subject No:** 10541186

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

**Form:** VITAL SIGNS - TEMP

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Oct/14/2020
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**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[98.3]
	Unit:	F
	Temperature Location:	ORAL CAVITY

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 15-Sep-2020 21:51

**Site No:** 1054

**Subject No:** 10541186

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[Form Comments](#)  
[eCRF Audit Trail History](#)

**Lab Urinalysis**

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

**Lab Result**

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

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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1054

**Subject No:** 10541186

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

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

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[Pt refused the 2nd vaccine and NP swab due to AEs and discomfort respectively, but is willing to come for future study visits.]

**Aliquot**

Please enter barcode for each aliquot.

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

**Visit:** V2\_VAX2\_L

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

**Site No:** 1054

**Subject No:** 10541186

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

**Form:** VACCINATION

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[Form Comments](#)

[eCRF Audit Trail History](#)

**Vaccination**

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

090177e196ae30d5\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:** 1054

**Subject No:** 10541186

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

**Form:** DATE OF VISIT

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** c4591001

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

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

**Site No:** 1054

**Subject No:** 10541186

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Nov/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	[BM98DC]
5.b	Sample ID	[BM98DD]
5.c	Sample ID	[BM98DF]

090177e196ae30d5\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:** 1054

**Subject No:** 10541186

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

**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:** 1054

**Subject No:** 10541186

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Visit:** V5\_MONTH12\_L

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

**Site No:** 1054

**Subject No:** 10541186

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V5\_MONTH12\_L

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

**Site No:** 1054

**Subject No:** 10541186

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Visit:** V6\_MONTH24\_L

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

**Site No:** 1054

**Subject No:** 10541186

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

**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:** 1054

**Subject No:** 10541186

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit    **Form:** DATE OF VISIT - ILLNESS ONSET

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

**Form Status:** Not Started

**Site No:** 1054

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject No:** 10541186

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit    **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

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

**Form Status:** Not Started

**Site No:** 1054

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject No:** 10541186

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

**Signs and Symptoms**

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

**Symptoms**

4.	Symptoms:	
	Was symptom present?	

**Symptoms - Other**

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

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit    **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

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

**Form Status:** Not Started

**Site No:** 1054

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject No:** 10541186

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit    **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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

**Form Status:** Not Started

**Site No:** 1054

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject No:** 10541186

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit    **Form:** HEALTH CARE UTILIZATION

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

**Form Status:** Not Started

**Site No:** 1054

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject No:** 10541186

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

**Health Care Utilization**

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

**Health Care Utilization Other**

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

**Health Care Utilization**

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

090177e196ae30d5\Final\Final On: 01-Apr-2021 04:18 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit    **Form:** ILLNESS DETAILS

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

**Form Status:** Not Started

**Site No:** 1054

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject No:** 10541186

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

**Illness Details**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA - New Unscheduled Visit      **Form:** DATE OF VISIT - ILLNESS CONVALESCENT

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

**Form Status:** Not Started

**Site No:** 1054

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject No:** 10541186

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA - New Unscheduled Visit      **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Form Status:** Not Started

**Site No:** 1054

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject No:** 10541186

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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**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:** 1054

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject No:** 10541186

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Repeat Swab**

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

090177e196ae30d5\Final\Final On: 01-Apr-2021 04:18 (GMT)

**Header Text:** c4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1054

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject No:** 10541186

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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**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:** 1054

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject No:** 10541186

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

**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:** 1054

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject No:** 10541186

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

**Unplanned Assessments**

1.	Assessments	
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Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1054

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject No: 10541186

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	lightheadedness	Sep/23/2020 12:40	NO End Date Time: Sep/23/2020 14:40	<a href="#">Repeating Pages</a>
2.	ADVERSE EVENT	2	nausea	Sep/23/2020 12:40	NO End Date Time: Sep/23/2020 14:40	<a href="#">Repeating Pages</a>

090177e196ae30d5\Final\Final On: 01-Apr-2021 04:18 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1054

**Subject No:** 10541186

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

**Form:** ADVERSE EVENT REPORT

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

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[eCRF Audit Trail History](#)  
[Form Audit Trail](#)

**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[lightheadedness]
4.	Start Date Time:	Sep/23/2020 12:40
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/23/2020 14:40
6.	Toxicity Grade:	1
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	DRUG WITHDRAWN
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED

090177e196ae30d5\Final\Final On: 01-Apr-2021 04:18 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1054

**Subject No:** 10541186

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

**Form:** ADVERSE EVENT REPORT

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

090177e196ae30d5\Final\Final On: 01-Apr-2021 04:18 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1054

**Subject No:** 10541186

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

**Form:** ADVERSE EVENT REPORT

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

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[eCRF Audit Trail History](#)  
[Form Audit Trail](#)

**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[nausea]
4.	Start Date Time:	Sep/23/2020 12:40
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/23/2020 14:40
6.	Toxicity Grade:	1
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	DRUG WITHDRAWN
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED

090177e196ae30d5\Final\Final On: 01-Apr-2021 04:18 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1054

**Subject No:** 10541186

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

**Form:** ADVERSE EVENT REPORT

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

090177e196ae30d5\Final\Final On: 01-Apr-2021 04:18 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

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

**Site No:** 1054

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject No:** 10541186

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1054

**Subject No:** 10541186

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

**Form:** MEDICATION ERROR

**Form Status:** Not Started

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

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**Medication Error**

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

090177e196ae30d5\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:** 1054

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject No:** 10541186

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

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



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1054

**Subject No:** 10541186

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

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

**Form Status:** Not Started

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

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**Concomitant Medications**

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

090177e196ae30d5\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:** 1054

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject No:** 10541186

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1054

**Subject No:** 10541186

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

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Status:** Not Started

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

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**Concomitant Medications**

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

090177e196ae30d5\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:** 1054

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject No:** 10541186

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1054

**Subject No:** 10541186

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

**Form:** RADIATION TREATMENT

**Form Status:** Not Started

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

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**Radiation Treatment**

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

**Header Text:** c4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

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

**Site No:** 1054

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject No:** 10541186

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1054

**Subject No:** 10541186

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

**Form:** TRANSFUSIONS

**Form Status:** Not Started

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

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

090177e196ae30d5\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:** 1054

**Subject No:** 10541186

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

**Form:** DISPOSITION - TREATMENT

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation /Death :	Sep/23/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	ADVERSE EVENT
4.	Specify Status:	[ ]



**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

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

**Site No:** 1054

**Subject No:** 10541186

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

**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:** 1054

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject No:** 10541186

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

**Vital Signs**

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

**Vital Signs Details**

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

**Form Status:** Not Started

**Site No:** 1054

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject No:** 10541186

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

**Lab Urinalysis**

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

**Lab Result**

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

090177e196ae30d5\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:** 1054

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject No:** 10541186

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

**Vaccination**

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

090177e196ae30d5\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:** 1054

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject No:** 10541186

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** CONTACT OUTCOME - MONTH 6

