

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1091

**Subject No:** 10911213

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

**Form:** COHORT\_SELECTION

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

**Site Name:** (1091) Aventiv Research Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Cohort Selection**

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

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

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1091

**Subject No:** 10911213

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

**Form:** MAIN INFORMED CONSENT

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

**Site Name:** (1091) Aventiv Research Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Informed Consent**

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

**Visit:** COHORT\_SELECTION

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

**Site No:** 1091

**Subject No:** 10911213

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

**Form:** DEMOGRAPHY

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

**Site Name:** (1091) Aventiv Research Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[10911213]
2.	Birth Date:	(b) (6) 1962
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e196ae3d12\Final\Final On: 01-Apr-2021 04:25 (GMT)

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 22-Apr-2020 21:02**Site No:** 1091**Subject No:** 10911213**Generated By:** (b) (4)**Form:** DATE OF VISIT**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1091) Aventiv Research Inc.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:31[eCRF Audit Trail History](#)**Date of Visit**

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



**Header Text:** c4591001

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

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

**Site No:** 1091

**Subject No:** 10911213

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

**Form:** INCLUSION/EXCLUSION CRITERIA

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

**Site Name:** (1091) Aventiv Research Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

**Form Comments**

**Inclusion Criteria Not Met**

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

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

**Header Text:** c4591001

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

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

**Site No:** 1091

**Subject No:** 10911213

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

**Form:** DISPOSITION - SCREENING

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

**Site Name:** (1091) Aventiv Research Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Disposition - Screening**

1.	Date of Completion/Discontinuation /Death	Sep/1/2020
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:** 1091**Subject No:** 10911213**Generated By:** (b) (4)**Form:** GENERAL MEDICAL HISTORY**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1091) Aventiv Research Inc.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:31**eCRF Audit Trail History****Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[anxiety]
	Start Date:	UNK/UNK/2013
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[hypertriglyceridemia]
	Start Date:	UNK/UNK/2019
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[brain injury]
	Start Date:	UNK/UNK/2006
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[chronic kidney disease]
	Start Date:	UNK/UNK/2013
	Ongoing:	YES
1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[depression]
	Start Date:	UNK/UNK/2013
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[esophageal reflux]
	Start Date:	UNK/UNK/2013
	Ongoing:	YES

**Header Text:** c4591001

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

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

**Site No:** 1091

**Subject No:** 10911213

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

**Form:** GENERAL MEDICAL HISTORY

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

**Site Name:** (1091) Aventiv Research Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[migraines]
	Start Date:	UNK/UNK/2006
	Ongoing:	YES
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[generalized osteoarthritis]
	Start Date:	UNK/UNK/2013
	Ongoing:	YES
1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[sleep apnea]
	Start Date:	UNK/UNK/2013
	Ongoing:	YES
1.j	Line/MH Number:	[10]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[vertigo]
	Start Date:	UNK/UNK/2006
	Ongoing:	YES
1.k	Line/MH Number:	[11]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[post traumatic stress disorder]
	Start Date:	UNK/UNK/2006
	Ongoing:	YES
1.l	Line/MH Number:	[12]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[right shoulder replacement]
	Start Date:	Nov/UNK/2019
	Ongoing:	NO End Date: Nov/UNK/2019

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**Header Text:** c4591001

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

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

**Site No:** 1091

**Subject No:** 10911213

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

**Form:** GENERAL MEDICAL HISTORY

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

**Site Name:** (1091) Aventiv Research Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

1 m	Line/MH Number:	[13]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[chronic right shoulder pain]
	Start Date:	UNK/UNK/2013
	Ongoing:	NO End Date: Nov/UNK/2019

090177e196ae3d12\Final\Final On: 01-Apr-2021 04:25 (GMT)

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 21-Aug-2020 02:51**Site No:** 1091**Subject No:** 10911213**Generated By:** (b) (4)**Form:** VITAL SIGNS - BASELINE**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1091) Aventiv Research Inc.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:31**eCRF Audit Trail History****Vital Signs**

1.	Date:	Sep/1/2020
2.	Weight:	[87.4]
3.	Unit:	kg
4.	Height:	[173.5]
5.	Unit:	cm
6.	Body Mass Index:	[29.0]

**Vital Signs Details**

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

**Header Text:** c4591001

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

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

**Site No:** 1091

**Subject No:** 10911213

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

**Form:** RANDOMIZATION

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

**Site Name:** (1091) Aventiv Research Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Sep/1/2020
2.	Randomization Number:	[248124]
3.	Randomization Group:	[ ]

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**Header Text:** c4591001

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

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

**Site No:** 1091

**Subject No:** 10911213

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site Name:** (1091) Aventiv Research Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Sep/1/2020
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	[BPR4KS]
5.b	Sample ID	[BPR4M0]
5.c	Sample ID	[BPR4KT]
5.d	Sample ID	[BP8MD0]

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**Header Text:** c4591001

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

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

**Site No:** 1091

**Subject No:** 10911213

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

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

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

**Site Name:** (1091) Aventiv Research Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

**eCRF Audit Trail History**

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/1/2020
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	[BP8MCW]
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090177e196ae3d12\Final\Final On: 01-Apr-2021 04:25 (GMT)

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 22-Apr-2020 21:04**Site No:** 1091**Subject No:** 10911213**Generated By:** (b) (4)**Form:** VACCINATION**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1091) Aventiv Research Inc.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:31**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/1/2020 11:56
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

**Header Text:** c4591001

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

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

**Site No:** 1091

**Subject No:** 10911213

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

**Form:** REACTOGENICITY DIARY

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

**Site Name:** (1091) Aventiv Research Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[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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090177e196ae3d12\Final\Final On: 01-Apr-2021 04:25 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1091

**Subject No:** 10911213

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

**Form:** DATE OF VISIT

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

**Site Name:** (1091) Aventiv Research Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Sep/21/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1091

**Subject No:** 10911213

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

**Form:** VITAL SIGNS - TEMP

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

**Site Name:** (1091) Aventiv Research Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Sep/21/2020
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**Vital Signs Details**

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

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1091**Subject No:** 10911213**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1091) Aventiv Research Inc.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:31**eCRF Audit Trail History****Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/21/2020
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	[BPYSWS]
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**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form Version:** 22-Apr-2020 21:04**Site No:** 1091**Subject No:** 10911213**Generated By:** (b) (4)**Form:** VACCINATION**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1091) Aventiv Research Inc.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:31**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/21/2020 09:50
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

**Header Text:** c4591001

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

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

**Site No:** 1091

**Subject No:** 10911213

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

**Form:** DATE OF VISIT

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

**Site Name:** (1091) Aventiv Research Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Nov/3/2020
2.	Erroneous Visit	



**Header Text:** c4591001

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

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

**Site No:** 1091

**Subject No:** 10911213

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site Name:** (1091) Aventiv Research Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

