

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911170

Subject Initials: ---

Generated By: (b) (4)

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

090177e196ae3d16\Final\Final On: 01-Apr-2021 04:25 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1091

Subject No: 10911170

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 Aug/25/2020
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Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911170

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10911170]
2.	Birth Date:	(b) (6)/1963
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1091

Subject No: 10911170

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	Aug/25/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1091

Subject No: 10911170

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
----	--	----------------

Exclusion Criteria Met

2.	Description of Exclusion Criterion Met	Not Applicable
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090177e196ae3d16\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: 10911170

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	Aug/25/2020
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: 10911170

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:	[postmenopausal]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[seasonal allergies]
	Start Date:	UNK/UNK/1973
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[tom meniscus (right)]
	Start Date:	UNK/UNK/2015
	Ongoing:	NO End Date: UNK/UNK/2015
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[tom meniscus (left)]
	Start Date:	UNK/UNK/2017
	Ongoing:	NO End Date: UNK/UNK/2017

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1091

Subject No: 10911170

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.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[tibia break (left)]
	Start Date:	Dec/28/2019
	Ongoing:	NO End Date: Dec/28/2019
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[bilateral osteoarthritis of knees]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[meniscus repair (right)]
	Start Date:	UNK/UNK/2015
	Ongoing:	NO End Date: UNK/UNK/2015
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[meniscus repair (left)]
	Start Date:	UNK/UNK/2017
	Ongoing:	NO End Date: UNK/UNK/2017

090177e196ae3d16\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: 10911170

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.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[anxiety]
	Start Date:	UNK/UNK/1983
	Ongoing:	YES
1.j	Line/MH Number:	[10]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[osteoarthritis of bilateral hallux]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES
1.k	Line/MH Number:	[11]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[sulfa drugs allergy]
	Start Date:	UNK/UNK/1990
	Ongoing:	YES
1.l	Line/MH Number:	[12]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[iodine allergy]
	Start Date:	UNK/UNK/1990
	Ongoing:	YES
1.m	Line/MH Number:	[13]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[latex allergy]
	Start Date:	UNK/UNK/1990
	Ongoing:	YES

090177e196ae3d16\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: 10911170

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:	Aug/25/2020
2.	Weight:	[105.9]
3.	Unit:	kg
4.	Height:	[171.0]
5.	Unit:	cm
6.	Body Mass Index:	[36.2]

Vital Signs Details

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

090177e196ae3d16\Final\Final On: 01-Apr-2021 04:25 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1091

Subject No: 10911170

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

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](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Aug/25/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae3d16\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: 10911170

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 :	Aug/25/2020
2.	Randomization Number:	[238310]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1091

Subject No: 10911170

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: Aug/25/2020
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	[BP8M5B]
5.b	Sample ID	[BP8M5C]
5.c	Sample ID	[BP8M59]
5.d	Sample ID	[BPR4FN]
5.e	Sample ID	[BPR4FP]

090177e196ae3d16\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: 10911170

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: Aug/25/2020
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	[BP8M4T]
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090177e196ae3d16\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: 10911170

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:	Aug/25/2020 11:24
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

090177e196ae3d16\Final\Final On: 01-Apr-2021 04:25 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1091

Subject No: 10911170

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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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1091

Subject No: 10911170

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/16/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1091

Subject No: 10911170

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/16/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[36.7]
	Unit:	C
	Temperature Location:	ORAL CAVITY

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1091

Subject No: 10911170

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

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

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Sep/16/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae3d16\Final\Final On: 01-Apr-2021 04:25 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1091

Subject No: 10911170

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/16/2020
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	[BPYSV0]
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090177e196ae3d16\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: 10911170

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/16/2020 11:58
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3d16\Final\Final On: 01-Apr-2021 04:25 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911170

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	Oct/14/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1091

Subject No: 10911170

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: Oct/14/2020
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	[BP8M1J]
5.b	Sample ID	[BSGXSH]
5.c	Sample ID	[BSGXSG]

090177e196ae3d16\Final\Final On: 01-Apr-2021 04:25 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1091

Subject No: 10911170

Generated By: (b) (4)

Form: DATE OF VISIT

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](#)

Date of Visit

1.	Date of Visit	Mar/10/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1091

Subject No: 10911170

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Mar/10/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BSGYCC]
5.b	Sample ID	[BSGYCB]
5.c	Sample ID	[BR1S75]
5.d	Sample ID	[BSGYCC]

090177e196ae3d16\Final\Final On: 01-Apr-2021 04:25 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1091

Subject No: 10911170

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: 10911170

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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090177e196ae3d16\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: 10911170

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: 10911170

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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090177e196ae3d16\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: 10911170

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: 10911170

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:	[]
----	------------------------	-----

090177e196ae3d16\Final\Final On: 01-Apr-2021 04:25 (GMT)

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: 10911170

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: 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: 10911170

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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090177e196ae3d16\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: 10911170

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: 10911170

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:	

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: 10911170

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: 10911170

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	[]
----	-----------	-----

090177e196ae3d16\Final\Final On: 01-Apr-2021 04:25 (GMT)

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911170

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 - 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: 10911170

Subject Initials: ---

Generated By: (b) (4)

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

Unplanned Assessments

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

090177e196ae3d16\Final\Final On: 01-Apr-2021 04:25 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911170

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Oct/14/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1091

Subject No: 10911170

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:	[]

090177e196ae3d16\Final\Final On: 01-Apr-2021 04:25 (GMT)

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New **Form:** DATE OF VISIT - REPEAT SWAB
Unscheduled Visit

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

Site No: 1091 **Site Name:** (1091) Aventiv Research Inc.