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

**Form Status:** Not Started

**Site No:** 1054

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject No:** 10541186

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

**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:** 1054

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject No:** 10541186

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

**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:** 1054

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject No:** 10541186

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

**Informed Consent - Asymptomatic Surveillance**

1.	Consent Was:	
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**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT - Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Form Status:** Not Started

**Site No:** 1054

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject No:** 10541186

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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**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:** 1054

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject No:** 10541186

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Visit:** Follow-Up - Unscheduled

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

**Site No:** 1054

**Subject No:** 10541186

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

**Form:** DISPOSITION - FOLLOW-UP

**Form Status:** Incomplete, Verified

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Disposition - Follow-Up**

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

**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:** 1054

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject No:** 10541186

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Jan/20/2021
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, Verified

**Site No:** 1054

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject No:** 10541186

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[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 per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2
----	---	---

090177e196ae30d5\Final\Final On: 01-Apr-2021 04:18 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1054

**Subject No:** 10541186

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

**Form:** TREATMENT UNBLINDED

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[Form Comments](#)

[eCRF Audit Trail History](#)

**Treatment Unblinded**

1.	Date Treatment Unblinded :	Jan/20/2021	<a href="#">Comments</a>
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION	<a href="#">Comments</a>

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1054

**Subject No:** 10541186

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

**Form:** WITHDRAWAL OF CONSENT

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[Form Comments](#)

[eCRF Audit Trail History](#)

**Withdrawal Of Consent**

			<a href="#">Comments</a>
1.	Withdrawal of Consent Date :	Not Applicable //	

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1054

**Subject No:** 10541186

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

**Form:** DEATH DETAILS CODED

**Form Status:** Not Started

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

**Death Details**

1.	Date of Collection / Notification of Death:	//
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**Cause of Death**

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



**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1054

**Subject No:** 10541186

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1054

**Subject No:** 10541186

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

**Form:** INFORMED CONSENT - FURTHER VACCINATION

**Form Status:** Not Started

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

**Informed Consent - Further Vaccination**

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

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1054

**Subject No:** 10541186

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

**Form:** INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

**Form Status:** Not Started

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

**Inclusion Criteria Not Met**

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

2.	Description of Exclusion Criterion Met	
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**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1054

**Subject No:** 10541186

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

**Form:** DISPOSITION - SCREENING FOR FURTHER VACCINATION

**Form Status:** Not Started

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

**Disposition - Screening for Further Vaccination**

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

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1054

**Subject No:** 10541186

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

**Form:** SUBJECT STATUS

**Form Status:** Data Complete, Verified

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Subject Status**

1.	Subject Status	DISCONTINUED
2.	Subject Status Date	Sep/23/2020

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

**Site No:** 1054

**Subject No:** 10541186

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

**Form:** CASEBOOK SIGNATURE FORM

**Form Status:** Data Complete, Verified

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Casebook Signature Form**

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

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

**Form Status:** Data Complete, Verified

**Site No:** 1054

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject No:** 10541186

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Audit Trail](#)

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

- CRF\_Sign
- CRF\_Sign\_1

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

**Header Text:** c4591001

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

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

**Site No:** 1054

**Subject No:** 10541186

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

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

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

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Item	Date	User	Comment
Form	Sep-24-2020 08:04:56 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Not Applicable



**Header Text:** c4591001

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

**Form Version:** 15-Sep-2020 21:51

**Site No:** 1054

**Subject No:** 10541186

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

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

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

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Item	Date	User	Comment
Form	Sep-24-2020 08:12:58 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Not Applicable

**Header Text:** c4591001

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

**Form Version:** 15-Sep-2020 21:51

**Site No:** 1054

**Subject No:** 10541186

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

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

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

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Item	Date	User	Comment
1	Sep-24-2020 08:12:58 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Not Applicable

**Header Text:** c4591001

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

**Form Version:** 15-Sep-2020 21:51

**Site No:** 1054

**Subject No:** 10541186

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

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**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

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Item	Date	User	Comment
2	Sep-24-2020 08:12:58 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Not Applicable

090177e196ae30d5\Final\Final On: 01-Apr-2021 04:18 (GMT)

**Header Text:** c4591001

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

**Form Version:** 15-Sep-2020 21:51

**Site No:** 1054

**Subject No:** 10541186

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

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

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

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Item	Date	User	Comment
3	Sep-24-2020 08:12:58 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Not Applicable

**Header Text:** c4591001

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

**Form Version:** 15-Sep-2020 21:51

**Site No:** 1054

**Subject No:** 10541186

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

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

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**Generated Time (GMT):** 29-Mar-2021 04:44

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Item	Date	User	Comment
4	Sep-24-2020 08:12:58 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Not Applicable

090177e196ae30d5\Final\Final On: 01-Apr-2021 04:18 (GMT)

**Header Text:** c4591001

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**Form Version:** 15-Sep-2020 21:51

**Site No:** 1054

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

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

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Item	Date	User	Comment
5	Sep-24-2020 08:12:58 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Not Applicable

**Header Text:** c4591001

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

**Form Version:** 15-Sep-2020 21:51

**Site No:** 1054

**Subject No:** 10541186

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

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

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

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Item	Date	User	Comment
6.a	Sep-24-2020 08:12:58 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Not Applicable

090177e196ae30d5\Final\Final On: 01-Apr-2021 04:18 (GMT)

**Header Text:** c4591001

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

**Form Version:** 15-Sep-2020 21:51

**Site No:** 1054

**Subject No:** 10541186

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

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

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

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Item	Date	User	Comment
6.a	Sep-24-2020 08:12:58 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Not Applicable



**Header Text:** c4591001

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

**Form Version:** 15-Sep-2020 21:51

**Site No:** 1054

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

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

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Item	Date	User	Comment
6.a	Sep-24-2020 08:12:58 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Not Applicable

090177e196ae30d5\Final\Final On: 01-Apr-2021 04:18 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 15-Sep-2020 21:51

**Site No:** 1054

**Subject No:** 10541186

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

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

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

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Item	Date	User	Comment
Form	Oct-16-2020 15:56:31 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 15-Sep-2020 21:51

**Site No:** 1054

**Subject No:** 10541186

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

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

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

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Item	Date	User	Comment
1	Oct-16-2020 15:56:31 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Not Applicable

090177e196ae30d5\Final\Final On: 01-Apr-2021 04:18 (GMT)

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

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**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

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**Generated Time (GMT):** 29-Mar-2021 04:44

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Item	Date	User	Comment
2	Oct-16-2020 15:56:31 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 15-Sep-2020 21:51