**eCRF Audit Trail History**

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Nov/3/2020
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	[BRFH2R]
5.b	Sample ID	[BLG1BW]
5.c	Sample ID	[BLG1BX]

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**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1091

**Subject No:** 10911213

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1091) Aventiv Research Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

**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:** 1091

**Subject No:** 10911213

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1091) Aventiv Research Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

**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:** 1091

**Subject No:** 10911213

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1091) Aventiv Research Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

**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:** 1091

**Subject No:** 10911213

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1091) Aventiv Research Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

**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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090177e196ae3d12\Final\Final On: 01-Apr-2021 04:25 (GMT)

**Header Text:** c4591001

**Visit:** V6\_MONTH24\_L

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

**Site No:** 1091

**Subject No:** 10911213

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1091) Aventiv Research Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

**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:** 1091

**Subject No:** 10911213

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1091) Aventiv Research Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

**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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090177e196ae3d12\Final\Final On: 01-Apr-2021 04:25 (GMT)

**Header Text:** c4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1091

**Site Name:** (1091) Aventiv Research Inc.

**Subject No:** 10911213

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

**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:** 1091

**Site Name:** (1091) Aventiv Research Inc.

**Subject No:** 10911213

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

**Signs and Symptoms**

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

**Symptoms**

4.	Symptoms:	
	Was symptom present?	

**Symptoms - Other**

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

**Header Text:** c4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1091

**Site Name:** (1091) Aventiv Research Inc.

**Subject No:** 10911213

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

**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:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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

**Form Status:** Not Started

**Site No:** 1091

**Site Name:** (1091) Aventiv Research Inc.

**Subject No:** 10911213

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

**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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090177e196ae3d12\Final\Final On: 01-Apr-2021 04:25 (GMT)

**Header Text:** c4591001

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

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

**Form Status:** Not Started

**Site No:** 1091

**Site Name:** (1091) Aventiv Research Inc.

**Subject No:** 10911213

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

**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?	
----	--	--

**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:** 1091

**Site Name:** (1091) Aventiv Research Inc.

**Subject No:** 10911213

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

**Illness Details**

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

090177e196ae3d12\Final\Final On: 01-Apr-2021 04:25 (GMT)

**Header Text:** c4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1091

**Site Name:** (1091) Aventiv Research Inc.

**Subject No:** 10911213

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

**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:** 1091

**Site Name:** (1091) Aventiv Research Inc.

**Subject No:** 10911213

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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

090177e196ae3d12\Final\Final On: 01-Apr-2021 04:25 (GMT)

<b>Header Text:</b> c4591001		
<b>Visit:</b> Unplanned - New Unscheduled Visit		<b>Form:</b> DATE OF VISIT
<b>Form Version:</b> 22-Apr-2020 21:02		<b>Form Status:</b> Not Started
<b>Site No:</b> 1091		<b>Site Name:</b> (1091) Aventiv Research Inc.
<b>Subject No:</b> 10911213		<b>Subject Initials:</b> ---
<b>Generated By:</b> (b) (4)		<b>Generated Time (GMT):</b> 29-Mar-2021 10:31
<b>Date of Visit</b>		
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:** 1091

**Site Name:** (1091) Aventiv Research Inc.

**Subject No:** 10911213

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

**Unplanned Assessments**

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

090177e196ae3d12\Final\Final On: 01-Apr-2021 04:25 (GMT)

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

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

**Site No:** 1091

**Subject No:** 10911213

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

**Form:** DISPOSITION - TREATMENT

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

**Site Name:** (1091) Aventiv Research Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Disposition - Treatment**

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

090177e196ae3d12\Final\Final On: 01-Apr-2021 04:25 (GMT)

**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

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

**Site No:** 1091

**Subject No:** 10911213

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

**Form:** DISPOSITION - FOLLOW-UP

**Form Status:** Not Started

**Site Name:** (1091) Aventiv Research Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

**Disposition - Follow-Up**

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

**Header Text:** c4591001**Visit:** POT\_COVID\_REPEAT\_SWAB - New  
Unscheduled Visit**Form:** DATE OF VISIT - REPEAT SWAB**Form Version:** 10-Oct-2020 15:57**Form Status:** Not Started**Site No:** 1091**Site Name:** (1091) Aventiv Research Inc.**Subject No:** 10911213**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:31**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Repeat Swab**

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

**Header Text:** c4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1091

**Site Name:** (1091) Aventiv Research Inc.

**Subject No:** 10911213

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911213

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	injection site soreness	Sep/2/2020 UNK:UNK	NO End Date Time:  Sep/9/2020 UNK:UNK	<a href="#">Repeating Pages</a>
2.	ADVERSE EVENT	2	injection site redness	Sep/22/2020 21:00	NO End Date Time:  Sep/24/2020 UNK:UNK	<a href="#">Repeating Pages</a>
3.	ADVERSE EVENT	3	injection site pain	Sep/22/2020 21:00	NO End Date Time:  Sep/24/2020 UNK:UNK	<a href="#">Repeating Pages</a>

090177e196ae3d12\Final\Final On: 01-Apr-2021 04:25 (GMT)

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1091**Subject No:** 10911213**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, Locked, Frozen**Site Name:** (1091) Aventiv Research Inc.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:31[Back to Form](#)[eCRF Audit Trail History](#)[Form Audit Trail](#)**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[injection site soreness]
4.	Start Date Time:	Sep/2/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/9/2020 UNK:UNK
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:	NOT APPLICABLE
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
14.	Did the adverse event cause the subject to be discontinued from the study?	NO

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1091

**Subject No:** 10911213

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

**Form:** ADVERSE EVENT REPORT

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

**Site Name:** (1091) Aventiv Research Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]
-----	---	-----



**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1091**Subject No:** 10911213**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, Locked, Frozen**Site Name:** (1091) Aventiv Research Inc.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:31[Back to Form](#)[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)	[injection site redness]
4.	Start Date Time:	Sep/22/2020 21:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/24/2020 UNK:UNK
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:	NOT APPLICABLE
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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1091

**Subject No:** 10911213

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

**Form:** ADVERSE EVENT REPORT

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

**Site Name:** (1091) Aventiv Research Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1091**Subject No:** 10911213**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, Locked, Frozen**Site Name:** (1091) Aventiv Research Inc.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:31

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[injection site pain]
4.	Start Date Time:	Sep/22/2020 21:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/24/2020 UNK:UNK
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:	NOT APPLICABLE
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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1091

**Subject No:** 10911213

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

**Form:** ADVERSE EVENT REPORT

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

**Site Name:** (1091) Aventiv Research Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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