**Site No:** 1054

**Subject No:** 10541186

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

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

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

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Item	Date	User	Comment
3	Oct-16-2020 15:56:31 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Not Applicable

090177e196ae30d5\Final\Final On: 01-Apr-2021 04:18 (GMT)

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

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

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Item	Date	User	Comment
4	Oct-16-2020 15:56:31 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 15-Sep-2020 21:51

**Site No:** 1054

**Subject No:** 10541186

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

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

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

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Item	Date	User	Comment
5	Oct-16-2020 15:56:31 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Not Applicable

090177e196ae30d5\Final\Final On: 01-Apr-2021 04:18 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 15-Sep-2020 21:51

**Site No:** 1054

**Subject No:** 10541186

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

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

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

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Item	Date	User	Comment
6.a	Oct-16-2020 15:56:31 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Not Applicable



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 15-Sep-2020 21:51

**Site No:** 1054

**Subject No:** 10541186

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

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

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

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Item	Date	User	Comment
6.a	Oct-16-2020 15:56:31 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Not Applicable

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**Form Version:** 15-Sep-2020 21:51

**Site No:** 1054

**Subject No:** 10541186

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

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

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

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Item	Date	User	Comment
6.a	Oct-16-2020 15:56:31 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1054

**Subject No:** 10541186

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

**Form:** VACCINATION - Comments

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

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Item	Date	User	Comment
Form	Oct-16-2020 15:59:08 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Pt withdrew consent at time of V2 NP swab.
Form	Oct-16-2020 15:57:51 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Pt withdrew consent at time of V2 NP swab. <hr/> Not Done

090177e196ae30d5\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:** 1054

**Subject No:** 10541186

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

**Form:** VACCINATION - Comments

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

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Item	Date	User	Comment
1	Oct-16-2020 15:57:51 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Pt withdrew consent at time of V2 NP swab. <hr/> Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1054

**Subject No:** 10541186

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

**Form:** VACCINATION - Comments

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

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Item	Date	User	Comment
2	Oct-16-2020 15:57:51 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Pt withdrew consent at time of V2 NP swab. <hr/> Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1054

**Subject No:** 10541186

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

**Form:** VACCINATION - Comments

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

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Item	Date	User	Comment
3	Oct-16-2020 15:57:51 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Pt withdrew consent at time of V2 NP swab. Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1054

**Subject No:** 10541186

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

**Form:** VACCINATION - Comments

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**Generated Time (GMT):** 29-Mar-2021 04:44

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Item	Date	User	Comment
4	Oct-16-2020 15:57:51 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Pt withdrew consent at time of V2 NP swab. <hr/> Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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**Subject No:** 10541186

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Item	Date	User	Comment
5	Oct-16-2020 15:57:51 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Pt withdrew consent at time of V2 NP swab. <hr/> Not Done



**Header Text:** c4591001

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Item	Date	User	Comment
6	Oct-16-2020 15:57:51 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Pt withdrew consent at time of V2 NP swab. <hr/> Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1054

**Subject No:** 10541186

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

**Form:** VACCINATION - Comments

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

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Item	Date	User	Comment
7	Oct-16-2020 15:57:51 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Pt withdrew consent at time of V2 NP swab. <hr/> Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1054

**Subject No:** 10541186

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

**Form:** VACCINATION - Comments

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

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Item	Date	User	Comment
8	Oct-16-2020 15:57:51 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Pt withdrew consent at time of V2 NP swab. <hr/> Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1054

**Subject No:** 10541186

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

**Form:** VACCINATION - Comments

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

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Item	Date	User	Comment
9	Oct-16-2020 15:57:51 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Pt withdrew consent at time of V2 NP swab. <hr/> Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1054

**Subject No:** 10541186

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

**Form:** VACCINATION - Comments

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

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Item	Date	User	Comment
10	Oct-16-2020 15:57:51 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Pt withdrew consent at time of V2 NP swab. <hr/> Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1054

**Subject No:** 10541186

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

**Form:** VACCINATION - Comments

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

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Item	Date	User	Comment
11	Oct-16-2020 15:57:51 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Pt withdrew consent at time of V2 NP swab. <hr/> Not Done

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1054

**Subject No:** 10541186

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

**Form:** TREATMENT UNBLINDED - Comments

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

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Item	Date	User	Comment
Form	Feb-22-2021 09:59:48 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	
Form	Oct-23-2020 08:32:32 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Not Applicable
Form	Oct-20-2020 13:41:33 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	
Form	Oct-20-2020 13:41:21 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Not Done

090177e196ae30d5\Final\Final On: 01-Apr-2021 04:18 (GMT)

**Header Text:** c4591001

**Visit:** Disposition

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

**Site No:** 1054

**Subject No:** 10541186

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

**Form:** TREATMENT UNBLINDED - Comments

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

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Item	Date	User	Comment
1	Feb-22-2021 09:59:48 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	
1	Oct-23-2020 08:32:32 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Not Applicable
1	Oct-20-2020 13:41:33 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	
1	Oct-20-2020 13:41:21 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Not Done



**Header Text:** c4591001

**Visit:** Disposition

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

**Site No:** 1054

**Subject No:** 10541186

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

**Form:** TREATMENT UNBLINDED - Comments

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

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Item	Date	User	Comment
2	Feb-22-2021 09:59:48 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	
2	Oct-23-2020 08:32:32 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Not Applicable
2	Oct-20-2020 13:41:33 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	
2	Oct-20-2020 13:41:21 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Not Done

090177e196ae30d5\Final\Final On: 01-Apr-2021 04:18 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1054

**Subject No:** 10541186

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

**Form:** WITHDRAWAL OF CONSENT - Comments

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

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Item	Date	User	Comment
Form	Oct-23-2020 08:32:17 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Not Applicable

**Header Text:** c4591001

**Visit:** Disposition

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

**Site No:** 1054

**Subject No:** 10541186

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

**Form:** WITHDRAWAL OF CONSENT - Comments

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

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Item	Date	User	Comment
1	Oct-23-2020 08:32:17 (UTC-08:00) Pacific Time (US & Canada)	Steven Choi (b) (4)	Not Applicable

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**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1054

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject No:** 10541186

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

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

- CRF\_Sign
- CRF\_Sign\_1

Name	Signature Meaning	Date	Type	Action
Steven Choi	N/A	Feb-22-2021 09:03:52 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated

**Affidavit:**  
N/A

Mark Leibowitz	Approved	Nov-16-2020 10:57:12 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, MarkLeibowitz, 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.

Steven Choi	N/A	Nov-11-2020 11:35:18 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**  
N/A

Mark Leibowitz	Approved	Nov-11-2020 10:15:40 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
----------------	----------	---	------	--------

**Affidavit:**

By my dated signature below, I, MarkLeibowitz, 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.