**Header Text:** c4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

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

**Site No:** 1091

**Site Name:** (1091) Aventiv Research Inc.

**Subject No:** 10911213

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

#	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:** 1091**Subject No:** 10911213**Generated By:** (b) (4)**Form:** MEDICATION ERROR**Form Status:** Not Started**Site Name:** (1091) Aventiv Research Inc.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:31[Back to Form](#)**Medication Error**

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

**Header Text:** c4591001

**Visit:** Logs

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

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

**Site No:** 1091

**Site Name:** (1091) Aventiv Research Inc.

**Subject No:** 10911213

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

#	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:** 1091**Subject No:** 10911213**Generated By:** (b) (4)**Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS**Form Status:** Not Started**Site Name:** (1091) Aventiv Research Inc.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:31[Back to Form](#)**Concomitant Medications**

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



**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Site No:** 1091

**Site Name:** (1091) Aventiv Research Inc.

**Subject No:** 10911213

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

#	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:** 1091**Subject No:** 10911213**Generated By:** (b) (4)**Form:** CONCOMITANT MEDICATIONS - PROHIBITED**Form Status:** Not Started**Site Name:** (1091) Aventiv Research Inc.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:31[Back to Form](#)**Concomitant Medications**

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

**Header Text:** c4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

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

**Site No:** 1091

**Site Name:** (1091) Aventiv Research Inc.

**Subject No:** 10911213

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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

090177e196ae3d12\Final\Final On: 01-Apr-2021 04:25 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1091

**Subject No:** 10911213

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

**Form:** RADIATION TREATMENT

**Form Status:** Not Started

**Site Name:** (1091) Aventiv Research Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[Back to Form](#)

**Radiation Treatment**

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

**Header Text:** c4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

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

**Site No:** 1091

**Site Name:** (1091) Aventiv Research Inc.

**Subject No:** 10911213

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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

090177e196ae3d12\Final\Final On: 01-Apr-2021 04:25 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1091

**Subject No:** 10911213

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

**Form:** TRANSFUSIONS

**Form Status:** Not Started

**Site Name:** (1091) Aventiv Research Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[Back to Form](#)

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1091

**Site Name:** (1091) Aventiv Research Inc.

**Subject No:** 10911213

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

**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:** 1091

**Site Name:** (1091) Aventiv Research Inc.

**Subject No:** 10911213

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

**Vital Signs**

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

**Vital Signs Details**

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



**Header Text:** c4591001**Visit:** Unplanned Vaccination - Unscheduled**Form:** VACCINATION**Form Version:** 10-Dec-2020 02:26**Form Status:** Not Started**Site No:** 1091**Site Name:** (1091) Aventiv Research Inc.**Subject No:** 10911213**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:31**Vaccination**

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

**Header Text:** c4591001**Visit:** Unplanned Vaccination - Unscheduled**Form:** CONTACT OUTCOME - MONTH 1**Form Version:** 10-Oct-2020 15:57**Form Status:** Not Started**Site No:** 1091**Site Name:** (1091) Aventiv Research Inc.**Subject No:** 10911213**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:31**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:** 1091

**Site Name:** (1091) Aventiv Research Inc.

**Subject No:** 10911213

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

**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:** 1091

**Site Name:** (1091) Aventiv Research Inc.

**Subject No:** 10911213

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

**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:** 1091

**Site Name:** (1091) Aventiv Research Inc.

**Subject No:** 10911213

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

**Informed Consent - Asymptomatic Surveillance**

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

090177e196ae3d12\Final\Final On: 01-Apr-2021 04:25 (GMT)

**Header Text:** c4591001

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Form Status:** Not Started

**Site No:** 1091

**Site Name:** (1091) Aventiv Research Inc.

**Subject No:** 10911213

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1091

**Site Name:** (1091) Aventiv Research Inc.

**Subject No:** 10911213

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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

090177e196ae3d12\Final\Final On: 01-Apr-2021 04:25 (GMT)

**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:** 1091

**Site Name:** (1091) Aventiv Research Inc.

**Subject No:** 10911213

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Feb/17/2021
2.	Erroneous Visit	



**Header Text:** c4591001

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1091

**Site Name:** (1091) Aventiv Research Inc.

**Subject No:** 10911213

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Further Vaccination Confirmation**

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

090177e196ae3d12\Final\Final On: 01-Apr-2021 04:25 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1091

**Subject No:** 10911213

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

**Form:** TREATMENT UNBLINDED

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

**Site Name:** (1091) Aventiv Research Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Treatment Unblinded**

1.	Date Treatment Unblinded :	Feb/22/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1091

**Subject No:** 10911213

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

**Form:** WITHDRAWAL OF CONSENT

**Form Status:** Not Started

**Site Name:** (1091) Aventiv Research Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

**Withdrawal Of Consent**

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

090177e196ae3d12\Final\Final On: 01-Apr-2021 04:25 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1091

**Subject No:** 10911213

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

**Form:** DEATH DETAILS CODED

**Form Status:** Not Started

**Site Name:** (1091) Aventiv Research Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

**Death Details**

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

**Cause of Death**

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

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1091

**Subject No:** 10911213

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

**Form:** SUBJECT STATUS

**Form Status:** Data Complete, Verified

**Site Name:** (1091) Aventiv Research Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Subject Status**

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Nov/3/2020

090177e196ae3d12\Final\Final On: 01-Apr-2021 04:25 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

**Site No:** 1091

**Subject No:** 10911213

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

**Form:** CASEBOOK SIGNATURE FORM

**Form Status:** Data Complete, Verified

**Site Name:** (1091) Aventiv Research Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Casebook Signature Form**

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

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

**Site No:** 1091

**Subject No:** 10911213

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

**Form:** CASEBOOK SIGNATURE FORM

**Form Status:** Data Complete, Verified

**Site Name:** (1091) Aventiv Research Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[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:** 30-Jul-2020 21:29

**Site No:** 1091

**Subject No:** 10911213

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

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

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

**Site Name:** (1091) Aventiv Research Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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Item	Date	User	Comment
Form	Sep-02-2020 13:58:12 (UTC-05:00) Eastern Time (US & Canada)		Not Applicable



**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

**Site No:** 1091

**Subject No:** 10911213

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

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

**Form Status:** Data Complete, Verified

**Site Name:** (1091) Aventiv Research Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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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
	N/A	Feb-24-2021 12:45:13 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated

**Affidavit:**

N/A

Samir Arora	Approved	Nov-12-2020 08:17:25 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
-------------	----------	---	------	--------

**Affidavit:**

By my dated signature below, I, SamirArora, 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.

090177e196ae3d12\Final\Final On: 01-Apr-2021 04:25 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1091

**Subject No:** 10911213

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

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

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

**Site Name:** (1091) Aventiv Research Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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

Date	Location	User	Value	Reason
Sep-02-2020 13:31:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	<input type="text"/> <input type="text"/> <input type="text"/>	<b>Data Entry:</b> 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 13:31:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	<input type="text"/> <input type="text"/> <input type="text"/>	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1091

**Subject No:** 10911213

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

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

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

**Site Name:** (1091) Aventiv Research Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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**1. Consent Was:**

Date	Location	User	Value	Reason
Sep-02-2020 13:32:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	<div><div></div><div></div><div></div></div>	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Sep/1/2020	Initial Entry

Header Text: c4591001

Visit: COHORT\_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1091

Subject No: 10911213

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1091) Aventiv Research Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

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**1. Subject ID**

Date	Location	User	Value	Reason
Sep-02-2020 13:31:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 10911213	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Sep-02-2020 13:31:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> (b) (6)/1962	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Sep-02-2020 13:32:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	   	<u>Data Entry:</u> MALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Sep-02-2020 13:32:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	   	<u>Data Entry:</u> NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 13:32:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	   	<u>Data Entry:</u> WHITE	Initial Entry

090177e196ae3d12\Final\Final On: 01-Apr-2021 04:25 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1091

**Subject No:** 10911213

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

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

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

**Site Name:** (1091) Aventiv Research Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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***1. Date of Visit***

Date	Location	User	Value	Reason
Sep-02-2020 13:57:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	<div><div></div><div></div><div></div></div>	<b>Data Entry:</b> Sep/1/2020	Initial Entry

090177e196ae3d12\Final\Final On: 01-Apr-2021 04:25 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1091

**Subject No:** 10911213

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

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

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

**Site Name:** (1091) Aventiv Research Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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

Date	Location	User	Value	Reason
Sep-02-2020 13:59:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/1/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Sep-02-2020 13:59:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Sep-02-2020 13:59:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000		<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae3d12\Final\Final On: 01-Apr-2021 04:25 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1091

Subject No: 10911213

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1091) Aventiv Research Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

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1.a

Date	Location	User	Value	Reason
Sep-02-2020 14:02:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 1 <b>Medical History Term:</b> anxiety <b>Start Date:</b> UNK/UNK/2013 <b>Ongoing:</b> YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Sep-02-2020 14:02:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

1.a Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-02-2020 14:02:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	_____	<b>Data Entry:</b> anxiety	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
Sep-02-2020 14:02:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	_____	<b>Data Entry:</b> UNK/UNK/2013	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Sep-02-2020 14:02:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	_____	<b>Data Entry:</b> YES	Initial Entry

1.b

Date	Location	User	Value	Reason
Sep-02-2020 14:03:19 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Initial Entry

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1091**Subject No:** 10911213**Generated By:** (b) (4)**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1091) Aventiv Research Inc.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:31

(US & Canada)			<b>Line/MH Number:</b> 2 <b>Medical History Term:</b> hypertriglyceridemia <b>Start Date:</b> UNK/UNK/2019 <b>Ongoing:</b> YES	
---------------	--	--	---	--

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

Date	Location	User	Value	Reason
Sep-02-2020 14:03:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 14:03:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000		<b>Data Entry:</b> hypertriglyceridemia	Initial Entry

**1.b Start Date:**

Date	Location	User	Value	Reason
Sep-02-2020 14:03:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000		<b>Data Entry:</b> UNK/UNK/2019	Initial Entry

**1.b Ongoing:**

Date	Location	User	Value	Reason
Sep-02-2020 14:03:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000		<b>Data Entry:</b> YES	Initial Entry

**1.c**

Date	Location	User	Value	Reason
Sep-02-2020 14:04:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 3 <b>Medical History Term:</b> brain injury <b>Start Date:</b> UNK/UNK/2006 <b>Ongoing:</b> YES	Initial Entry



**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1091**Subject No:** 10911213**Generated By:** (b) (4)**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1091) Aventiv Research Inc.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:31**1.c Line/MH Number:**

Date	Location	User	Value	Reason
Sep-02-2020 14:04:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 14:04:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	_____	<b>Data Entry:</b> brain injury	Initial Entry

**1.c Start Date:**

Date	Location	User	Value	Reason
Sep-02-2020 14:04:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	_____	<b>Data Entry:</b> UNK/UNK/2006	Initial Entry

**1.c Ongoing:**

Date	Location	User	Value	Reason
Sep-02-2020 14:04:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	_____	<b>Data Entry:</b> YES	Initial Entry

**1.d**

Date	Location	User	Value	Reason
Sep-02-2020 14:05:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number</b> 4 : <b>Medical History T</b> chronic kidney dis <b>erm:</b> ease <b>Start Date:</b> UNK/UNK/2013 <b>Ongoing:</b> YES	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1091

Subject No: 10911213

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1091) Aventiv Research Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

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

Date	Location	User	Value	Reason
Sep-02-2020 14:05:29 (UTC-05:00) Eastern 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-02-2020 14:05:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> chronic kidney disease	Initial Entry

**1.d Start Date:**

Date	Location	User	Value	Reason
Sep-02-2020 14:05:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2013	Initial Entry

**1.d Ongoing:**

Date	Location	User	Value	Reason
Sep-02-2020 14:05:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**1.e**

Date	Location	User	Value	Reason
Sep-02-2020 14:06:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 5 <b>Medical History Term:</b> depression <b>Start Date:</b> UNK/UNK/2013 <b>Ongoing:</b> YES	Initial Entry

090177e196ae3d12\Final\Final On: 01-Apr-2021 04:25 (GMT)

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1091**Subject No:** 10911213**Generated By:** (b) (4)**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1091) Aventiv Research Inc.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:31**1.e Line/MH Number:**

Date	Location	User	Value	Reason
Sep-02-2020 14:06:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 5	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 14:06:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> depression	Initial Entry

**1.e Start Date:**

Date	Location	User	Value	Reason
Sep-02-2020 14:06:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2013	Initial Entry

**1.e Ongoing:**

Date	Location	User	Value	Reason
Sep-02-2020 14:06:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**1.f**

Date	Location	User	Value	Reason
Sep-02-2020 14:07:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 6 <b>Medical History Term:</b> esophageal reflux <b>Start Date:</b> UNK/UNK/2013 <b>Ongoing:</b> YES	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1091

Subject No: 10911213

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1091) Aventiv Research Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

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

Date	Location	User	Value	Reason
Sep-02-2020 14:07:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 6	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 14:07:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> esophageal reflux	Initial Entry

**1.f Start Date:**

Date	Location	User	Value	Reason
Sep-02-2020 14:07:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2013	Initial Entry

**1.f Ongoing:**

Date	Location	User	Value	Reason
Sep-02-2020 14:07:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**1.g**

Date	Location	User	Value	Reason
Sep-02-2020 14:07:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 7 <b>Medical History Term:</b> migraines <b>Start Date:</b> UNK/UNK/2006 <b>Ongoing:</b> YES	Initial Entry