090177e196ae30d5\Final\Final On: 01-Apr-2021 04:18 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1054

**Subject No:** 10541186

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

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

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

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

Date	Location	User	Value	Reason
Sep-24-2020 08:03:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> 08 SEP 2020	Initial Entry

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

Date	Location	User	Value	Reason
Sep-24-2020 08:03:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1054

**Subject No:** 10541186

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

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

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

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***I. Consent Was:***

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Sep-24-2020 08:03:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b><u>Data Entry:</u></b> OBTAINED Date Written Consent Obtained  Sep/23/2020	Transcription Error
Sep-24-2020 08:03:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b><u>Data Entry:</u></b> OBTAINED Date Written Consent Obtained  Sep/24/2020	Initial Entry

Header Text: c4591001

Visit: COHORT\_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1054

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject No: 10541186

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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**1. Subject ID**

Date	Location	User	Value	Reason
Sep-24-2020 08:03:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 10541186	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Sep-24-2020 08:03:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6)/1949	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Sep-24-2020 08:04:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> FEMALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Sep-24-2020 08:04:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<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-24-2020 08:04:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> BLACK OR AFRICAN AMERICAN	Initial Entry

090177e196ae30d5\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:** 1054

**Subject No:** 10541186

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

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

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

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*I. Date of Visit*

Date	Location	User	Value	Reason
Sep-24-2020 08:04:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> Sep/23/2020	Initial Entry



**Header Text:** c4591001

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

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

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

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

**Site No:** 1054

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject No:** 10541186

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

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

Date	Location	User	Value	Reason
Sep-24-2020 08:05:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> Sep/23/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Sep-24-2020 08:05:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Sep-24-2020 08:05:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae30d5\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: 1054

Subject No: 10541186

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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*I.a*

Date	Location	User	Value	Reason
Sep-24-2020 08:06:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 1 <b>Medical History Term:</b> appendicitis <b>Start Date:</b> Feb/14/2017 <b>Ongoing:</b> NO End Date: Feb/14/2017	Initial Entry

*I.a Line/MH Number:*

Date	Location	User	Value	Reason
Sep-24-2020 08:06:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

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

Date	Location	User	Value	Reason
Sep-24-2020 08:06:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> appendicitis	Initial Entry

*I.a Start Date:*

Date	Location	User	Value	Reason
Sep-24-2020 08:06:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> Feb/14/2017	Initial Entry

*I.a Ongoing:*

Date	Location	User	Value	Reason
Sep-24-2020 08:06:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> NO End Date: Feb/14/2017	Initial Entry

090177e196ae30d5\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: 1054

Subject No: 10541186

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

I.b

Date	Location	User	Value	Reason
Sep-24-2020 08:06:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 2 <b>Medical History Term:</b> appendectomy <b>Start Date:</b> Feb/14/2017 <b>Ongoing:</b> NO End Date: Feb/14/2017 7	Initial Entry

I.b Line/MH Number:

Date	Location	User	Value	Reason
Sep-24-2020 08:06:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

I.b Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-24-2020 08:06:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> appendectomy	Initial Entry

I.b Start Date:

Date	Location	User	Value	Reason
Sep-24-2020 08:06:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> Feb/14/2017	Initial Entry

I.b Ongoing:

Date	Location	User	Value	Reason
Sep-24-2020 08:06:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> NO End Date: Feb/14/2017	Initial Entry

I.c

090177e196ae30d5\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: 1054

Subject No: 10541186

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Sep-24-2020 08:08:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 3 <b>Medical History Term:</b> lactose intolerance <b>Start Date:</b> UNK/UNK/2016 <b>Ongoing:</b> YES	Initial Entry

*I.c Line/MH Number:*

Date	Location	User	Value	Reason
Sep-24-2020 08:08:39 (UTC-08:00) Pacific 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-24-2020 08:08:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> lactose intolerance	Initial Entry

*I.c Start Date:*

Date	Location	User	Value	Reason
Sep-24-2020 08:08:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> UNK/UNK/2016	Initial Entry

*I.c Ongoing:*

Date	Location	User	Value	Reason
Sep-24-2020 08:08:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> YES	Initial Entry

*I.d*

Date	Location	User	Value	Reason
Sep-24-2020 08:09:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 4 <b>Medical History Term:</b> cyst, R axilla	Initial Entry

090177e196ae30d5\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: 1054

Subject No: 10541186

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

			<b>Start Date:</b>	UNK/UNK/2019	
			<b>Ongoing:</b>	YES	

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

Date	Location	User	Value	Reason
Sep-24-2020 08:09:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 4	Initial Entry

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

Date	Location	User	Value	Reason
Sep-24-2020 08:09:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> cyst, R axilla	Initial Entry

***1.d Start Date:***

Date	Location	User	Value	Reason
Sep-24-2020 08:09:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> UNK/UNK/2019	Initial Entry

***1.d Ongoing:***

Date	Location	User	Value	Reason
Sep-24-2020 08:09:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae30d5\Final\Final On: 01-Apr-2021 04:18 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1054

**Subject No:** 10541186

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

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

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

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

Date	Location	User	Value	Reason
Sep-24-2020 08:09:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> The subject is NOT known to be HIV POSITIVE	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 15-Sep-2020 21:56

Site No: 1054

Subject No: 10541186

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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**1. Date:**

Date	Location	User	Value	Reason
Sep-24-2020 08:11:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> Sep/23/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Sep-24-2020 08:11:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> 84.35	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Sep-24-2020 08:11:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> kg	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Sep-24-2020 08:11:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> 172.72	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Sep-24-2020 08:11:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> cm	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
Sep-24-2020 08:11:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 28.3	Initial Entry

**7.a**

090177e196ae30d5\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1054

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject No: 10541186

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Sep-24-2020 08:11:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 97.7 <b>Temperature Unit:</b> F <b>Temperature Location:</b> ORAL CAVITY	Initial Entry

**7.a Record Identifier:**

Date	Location	User	Value	Reason
Sep-24-2020 08:11:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> 1	Initial Entry

**7.a Temperature:**

Date	Location	User	Value	Reason
Sep-24-2020 08:11:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> 97.7	Initial Entry

**7.a Unit:**

Date	Location	User	Value	Reason
Sep-24-2020 08:11:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> F	Initial Entry

**7.a Temperature Location:**

Date	Location	User	Value	Reason
Sep-24-2020 08:11:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae30d5\Final\Final On: 01-Apr-2021 04:18 (GMT)



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 15-Sep-2020 21:51

Site No: 1054

Subject No: 10541186

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Sep-24-2020 08:12:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Not Applicable	Initial Entry
Sep-24-2020 08:12:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Sep-24-2020 08:11:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Sep-24-2020 08:12:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Not Applicable	Initial Entry
Sep-24-2020 08:12:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Sep-24-2020 08:11:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Sep-24-2020 08:12:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry
Sep-24-2020 08:12:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-24-2020 08:12:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b>	Transcription Error
Sep-24-2020 08:12:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Date of collection is reported, but result is missing. Please review

090177e196ae30d5\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1054

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject No: 10541186

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

				and update as appropriate.
Sep-24-2020 08:11:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> Sep/23/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-24-2020 08:12:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Not Applicable	Initial Entry
Sep-24-2020 08:12:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Sep-24-2020 08:11:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-24-2020 08:12:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Not Applicable	Initial Entry
Sep-24-2020 08:12:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Sep-24-2020 08:11:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-24-2020 08:12:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Choriogonadotropin Beta_PX113 <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable	Initial Entry
Sep-24-2020 08:12:16	ACV0PFEINFP6000	auto calc	<b>Data Entry:</b>	Transcription Error

090177e196ae30d5\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 15-Sep-2020 21:51

Site No: 1054

Subject No: 10541186

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

(UTC-08:00) Pacific Time (US & Canada)		(autocalc)	<b>Sponsor-Defined Identifier:</b> <b>Test::</b> Choriogonadotropin Beta_PX113 <b>Result::</b> <b>Not Done::</b>	
Sep-24-2020 08:11:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 113 <b>Test::</b> Choriogonadotropin Beta_PX113 <b>Result::</b> NEGATIVE <b>Not Done::</b>	Initial Entry

**6.a Sponsor ID:**

Date	Location	User	Value	Reason
Sep-24-2020 08:12:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Not Applicable	Initial Entry
Sep-24-2020 08:12:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Sep-24-2020 08:11:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

**6.a Test:**

Date	Location	User	Value	Reason
Sep-24-2020 08:11:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Sep-24-2020 08:12:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry
Sep-24-2020 08:12:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b>	Transcription Error

090177e196ae30d5\Final\Final On: 01-Apr-2021 04:18 (GMT)

**Header Text:** c4591001

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

**Form Version:** 15-Sep-2020 21:51

**Site No:** 1054

**Subject No:** 10541186

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

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

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

Sep-24-2020 08:11:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> NEGATIVE	Initial Entry
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**6.a Not Done:**

Date	Location	User	Value	Reason
Sep-24-2020 08:12:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1054

**Subject No:** 10541186

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

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

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Sep-24-2020 08:14:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> Sep/23/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Sep-24-2020 08:14:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> 264594	Initial Entry

090177e196ae30d5\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: 1054

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject No: 10541186

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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**1. Data Origin**

Date	Location	User	Value	Reason
Sep-24-2020 08:14:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-24-2020 08:14:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-24-2020 08:17:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-24-2020 08:14:41 (UTC-08:00) Pacific 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-24-2020 08:14:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> YES Date of Collection:  Sep/23/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-24-2020 08:17:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> <b>Sample ID:</b> BPYWXM	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Sep-24-2020 08:17:02	ACV0PFEINFP6000	Steven	<b>Data Entry:</b>	Initial Entry

090177e196ae30d5\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:** 1054

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject No:** 10541186

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

(UTC-08:00) Pacific Time (US & Canada)		Choi (b) (4)	BPYWXM	
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**5.b**

Date	Location	User	Value	Reason
Sep-24-2020 08:17:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> <b>Sample ID:</b> BPYWXN	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Sep-24-2020 08:17:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> BPYWXN	Initial Entry

090177e196ae30d5\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: 1054

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject No: 10541186

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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**1. Data Origin**

Date	Location	User	Value	Reason
Sep-24-2020 08:15:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-24-2020 08:15:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-24-2020 08:17:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-24-2020 08:15:07 (UTC-08:00) Pacific 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-24-2020 08:15:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> YES Date of Collection:  Sep/23/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-24-2020 08:17:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> <b>Sample ID:</b> BPYWXP	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Sep-24-2020 08:17:28	ACV0PFEINFP6000	Steven	<b>Data Entry:</b>	Initial Entry

090177e196ae30d5\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:** 1054

**Subject No:** 10541186

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

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

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

(UTC-08:00) Pacific Time  
(US & Canada)

Choi

(b) (4)

BPYWXP

090177e196ae30d5\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: 1054

Subject No: 10541186

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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

Date	Location	User	Value	Reason
Sep-24-2020 08:15:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Sep-24-2020 08:15:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Sep-24-2020 08:15:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Sep-24-2020 08:15:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> Sep/23/2020 12:32	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Sep-24-2020 08:15:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Sep-24-2020 08:15:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

090177e196ae30d5\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:** 1054

**Subject No:** 10541186

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

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

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Sep-24-2020 08:15:50 (UTC-08:00) Pacific 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-24-2020 08:15:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OBSE RVATION 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-24-2020 08:15:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae30d5\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:** 1054

**Subject No:** 10541186

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

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

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

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*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Sep-24-2020 08:15:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1054

**Subject No:** 10541186

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

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

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

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*I. Date of Visit*

Date	Location	User	Value	Reason
Oct-16-2020 16:00:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> Oct/14/2020	Transcription Error
Oct-16-2020 15:48:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> Oct/16/2020	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 10-Oct-2020 16:01

Site No: 1054

Subject No: 10541186

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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**1. Date:**

Date	Location	User	Value	Reason
Oct-16-2020 16:00:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> Oct/14/2020	Transcription Error
Oct-16-2020 15:56:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> Oct/16/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Oct-16-2020 15:56:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 98.3 <b>Temperature Unit:</b> F <b>Temperature Location::</b> ORAL CAVITY	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Oct-16-2020 15:56:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> 1	Initial Entry

**2.a Temperature:**

Date	Location	User	Value	Reason
Oct-16-2020 15:56:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> 98.3	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Oct-16-2020 15:56:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> F	Initial Entry

**2.a Temperature Location:**

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090177e196ae30d5\Final\Final On: 01-Apr-2021 04:18 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1054

**Subject No:** 10541186

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

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

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Oct-16-2020 15:56:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<u>Data Entry:</u> ORAL CAVITY	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 15-Sep-2020 21:51

Site No: 1054

Subject No: 10541186

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Oct-16-2020 15:56:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Oct-16-2020 15:56:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Oct-16-2020 15:56:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

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

Date	Location	User	Value	Reason
Oct-16-2020 15:56:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Oct-16-2020 15:56:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6.a**

Date	Location	User	Value	Reason
Oct-16-2020 15:56:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable	Initial Entry

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Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 15-Sep-2020 21:51

Site No: 1054

Subject No: 10541186

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

			<b>Result:</b>	Not Applicable
			<b>Not Done:</b>	Not Applicable

**6.a Sponsor ID:**

Date	Location	User	Value	Reason
Oct-16-2020 15:56:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6.a Test:**