090177e196ae3d12\Final\Final On: 01-Apr-2021 04:25 (GMT)

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1091**Subject No:** 10911213**Generated By:** (b) (4)**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1091) Aventiv Research Inc.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:31**1.g Line/MH Number:**

Date	Location	User	Value	Reason
Sep-02-2020 14:07:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 7	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 14:07:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> migraines	Initial Entry

**1.g Start Date:**

Date	Location	User	Value	Reason
Sep-02-2020 14:07:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2006	Initial Entry

**1.g Ongoing:**

Date	Location	User	Value	Reason
Sep-02-2020 14:07:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**1.h**

Date	Location	User	Value	Reason
Sep-02-2020 14:08:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Number 8 r: Medical History generalized osteoarthritis Term: Start Date: UNK/UNK/2013 Ongoing: YES	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1091

Subject No: 10911213

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1091) Aventiv Research Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

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

Date	Location	User	Value	Reason
Sep-02-2020 14:08:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 8	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 14:08:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> generalized osteoarthritis	Initial Entry

**1.h Start Date:**

Date	Location	User	Value	Reason
Sep-02-2020 14:08:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2013	Initial Entry

**1.h Ongoing:**

Date	Location	User	Value	Reason
Sep-02-2020 14:08:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**1.i**

Date	Location	User	Value	Reason
Sep-02-2020 14:09:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 9 <b>Medical History Term:</b> sleep apnea <b>Start Date:</b> UNK/UNK/2013 <b>Ongoing:</b> YES	Initial Entry

090177e196ae3d12\Final\Final On: 01-Apr-2021 04:25 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1091

Subject No: 10911213

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1091) Aventiv Research Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

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

Date	Location	User	Value	Reason
Sep-02-2020 14:09:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 9	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 14:09:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	   	<b>Data Entry:</b> sleep apnea	Initial Entry

***1.i Start Date:***

Date	Location	User	Value	Reason
Sep-02-2020 14:09:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	   	<b>Data Entry:</b> UNK/UNK/2013	Initial Entry

***1.i Ongoing:***

Date	Location	User	Value	Reason
Sep-02-2020 14:09:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	   	<b>Data Entry:</b> YES	Initial Entry

***1.j***

Date	Location	User	Value	Reason
Sep-02-2020 14:09:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 10 <b>Medical History Term:</b> vertigo <b>Start Date:</b> UNK/UNK/2006 <b>Ongoing:</b> YES	Initial Entry

090177e196ae3d12\Final\Final On: 01-Apr-2021 04:25 (GMT)

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1091**Subject No:** 10911213**Generated By:** (b) (4)**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1091) Aventiv Research Inc.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:31***1.j Line/MH Number:***

Date	Location	User	Value	Reason
Sep-02-2020 14:09:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 10	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 14:09:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> vertigo	Initial Entry

***1.j Start Date:***

Date	Location	User	Value	Reason
Sep-02-2020 14:09:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2006	Initial Entry

***1.j Ongoing:***

Date	Location	User	Value	Reason
Sep-02-2020 14:09:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1091

Subject No: 10911213

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1091) Aventiv Research Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

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1.k

Date	Location	User	Value	Reason
Sep-02-2020 14:10:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> <b>Medical History</b> post traumatic stress <b>Term:</b> disorder <b>Start Date:</b> UNK/UNK/2006 <b>Ongoing:</b> YES	Initial Entry

1.k Line/MH Number:

Date	Location	User	Value	Reason
Sep-02-2020 14:10:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 11	Initial Entry

1.k Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-02-2020 14:10:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000		<b>Data Entry:</b> post traumatic stress disorder	Initial Entry

1.k Start Date:

Date	Location	User	Value	Reason
Sep-02-2020 14:10:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000		<b>Data Entry:</b> UNK/UNK/2006	Initial Entry

1.k Ongoing:

Date	Location	User	Value	Reason
Sep-02-2020 14:10:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000		<b>Data Entry:</b> YES	Initial Entry

1.l

Date	Location	User	Value	Reason
Sep-02-2020 14:13:02 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number</b> 12	Initial Entry

090177e196ae3d12\Final\Final On: 01-Apr-2021 04:25 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1091

Subject No: 10911213

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1091) Aventiv Research Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

(US & Canada)			er: Medical History right shoulder repla Term: cement Start Date: Nov/UNK/2019 Ongoing: NO End Date: Nov/UNK/2019	
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**1.1 Line/MH Number:**

Date	Location	User	Value	Reason
Sep-02-2020 14:13:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 12	Initial Entry

**1.1 Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Sep-02-2020 14:13:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000		<u>Data Entry:</u> right shoulder replacement	Initial Entry

**1.1 Start Date:**

Date	Location	User	Value	Reason
Sep-02-2020 14:13:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000		<u>Data Entry:</u> Nov/UNK/2019	Initial Entry

**1.1 Ongoing:**

Date	Location	User	Value	Reason
Sep-02-2020 14:13:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000		<u>Data Entry:</u> NO End Date: Nov/UNK/2019	Initial Entry

**1.m**

Date	Location	User	Value	Reason
Sep-02-2020 14:14:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000		<u>Data Entry:</u> Line/MH Num 13 ber:	Transcription Error

090177e196ae3d12\Final\Final On: 01-Apr-2021 04:25 (GMT)

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1091**Subject No:** 10911213**Generated By:** (b) (4)**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1091) Aventiv Research Inc.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:31

			<b>Medical History Term:</b> chronic right shoulder pain <b>Start Date:</b> UNK/UNK/2013 <b>Ongoing:</b> NO End Date: Nov/UNK/2019	
Sep-02-2020 14:14:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000		<b>Data Entry:</b> <b>Line/MH Number:</b> 13 <b>Medical History Term:</b> chronic right shoulder pain <b>Start Date:</b> UNK/UNK/2013 <b>Ongoing:</b> YES	Initial Entry
Sep-02-2020 14:13:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 13 <b>Medical History Term:</b> chronic right shoulder pain <b>Start Date:</b> UNK/UNK/2013 <b>Ongoing:</b>	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1091

Subject No: 10911213

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1091) Aventiv Research Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

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

Date	Location	User	Value	Reason
Sep-02-2020 14:13:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 13	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 14:13:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000		<b>Data Entry:</b> chronic right shoulder pain	Initial Entry

**1.m Start Date:**

Date	Location	User	Value	Reason
Sep-02-2020 14:13:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000		<b>Data Entry:</b> UNK/UNK/2013	Initial Entry

**1.m Ongoing:**

Date	Location	User	Value	Reason
Sep-02-2020 14:14:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000		<b>Data Entry:</b> NO End Date: Nov/UNK/2019	Transcription Error
Sep-02-2020 14:14:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000		<b>Data Entry:</b> YES	Initial Entry

090177e196ae3d12\Final\Final On: 01-Apr-2021 04:25 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:51

Site No: 1091

Subject No: 10911213

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1091) Aventiv Research Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

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**1. Date:**

Date	Location	User	Value	Reason
Sep-02-2020 14:16:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sep/1/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Sep-02-2020 14:16:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000		<u>Data Entry:</u> 87.4	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Sep-02-2020 14:16:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> kg	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Sep-02-2020 14:16:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000		<u>Data Entry:</u> 173.5	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Sep-02-2020 14:16:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000		<u>Data Entry:</u> cm	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
Sep-02-2020 14:16:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 29.0	Initial Entry

**7.a**

Date	Location	User	Value	Reason
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090177e196ae3d12\Final\Final On: 01-Apr-2021 04:25 (GMT)

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 21-Aug-2020 02:51**Site No:** 1091**Subject No:** 10911213**Generated By:** (b) (4)**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1091) Aventiv Research Inc.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:31

Sep-02-2020 14:16:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000		<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 36.8 <b>Temperature Unit:</b> C <b>Temperature Location::</b> ORAL CAVITY	Initial Entry
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**7.a Record Identifier:**

Date	Location	User	Value	Reason
Sep-02-2020 14:16:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000		<b>Data Entry:</b> 1	Initial Entry

**7.a Temperature:**

Date	Location	User	Value	Reason
Sep-02-2020 14:16:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000		<b>Data Entry:</b> 36.8	Initial Entry

**7.a Unit:**

Date	Location	User	Value	Reason
Sep-02-2020 14:16:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000		<b>Data Entry:</b> C	Initial Entry

**7.a Temperature Location:**

Date	Location	User	Value	Reason
Sep-02-2020 14:16:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000		<b>Data Entry:</b> ORAL CAVITY	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1091

**Subject No:** 10911213

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

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

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

**Site Name:** (1091) Aventiv Research Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Sep-02-2020 14:17:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/1/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Sep-02-2020 14:17:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 248124	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1091

Subject No: 10911213

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1091) Aventiv Research Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

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**1. Data Origin**

Date	Location	User	Value	Reason
Sep-02-2020 14:18:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-02-2020 14:18:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-03-2020 12:09:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-03-2020 01:31:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000		Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-02-2020 14:18:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-02-2020 14:18:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000		<u>Data Entry:</u> YES Date of Collection:  Sep/1/2020	Initial Entry

**4. If no sample was collected or sample was not collected according to protocol, please provide reason:**

Date	Location	User	Value	Reason
Sep-03-2020 12:09:59 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query

090177e196ae3d12\Final\Final On: 01-Apr-2021 04:25 (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:** 1091**Site Name:** (1091) Aventiv Research Inc.**Subject No:** 10911213**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:31

(US & Canada)				
Sep-03-2020 12:09:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000		<b>Data Entry:</b>	Transcription Error
Sep-03-2020 12:09:39 (UTC-05:00) Eastern 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 the field and re-enter without adding extra spaces or using enter or tab keys.
Sep-03-2020 12:09:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000		<b>Data Entry:</b> BPR4M0	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-03-2020 12:09:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000		<b>Data Entry:</b> Sample ID: BPR4KS	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Sep-03-2020 12:09:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000		<b>Data Entry:</b> BPR4KS	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Sep-03-2020 12:10:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000		<b>Data Entry:</b> Sample ID: BPR4M0	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1091

Subject No: 10911213

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1091) Aventiv Research Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

**5.b Sample ID**

Date	Location	User	Value	Reason
Sep-03-2020 12:10:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	<input type="text"/> <input type="text"/> <input type="text"/>	<b>Data Entry:</b> BPR4M0	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Sep-03-2020 12:10:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	<input type="text"/> <input type="text"/> <input type="text"/>	<b>Data Entry:</b> Sample ID: BPR4KT	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Sep-03-2020 12:10:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	<input type="text"/> <input type="text"/> <input type="text"/>	<b>Data Entry:</b> BPR4KT	Initial Entry

**5.d**

Date	Location	User	Value	Reason
Sep-03-2020 12:11:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	<input type="text"/> <input type="text"/> <input type="text"/>	<b>Data Entry:</b> Sample ID: BP8MD0	Initial Entry

**5.d Sample ID**

Date	Location	User	Value	Reason
Sep-03-2020 12:11:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	<input type="text"/> <input type="text"/> <input type="text"/>	<b>Data Entry:</b> BP8MD0	Initial Entry

090177e196ae3d12\Final\Final On: 01-Apr-2021 04:25 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1091

Subject No: 10911213

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1091) Aventiv Research Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

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**1. Data Origin**

Date	Location	User	Value	Reason
Sep-02-2020 14:18:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-02-2020 14:18:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-03-2020 14:04:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-03-2020 01:31:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-02-2020 14:18:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-02-2020 14:18:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES Date of Collection:  Sep/1/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-03-2020 14:04:46 (UTC-05:00) Eastern Time	ACV0PFEINFP6000		<u>Data Entry:</u>	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1091

**Subject No:** 10911213

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

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

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

**Site Name:** (1091) Aventiv Research Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

(US & Canada)			<b>Sample ID:</b> BP8MCW	
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**5.a Sample ID**

Date	Location	User	Value	Reason
Sep-03-2020 14:04:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000		<u><b>Data Entry:</b></u> BP8MCW	Initial Entry

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 22-Apr-2020 21:04**Site No:** 1091**Subject No:** 10911213**Generated By:** (b) (4)**Form:** VACCINATION - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1091) Aventiv Research Inc.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:31[Back to Form](#)**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Sep-02-2020 14:20:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Sep-02-2020 14:20:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Sep-02-2020 14:20:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Sep-02-2020 14:20:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/1/2020 11:56	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Sep-02-2020 14:20:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Sep-02-2020 14:20:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000		<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
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**Header Text:** c4591001

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

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

**Site No:** 1091

**Subject No:** 10911213

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

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

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

**Site Name:** (1091) Aventiv Research Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

Sep-02-2020 14:20:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry
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**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Sep-02-2020 14:20:23 (UTC-05:00) Eastern 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-02-2020 14:20:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	   	<b>Data Entry:</b> YES	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1091

**Subject No:** 10911213

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

**Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

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

**Site Name:** (1091) Aventiv Research Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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**1. Select appropriate response - Reactogenicity diary collection**

Date	Location	User	Value	Reason
Sep-02-2020 14:20:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJ ECT	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1091

**Subject No:** 10911213

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

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

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

**Site Name:** (1091) Aventiv Research Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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***1. Date of Visit***

Date	Location	User	Value	Reason
Sep-23-2020 10:16:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/21/2020	Initial Entry



Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 15-Sep-2020 21:54

Site No: 1091

Subject No: 10911213

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1091) Aventiv Research Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