Date	Location	User	Value	Reason
Oct-16-2020 15:56:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Oct-16-2020 15:56:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6.a Not Done:**

Date	Location	User	Value	Reason
Oct-16-2020 15:56:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

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Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1054

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject No: 10541186

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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**1. Data Origin**

Date	Location	User	Value	Reason
Oct-16-2020 15:57:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-16-2020 15:57:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-16-2020 15:57:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<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
Oct-19-2020 08:17:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> Pt refused the 2nd vaccine and NP swab due to AEs and discomfort respectively, but is willing to come for future study visits.	Transcription Error
Oct-16-2020 15:57:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-16-2020 15:57:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> Pt withdrew consent at time of V2 NP swab.	Transcription Error
Oct-16-2020 15:57:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Entered text has either a carriage return (line break) or extra spaces at the end of the text or between words. Please correct by removing all data in

090177e196ae30d5\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:** 1054

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

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**Subject Initials:** ---

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

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				the field and re-enter without adding extra spaces or using enter or tab keys.
Oct-16-2020 15:57:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> Pt withdrew consent at time of V2 NP swab.	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1054

Subject No: 10541186

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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

Date	Location	User	Value	Reason
Oct-16-2020 15:57:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> Not Done	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Oct-16-2020 15:57:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> Not Done	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Oct-16-2020 15:57:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> Not Done	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Oct-21-2020 19:58:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_EC001_2_06_AN
Oct-21-2020 10:52:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Query 1: Answered	Query is ambiguous
Oct-21-2020 02:39:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	DM:Randomization number is recorded and the final disposition date is present on the Disposition - Follow-up eCRF, but there is no dosing date present on the Treatment eCRF. Please review and update as appropriate.

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Subject No: 10541186

Generated By: (b) (4)

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Oct-19-2020 08:20:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Query 1: Ans wered	Changed data per query
Oct-17-2020 01:07:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Op ened	DMW5060540;Randomization number is recorded and the final disposition date is present on the Disposition - Follow-up eCRF, but there is no dosing date present on the Treatment eCRF. Please review and update as appropriate.
Oct-16-2020 15:57:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry</b> : Not D one	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-16-2020 15:57:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> Not Done	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Oct-16-2020 15:57:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> Not Done	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Oct-16-2020 15:57:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> Not Done	Initial Entry

8. Actual Dose:

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

**Visit:** V2\_VAX2\_L

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

**Site No:** 1054

**Subject No:** 10541186

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

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

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

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Oct-16-2020 15:57:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> Not Done	Initial Entry
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**9. Unit:**

Date	Location	User	Value	Reason
Oct-16-2020 15:57:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> Not Done	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Oct-16-2020 15:57:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> Not Done	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-16-2020 15:57:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> Not Done	Initial Entry

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**Header Text:** c4591001

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

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

**Site No:** 1054

**Subject No:** 10541186

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

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

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

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*I. Date of Visit*

Date	Location	User	Value	Reason
Nov-11-2020 11:35:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> Nov/11/2020	Initial Entry

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1054

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject No: 10541186

Subject Initials: ---

Generated By: (b) (4)

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**1. Data Origin**

Date	Location	User	Value	Reason
Nov-11-2020 11:35:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Nov-11-2020 11:35:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Nov-11-2020 14:09:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-11-2020 11:35:26 (UTC-08:00) Pacific 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.
Nov-11-2020 11:35:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> YES Date of Collection:  Nov/11/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Nov-11-2020 14:09:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> <b>Sample ID:</b> BM98DC	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Nov-11-2020 14:09:24	ACV0PFEINFP6000	Steven	<b>Data Entry:</b>	Initial Entry

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Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF  
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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1054

Site Name: (1054) Collaborative Neuroscience Network, LLC.

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Subject Initials: ---

Generated By: (b) (4)

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(UTC-08:00) Pacific Time (US & Canada)		Choi (b) (4)	BM98DC	
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5.b

Date	Location	User	Value	Reason
Nov-11-2020 14:09:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<u>Data Entry:</u> Sample ID: BM98DD	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Nov-11-2020 14:09:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<u>Data Entry:</u> BM98DD	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-11-2020 14:09:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<u>Data Entry:</u> Sample ID: BM98DF	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Nov-11-2020 14:09:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<u>Data Entry:</u> BM98DF	Initial Entry

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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**Site No:** 1054

**Subject No:** 10541186

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

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

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Date	Location	User	Value	Reason
Oct-16-2020 16:03:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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**Subject No:** 10541186

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

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

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Date	Location	User	Value	Reason
Oct-16-2020 16:03:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Form Created	

Header Text: c4591001

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Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

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**1. Category:**

Date	Location	User	Value	Reason
Oct-16-2020 16:03:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Oct-16-2020 16:03:13 (UTC-08:00) Pacific 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
Oct-16-2020 16:03:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> lightheadedness	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Oct-16-2020 16:03:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> Sep/23/2020 12:40	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Oct-16-2020 16:03:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> NO End Date Time: Sep/23/2020 14:40	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Oct-16-2020 16:03:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> 1	Initial Entry

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Header Text: c4591001

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Form Status: Data Complete, Locked, Frozen

Site No: 1054

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject No: 10541186

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Oct-16-2020 16:03:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Oct-16-2020 16:03:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-16-2020 16:03:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-16-2020 05:18:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	STAT, SPA confirmed it's OK to have more than 1 AE with DRUG WITHDRAWN
Nov-15-2020 08:42:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	Only 1 AE should have DRUG WITHDRAWN as Action Taken. Please have the PI decide which one would be the most appropriate.
Nov-11-2020 14:03:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Candidate	DM: Do not issue query. Sending to Triad team for CRA assistance.

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1054

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Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

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Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Nov-11-2020 08:44:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Query 3: Answered	As written. Both AEs have the same start and stop date/time. Designating one AE to be DRUG WITHDRAWN as the LATEST ACTION TAKEN WITH STUDY DRUG and the other as NOT APPLICABLE would be arbitrary at best.
Nov-10-2020 19:13:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	Only one primary Adverse Event should be chosen to have question 'LATEST ACTION TAKEN WITH STUDY DRUG' that would indicate DRUG WITHDRAWN. Multiple are selected at this time, please select ONLY Primary Adverse Event.
Nov-10-2020 19:12:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	issued in error
Nov-10-2020 18:27:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Only one primary Adverse Event should be chosen to have question 'Did the adverse event cause the subject to be discontinued from the study?' answered as YES if applicable. Please chose Primary Adverse Event.
Oct-20-2020 12:25:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Closed	Response satisfies query
Oct-20-2020 08:34:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Query 1: Answered	Changed data per query

090177e196ae30d5\Final\Final On: 01-Apr-2021 04:18 (GMT)

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1054**Subject No:** 10541186**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen**Site Name:** (1054) Collaborative Neuroscience Network, LLC.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:44

Oct-19-2020 12:49:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Reissued:Opened	CLINQUERY: Reason for EOT is entered as OTHER. If these adverse events led to the decision to withdraw from treatment, then EOT should match with reason ADVERSE EVENT
Oct-19-2020 08:20:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Query 1: Answered	Changed data per query
Oct-19-2020 04:50:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Opened	CLINQUERY: Lightheadedness and nausea are reported to lead to 'Drug Withdrawn'. If these entries are correct, and subject will not go on to receive Vaccination 2 due to these events, then please complete the EOT tab to indicate treatment discontinuation.
Oct-16-2020 16:03:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> DRUG WITHDRAWN	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Oct-16-2020 16:03:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Oct-16-2020 16:03:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**13. What was the outcome of this adverse event?:**

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

**Visit:** Logs - Unscheduled

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

**Site No:** 1054

**Subject No:** 10541186

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

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

Oct-16-2020 16:03:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry
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**14. Did the adverse event cause the subject to be discontinued from the study?**

Date	Location	User	Value	Reason
Oct-16-2020 16:03:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> NO	Initial Entry



Header Text: c4591001

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Subject No: 10541186

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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**1. Category:**

Date	Location	User	Value	Reason
Oct-16-2020 16:03:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Oct-16-2020 16:03:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Oct-16-2020 16:03:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> nausea	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Oct-16-2020 16:03:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> Sep/23/2020 12:40	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Oct-16-2020 16:03:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> NO End Date Time:  Sep/23/2020 14:40	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Oct-16-2020 16:03:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> 1	Initial Entry

090177e196ae30d5\Final\Final On: 01-Apr-2021 04:18 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1054

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Subject No: 10541186

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Oct-16-2020 16:03:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Oct-16-2020 16:03:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-16-2020 16:03:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-16-2020 05:19:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	STAT, SPA confirmed it's OK to have more than 1 AE with DRUG WITHDRAWN
Nov-15-2020 08:42:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	Only 1 AE should have DRUG WITHDRAWN as Action Taken. Please have the PI decide which one would be the most appropriate.
Nov-11-2020 14:03:47	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Candid	DM: Do not issue query. Sending to

090177e196ae30d5\Final\Final On: 01-Apr-2021 04:18 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1054

**Subject No:** 10541186

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

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

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(UTC-08:00) Pacific Time (US & Canada)			ate	Triad team for CRA assistance.
Nov-11-2020 08:44:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Query 3: Answered	As written. Both AEs have the same start and stop date/time. Designating one AE to be DRUG WITHDRAWN as the LATEST ACTION TAKEN WITH STUDY DRUG and the other as NOT APPLICABLE would be arbitrary at best.
Nov-10-2020 19:14:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	Only one primary Adverse Event should be chosen to have question 'LATEST ACTION TAKEN WITH STUDY DRUG' that would indicate DRUG WITHDRAWN. Multiple are selected at this time, please select ONLY Primary Adverse Event.
Nov-10-2020 19:13:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	issued in error
Nov-10-2020 18:28:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Only one primary Adverse Event should be chosen to have question 'Did the adverse event cause the subject to be discontinued from the study?' answered as YES if

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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, Locked, Frozen

Site No: 1054

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject No: 10541186

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Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

				applicable. Please chose Primary Adverse Event.
Oct-20-2020 12:39:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_AE001_32
Oct-20-2020 08:32:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Query 1: Answered	Changed data per query
Oct-19-2020 20:50:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW5068940;The Latest Action to Study Treatment is DRUG WITHDRAWN, but the Disposition-Treatment Form Status is not DEATH OR ADVERSE EVENT. Please review and update as appropriate.
Oct-16-2020 16:03:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> DRUG WIT HDRAWN	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-16-2020 16:03:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-16-2020 16:03:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> NO	Initial Entry

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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**Site No:** 1054

**Subject No:** 10541186

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

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

**13. What was the outcome of this adverse event?:**

Date	Location	User	Value	Reason
Oct-16-2020 16:03:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

**14. Did the adverse event cause the subject to be discontinued from the study?**

Date	Location	User	Value	Reason
Oct-16-2020 16:03:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**Header Text:** c4591001**Visit:** End of Treatment - Unscheduled**Form Version:** 15-Sep-2020 21:55**Site No:** 1054**Subject No:** 10541186**Generated By:** (b) (4)**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1054) Collaborative Neuroscience Network, LLC.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:44[Back to Form](#)**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Nov-11-2020 10:02:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-11-2020 08:36:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Nov-11-2020 08:36:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> Sep/23/2020	Changed Information
Nov-10-2020 18:29:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	The discontinuation date of 14OCT2020 should be relative to the AE causing the the withdrawal of the study vaccine, AE start 23SEP2020 and end 23SEP2020. Please adjust Discontinuation date.
Oct-19-2020 08:19:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> Oct/14/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Oct-19-2020 08:19:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Oct-21-2020 07:01:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Not required.
Oct-20-2020 08:32:01 (UTC-08:00) Pacific Time	ACV0PFEINFP6000	Steven Choi (b) (4)	Query 2: Answered	As written. Pt is still in study, but refused

**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:** 1054**Site Name:** (1054) Collaborative Neuroscience Network, LLC.**Subject No:** 10541186**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44

(US & Canada)				VAX2 and the NP swab. Moreover, saying that "the adverse event caused the pt to discontinue study treatment" would be more accurate.
Oct-20-2020 08:29:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-20-2020 08:29:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Status is reported as Adverse Event, but there is no Adverse Event with 'Did the adverse event cause the subject to be discontinued from the study' reported as YES. Please check and correct the data.
Oct-20-2020 08:29:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Response to "Status" is ADVERSE EVENT but "Specify Status" is Provided.
Oct-20-2020 08:29:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> ADVERSE EVENT	Changed Information
Oct-19-2020 08:19:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> OTHER	Initial Entry

**4. Specify Status:**

Date	Location	User	Value	Reason
Oct-20-2020 08:29:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b>	Transcription Error
Oct-19-2020 08:19:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> Pt refused the 2nd vaccine and NP swab, but is willing to come for future study visits.	Initial Entry

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:53

Form Status: Incomplete, Verified

Site No: 1054

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject No: 10541186

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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

Date	Location	User	Value	Reason
Oct-21-2020 08:14:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<u>Data Entry:</u>	Transcription Error
Oct-16-2020 16:00:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<u>Data Entry:</u> Oct/14/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Oct-21-2020 08:14:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	Transcription Error
Oct-16-2020 16:00:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> FOLLOW-UP	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Oct-21-2020 12:53:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 2: Closed	Response satisfies query
Oct-21-2020 08:14:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Query 2: Answered	Changed data per query
Oct-21-2020 03:22:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 2: Reissued:Opened	CLINQUERY: Thanks for the update - to 'remove' the date on this field: if you cannot remove the date, consider applying a 'not applicable' comment to that field for now
Oct-20-2020 13:42:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Closed	Close Auto Query