[Back to Form](#)**1. Date:**

Date	Location	User	Value	Reason
Sep-23-2020 10:17:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/21/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-23-2020 10:17:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 36.8 <b>Temperature Unit:</b> C <b>Temperature Location:</b> ORAL CAVITY	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Sep-23-2020 10:17:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	_____	<b>Data Entry:</b> 1	Initial Entry

**2.a Temperature:**

Date	Location	User	Value	Reason
Sep-23-2020 10:17:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	_____	<b>Data Entry:</b> 36.8	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Sep-23-2020 10:17:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	_____	<b>Data Entry:</b> C	Initial Entry

**2.a Temperature Location:**

Date	Location	User	Value	Reason
Sep-23-2020 10:17:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	_____	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:03

Site No: 1091

Subject No: 10911213

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1091) Aventiv Research Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

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**1. Data Origin**

Date	Location	User	Value	Reason
Sep-22-2020 12:23:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-22-2020 12:23:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-22-2020 12:23:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-22-2020 12:23:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-22-2020 12:23:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	   	<b>Data Entry:</b> YES Date of Collection:  Sep/21/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-22-2020 12:23:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	   	<b>Data Entry:</b> Sample ID: BPYSWS	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Sep-22-2020 12:23:48 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	   	<b>Data Entry:</b> BPYSWS	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1091

**Subject No:** 10911213

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

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

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

**Site Name:** (1091) Aventiv Research Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

(US & Canada)

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

090177e196ae3d12\Final\Final On: 01-Apr-2021 04:25 (GMT)

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form Version:** 22-Apr-2020 21:04**Site No:** 1091**Subject No:** 10911213**Generated By:** (b) (4)**Form:** VACCINATION - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1091) Aventiv Research Inc.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:31[Back to Form](#)**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Sep-23-2020 10:18:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Sep-23-2020 10:18:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Sep-23-2020 10:18:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Sep-23-2020 10:18:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/21/2020 09:50	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Sep-23-2020 10:18:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Sep-23-2020 10:18:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1091

**Subject No:** 10911213

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

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

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

**Site Name:** (1091) Aventiv Research Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

Sep-23-2020 10:18:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry
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**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Sep-23-2020 10:18:53 (UTC-05:00) Eastern 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-23-2020 10:18:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3d12\Final\Final On: 01-Apr-2021 04:25 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form Version: 22-Apr-2020 21:02

Site No: 1091

Subject No: 10911213

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1091) Aventiv Research Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

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**1. Date of Visit**

Date	Location	User	Value	Reason
Nov-10-2020 01:19:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000		Query 1: Closed	Closed per SITE response, added to PD tracker for Clinical Review
Nov-09-2020 14:57:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000		Query 1: Answered	V2 out of window due to subject's availability
Nov-05-2020 01:32:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Opened	PDQ: Date of visit at V3_MONTH1_POSTVAX2_L is out of window for 8 days from V2_VAX2_L DOV or V2 Vaccination date. Please verify and update. Else, confirm in query response appropriately. (b) (4)
Nov-04-2020 09:10:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000		Data Entry : Nov/3 /2020	Initial Entry

090177e196ae3d12\Final\Final On: 01-Apr-2021 04:25 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911213

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

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**1. Data Origin**

Date	Location	User	Value	Reason
Nov-04-2020 09:11:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Nov-04-2020 09:11:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Nov-04-2020 09:11:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-04-2020 09:11:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-04-2020 09:11:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000		<b>Data Entry:</b> YES Date of Collection:  Nov/3/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Nov-04-2020 09:11:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000		<b>Data Entry:</b> Sample ID: BRFH2R	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Nov-04-2020 09:11:24 (UTC-05:00) Eastern Time	ACV0PFEINFP6000		<b>Data Entry:</b> BRFH2R	Initial Entry

**Header Text:** c4591001

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

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

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

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

**Site No:** 1091

**Site Name:** (1091) Aventiv Research Inc.

**Subject No:** 10911213

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

(US & Canada)				
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**5.b**

Date	Location	User	Value	Reason
Nov-04-2020 09:11:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000		<u>Data Entry:</u> Sample ID: BLG1BW	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Nov-04-2020 09:11:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000		<u>Data Entry:</u> BLG1BW	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Nov-04-2020 09:11:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000		<u>Data Entry:</u> Sample ID: BLG1BX	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Nov-04-2020 09:11:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000		<u>Data Entry:</u> BLG1BX	Initial Entry

090177e196ae3d12\Final\Final On: 01-Apr-2021 04:25 (GMT)



Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1091

Subject No: 10911213

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1091) Aventiv Research Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

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

Date	Location	User	Value	Reason
Nov-04-2020 13:18:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	<input type="text"/> <input type="text"/> <input type="text"/>	<u>Data Entry:</u> Nov/3/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Nov-04-2020 13:18:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Nov-04-2020 13:18:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	<input type="text"/> <input type="text"/> <input type="text"/>	<u>Data Entry:</u> COMPLETED	Initial Entry

090177e196ae3d12\Final\Final On: 01-Apr-2021 04:25 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1091

**Subject No:** 10911213

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

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1091) Aventiv Research Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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Date	Location	User	Value	Reason
Sep-23-2020 10:21:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000		Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1091

**Subject No:** 10911213

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

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1091) Aventiv Research Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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Date	Location	User	Value	Reason
Nov-04-2020 13:22:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000		Form Created	

090177e196ae3d12\Final\Final On: 01-Apr-2021 04:25 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1091

**Subject No:** 10911213

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

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1091) Aventiv Research Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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Date	Location	User	Value	Reason
Nov-04-2020 13:24:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1091**Subject No:** 10911213**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen**Site Name:** (1091) Aventiv Research Inc.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:31[Back to Form](#)**1. Category:**

Date	Location	User	Value	Reason
Sep-23-2020 10:21:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Sep-23-2020 10:21:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**3. Adverse Event:***(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Sep-23-2020 10:21:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	   	<b>Data Entry:</b> injection site soreness	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Sep-23-2020 10:21:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	   	<b>Data Entry:</b> Sep/2/2020 UNK:UNK	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Sep-23-2020 10:21:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	   	<b>Data Entry:</b> NO End Date Time:  Sep/9/2020 UNK:UNK	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Sep-23-2020 10:21:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	   	<b>Data Entry:</b> 1	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1091

Subject No: 10911213

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1091) Aventiv Research Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

**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
Sep-23-2020 10:21:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	<input type="text"/> <input type="text"/> <input type="text"/>	<u>Data Entry:</u> 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
Sep-23-2020 10:21:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	<input type="text"/> <input type="text"/> <input type="text"/>	<u>Data Entry:</u> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Sep-23-2020 10:21:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	<input type="text"/> <input type="text"/> <input type="text"/>	<u>Data Entry:</u> RELATED	Initial Entry