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**Header Text:** c4591001**Visit:** Follow-Up - Unscheduled**Form:** DISPOSITION - FOLLOW-UP - eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:53**Form Status:** Incomplete, Verified**Site No:** 1054**Site Name:** (1054) Collaborative Neuroscience Network, LLC.**Subject No:** 10541186**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44

Oct-20-2020 13:42:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Oct-20-2020 13:42:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b>	Transcription Error
Oct-20-2020 13:42:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	Response to "Status" is OTHER but "Specify Status" is missing.
Oct-20-2020 10:03:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 2: Opened	CLINQUERY: Per information provided, subject will continue on in study (just discontinued from treatment). if that is correct, please leave this FUP tab blank to indicate subject will continue with follow up
Oct-19-2020 08:18:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> OTHER	Transcription Error
Oct-16-2020 16:01:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-16-2020 16:00:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Response to "Status" is WITHDRAWAL BY SUBJECT but "Specify Status" is missing.
Oct-16-2020 16:00:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> WITHDRAWAL BY SUBJECT	Initial Entry

**4. Specify Status:**

Date	Location	User	Value	Reason
Oct-20-2020 13:42:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b>	Transcription Error
Oct-19-2020 08:18:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> Pt refused the 2nd vaccine and NP sw ab, but is willing to come for future st	Transcription Error

**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

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

**Site No:** 1054

**Subject No:** 10541186

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

**Form:** DISPOSITION - FOLLOW-UP - eCRF Audit Trail History

**Form Status:** Incomplete, Verified

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

			udy visits.	
Oct-16-2020 16:01:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> Pt withdrew consent for personal reas ons.	Initial Entry

**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:** 1054

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject No:** 10541186

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

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*I. Date of Visit*

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Feb-22-2021 09:03:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> Jan/20/2021	Initial Entry

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact - Unscheduled **Form:** FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail History

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

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

**Site No:** 1054

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject No:** 10541186

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

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**I. Select appropriate response - Is participant willing to return for Vaccination 3?**

Date	Location	User	Value	Reason
Feb-22-2021 10:00:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-22-2021 09:03:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Feb-22-2021 09:03:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> Participant is willing to return for Vaccination 3 Participant is:  eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2	Initial Entry

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**Header Text:** c4591001**Visit:** Disposition - Unscheduled**Form Version:** 22-Apr-2020 21:03**Site No:** 1054**Subject No:** 10541186**Generated By:** (b) (4)**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1054) Collaborative Neuroscience Network, LLC.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:44[Back to Form](#)**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Feb-22-2021 10:00:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> Jan/20/2021	Initial Entry
Feb-22-2021 09:59:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b>	Initial Entry
Oct-23-2020 17:34:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Erica Weaver (b) (4)	Query 1: Closed	Response satisfies query
Oct-23-2020 08:32:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Query 1: Answered	Changed data per query
Oct-23-2020 08:32:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry
Oct-21-2020 23:36:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Opened	DM: Kindly consider to update this form if require else mark as Not applicable by selecting form level comment. Thank you.
Oct-20-2020 13:41:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b>	Initial Entry
Oct-20-2020 13:41:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> Not Done	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Feb-22-2021 10:00:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION	Initial Entry
Feb-22-2021 09:59:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b>	Initial Entry

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1054

**Subject No:** 10541186

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

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

Oct-23-2020 08:32:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry
Oct-20-2020 13:41:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b>	Initial Entry
Oct-20-2020 13:41:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> Not Done	Initial Entry

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1054

Subject No: 10541186

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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**I. Withdrawal of Consent Date :**

Date	Location	User	Value	Reason
Oct-23-2020 17:34:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Erica Weaver (b) (4)	Query 2: Closed	Response satisfies query
Oct-23-2020 08:32:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	Query 2: Answered	Changed data per query
Oct-23-2020 08:32:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry
Oct-21-2020 23:47:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	DM: Kindly consider to update this form if require else mark as Not applicable by selecting form level comment. Thank you.
Oct-20-2020 14:16:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Closed	Response satisfies query
Oct-20-2020 13:41:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-20-2020 13:41:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b>	Transcription Error
Oct-20-2020 10:05:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Opened	CLINQUERY: WOC is reported as 14Oct20 yet information suggests subject will remain in study for follow up (discontinued from treatment). Please review since this WOC matches to withdrawal of consent to participate in the study overall
Oct-16-2020 15:59:45	ACV0PFEINFP6000	Steven Choi	<b>Data Entry:</b>	Initial Entry

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**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1054

**Subject No:** 10541186

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

**Form:** WITHDRAWAL OF CONSENT - eCRF Audit Trail History

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

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

(UTC-08:00) Pacific Time  
(US & Canada)

(b) (4)

Oct/14/2020



Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1054

Subject No: 10541186

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1054) Collaborative Neuroscience Network, LLC.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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**1. Subject Status**

Date	Location	User	Value	Reason
Oct-20-2020 13:42:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DISCONTINUED	Transcription Error
Oct-20-2020 08:29:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DISCONTINUED	Changed Information
Oct-19-2020 08:19:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DISCONTINUED	Initial Entry
Oct-19-2020 08:18:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DISCONTINUED	Transcription Error
Oct-16-2020 16:00:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DISCONTINUED	Initial Entry
Sep-24-2020 08:14:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Sep-24-2020 08:05:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

**2. Subject Status Date**

Date	Location	User	Value	Reason
Nov-11-2020 08:36:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/23/2020	Changed Information
Oct-21-2020 08:14:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/14/2020	Transcription Error
Oct-20-2020 13:42:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/14/2020	Transcription Error
Oct-20-2020 08:29:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/14/2020	Changed Information

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**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1054

**Subject No:** 10541186

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

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

**Form Status:** Data Complete, Verified

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

Oct-19-2020 08:19:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/14/2020	Initial Entry
Oct-19-2020 08:18:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/14/2020	Transcription Error
Oct-16-2020 16:00:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/14/2020	Initial Entry
Sep-24-2020 08:14:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/23/2020	Initial Entry
Sep-24-2020 08:05:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/23/2020	Initial Entry

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**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

**Site No:** 1054

**Subject No:** 10541186

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

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

**Form Status:** Data Complete, Verified

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

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*I. Casebook Signature*

Date	Location	User	Value	Reason
Oct-05-2020 12:02:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Steven Choi (b) (4)	<b>Data Entry:</b> Click Here to Enable	Initial Entry