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Sep-23-2020 10:21:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	<input type="text"/> <input type="text"/> <input type="text"/>	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Sep-23-2020 10:21:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	<input type="text"/> <input type="text"/> <input type="text"/>	<u>Data Entry:</u> NO	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Sep-23-2020 10:22:22 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	<input type="text"/> <input type="text"/> <input type="text"/>	<u>Data Entry:</u> NO	Initial Entry

090177e196ae3d12\Final\Final On: 01-Apr-2021 04:25 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1091

**Subject No:** 10911213

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

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Site Name:** (1091) Aventiv Research Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

(US & Canada)

**13. What was the outcome of this adverse event?:**

Date	Location	User	Value	Reason
Sep-23-2020 10:21:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000		<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
Sep-23-2020 10:21:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000		<b>Data Entry:</b> NO	Initial Entry

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1091**Subject No:** 10911213**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen**Site Name:** (1091) Aventiv Research Inc.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:31[Back to Form](#)**1. Category:**

Date	Location	User	Value	Reason
Nov-04-2020 13:22:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Nov-04-2020 13:22:08 (UTC-05:00) Eastern 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
Nov-04-2020 13:22:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	   	<b>Data Entry:</b> injection site redness	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Nov-04-2020 13:22:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	   	<b>Data Entry:</b> Sep/22/2020 21:00	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Nov-04-2020 13:22:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	   	<b>Data Entry:</b> NO End Date Time:  Sep/24/2020 UNK:UNK	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Nov-04-2020 13:22:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	   	<b>Data Entry:</b> 1	Initial Entry



Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1091

Subject No: 10911213

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1091) Aventiv Research Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

**7. Is the adverse event serious?**

**If Yes, NOTIFY PFIZER IMMEDIATELY.**

**Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).**

Date	Location	User	Value	Reason
Nov-04-2020 13:22:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	<input type="text"/> <input type="text"/> <input type="text"/>	<u>Data Entry:</u> 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
Nov-04-2020 13:22:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	<input type="text"/> <input type="text"/> <input type="text"/>	<u>Data Entry:</u> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Nov-04-2020 13:22:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	<input type="text"/> <input type="text"/> <input type="text"/>	<u>Data Entry:</u> RELATED	Initial Entry

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Nov-04-2020 13:22:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	<input type="text"/> <input type="text"/> <input type="text"/>	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Nov-04-2020 13:22:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	<input type="text"/> <input type="text"/> <input type="text"/>	<u>Data Entry:</u> NO	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Nov-04-2020 13:22:08 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	<input type="text"/> <input type="text"/> <input type="text"/>	<u>Data Entry:</u> NO	Initial Entry

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1091

**Subject No:** 10911213

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

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Site Name:** (1091) Aventiv Research Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

(US & Canada)

**13. What was the outcome of this adverse event?:**

Date	Location	User	Value	Reason
Nov-04-2020 13:22:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000		<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
Nov-04-2020 13:22:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000		<b>Data Entry:</b> NO	Initial Entry

090177e196ae3d12\Final\Final On: 01-Apr-2021 04:25 (GMT)

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1091**Subject No:** 10911213**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen**Site Name:** (1091) Aventiv Research Inc.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:31[Back to Form](#)**1. Category:**

Date	Location	User	Value	Reason
Nov-04-2020 13:24:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Nov-04-2020 13:24:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

**3. Adverse Event:***(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Nov-04-2020 13:24:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> injection site pain	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Nov-04-2020 13:24:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/22/2020 21:00	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Nov-04-2020 13:24:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Sep/24/2020 UNK:UNK	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Nov-04-2020 13:24:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1091

Subject No: 10911213

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1091) Aventiv Research Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

**7. Is the adverse event serious?**

**If Yes, NOTIFY PFIZER IMMEDIATELY.**

**Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).**

Date	Location	User	Value	Reason
Nov-04-2020 13:24:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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
Nov-04-2020 13:24:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Nov-04-2020 13:24:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RELATED	Initial Entry

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Nov-04-2020 13:24:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Nov-04-2020 13:24:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Nov-04-2020 13:24:47 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1091

**Subject No:** 10911213

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

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Site Name:** (1091) Aventiv Research Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

(US & Canada)

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

**13. What was the outcome of this adverse event?:**

Date	Location	User	Value	Reason
Nov-04-2020 13:24:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<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
Nov-04-2020 13:24:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	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:** 1091

**Site Name:** (1091) Aventiv Research Inc.

**Subject No:** 10911213

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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*1. Date of Visit*

Date	Location	User	Value	Reason
Feb-24-2021 12:45:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	<div></div> <div></div>	<b>Data Entry:</b> Feb/17/2021	Initial Entry

090177e196ae3d12\Final\Final On: 01-Apr-2021 04:25 (GMT)

**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

**Site No:** 1091

**Site Name:** (1091) Aventiv Research Inc.

**Subject No:** 10911213

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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

Date	Location	User	Value	Reason
Feb-24-2021 12:45:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-24-2021 12:45:23 (UTC-05:00) Eastern 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-24-2021 12:45:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	<div><div></div><div></div></div>	<b>Data Entry:</b> Participant is willing to return for Vaccination 3 Participant is:  eligible and NOT confirmed to have received only placebo at Vaccination 1/2	Initial Entry

090177e196ae3d12\Final\Final On: 01-Apr-2021 04:25 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1091

**Subject No:** 10911213

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

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

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

**Site Name:** (1091) Aventiv Research Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Feb-24-2021 12:45:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/22/2021	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Feb-24-2021 12:45:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000		<b>Data Entry:</b> ASSESS ELIGIBILITY FOR ADDIT IONAL VACCINATION	Initial Entry



**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1091

**Subject No:** 10911213

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

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

**Form Status:** Data Complete, Verified

**Site Name:** (1091) Aventiv Research Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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**1. Subject Status**

Date	Location	User	Value	Reason
Nov-04-2020 13:18:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Sep-02-2020 14:17:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Sep-02-2020 13:59:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

**2. Subject Status Date**

Date	Location	User	Value	Reason
Nov-04-2020 13:18:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Nov/3/2020	Initial Entry
Sep-02-2020 14:17:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/1/2020	Initial Entry
Sep-02-2020 13:59:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/1/2020	Initial Entry

090177e196ae3d12\Final\Final On: 01-Apr-2021 04:25 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

**Site No:** 1091

**Subject No:** 10911213

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

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

**Form Status:** Data Complete, Verified

**Site Name:** (1091) Aventiv Research Inc.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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**1. Casebook Signature**

Date	Location	User	Value	Reason
Nov-12-2020 08:17:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Samir Arora (b) (4)	<b>Data Entry:</b> Click Here to Enable	Initial Entry

090177e196ae3d12\Final\Final On: 01-Apr-2021 04:25 (GMT)