Subject No: 10911170 **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: 10911170

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	[]
----	-----------	-----

090177e196ae3d16\Final\Final On: 01-Apr-2021 04:25 (GMT)

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: 10911170

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	enlarged left axillary lymph node	Sep/3/2020 UNK:UNK	NO End Date Time: Sep/30/2020 UNK:UNK	Repeating Pages

090177e196ae3d16\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: 10911170

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:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[enlarged left axillary lymph node]
4.	Start Date Time:	Sep/3/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/30/2020 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

090177e196ae3d16\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: 10911170

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

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
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: 10911170

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.						Repeating Pages

090177e196ae3d16\Final\Final On: 01-Apr-2021 04:25 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1091

Subject No: 10911170

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

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Medication Error

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

090177e196ae3d16\Final\Final On: 01-Apr-2021 04:25 (GMT)

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: 10911170

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.	1	VACCINATIONS	NO	Influenza vaccine	Nov/UNK/2020	Repeating Pages

090177e196ae3d16\Final\Final On: 01-Apr-2021 04:25 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911170

Subject Initials: ---

Generated By: (b) (4)

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

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Concomitant Medications

1.	What is the medication identifier?	[1]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
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).	[Influenza vaccine]
5.	Date:	Nov/UNK/2020

090177e196ae3d16\Final\Final On: 01-Apr-2021 04:25 (GMT)

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: 10911170

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.						Repeating Pages

090177e196ae3d16\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: 10911170

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

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Concomitant Medications

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

090177e196ae3d16\Final\Final On: 01-Apr-2021 04:25 (GMT)

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: 10911170

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.						Repeating Pages

090177e196ae3d16\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: 10911170

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

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Radiation Treatment

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

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911170

Subject Initials: ---

Generated By: (b) (4)

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

#	Transfusion Type	Date of Transfusion	Form Instance
1.			Repeating Pages

090177e196ae3d16\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: 10911170

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: 10911170

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: 10911170

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: LAB URINALYSIS - PREGNANCY TEST

Form Version: 20-Feb-2021 02:14

Form Status: Not Started

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911170

Subject Initials: ---

Generated By: (b) (4)

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

Lab Urinalysis

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

Lab Result

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

090177e196ae3d16\Final\Final On: 01-Apr-2021 04:25 (GMT)

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: 10911170

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?	

090177e196ae3d16\Final\Final On: 01-Apr-2021 04:25 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: CONTACT OUTCOME - MONTH 1

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911170

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: 10911170

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: 10911170

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: 10911170

Subject Initials: ---

Generated By: (b) (4)

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

Informed Consent - Asymptomatic Surveillance

1.	Consent Was:	
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Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911170

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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090177e196ae3d16\Final\Final On: 01-Apr-2021 04:25 (GMT)

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: 10911170

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: 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: 10911170

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	Dec/16/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911170

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
----	---	--

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1091

Subject No: 10911170

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 :	Dec/16/2020
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: 10911170

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 :	//
----	------------------------------	----

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911170

Subject Initials: ---

Generated By: (b) (4)

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

Death Details

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

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1091

Subject No: 10911170

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	Oct/14/2020

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911170

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Casebook Signature Form

1.	Casebook Signature	Click Here to Enable
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090177e196ae3d16\Final\Final On: 01-Apr-2021 04:25 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911170

Subject Initials: ---

Generated By: (b) (4)

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
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1091

Subject No: 10911170

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

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-26-2020 09:56:11 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911170

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
(b) (6)	N/A	Jan-11-2021 19:54:36 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated

Affidavit:

N/A

Samir Arora	Approved	Nov-02-2020 10:44:25 (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.

090177e196ae3d16\Final\Final On: 01-Apr-2021 04:25 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911170

Subject Initials: ---

Generated By: (b) (4)

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

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-26-2020 09:53:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-26-2020 09:53:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae3d16\Final\Final On: 01-Apr-2021 04:25 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1091

Subject No: 10911170

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

[Back to Form](#)

I. Consent Was:

Date	Location	User	Value	Reason
Aug-26-2020 09:54:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Aug/25/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1091

Subject No: 10911170

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
Aug-26-2020 09:53:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 10911170	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-26-2020 09:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> (b) (6)/1963	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-26-2020 09:54:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-26-2020 09:54:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<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
Aug-26-2020 09:54:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> WHITE	Initial Entry

090177e196ae3d16\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: 10911170

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
Aug-26-2020 09:55:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/25/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1091

Subject No: 10911170

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
Aug-26-2020 09:57:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Aug/25/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-26-2020 09:57:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-26-2020 09:57:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> COMPLETED	Initial Entry

090177e196ae3d16\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: 10911170

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

[Back to Form](#)

1.a

Date	Location	User	Value	Reason
Aug-26-2020 10:02:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 1 : Medical History T postmenopausal Start Date: UNK/UNK/2015 Ongoing: YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-26-2020 10:02:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Aug-26-2020 10:02:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: postmenopausal	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
Aug-26-2020 10:02:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2015	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Aug-26-2020 10:02:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3d16\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: 10911170

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.b

Date	Location	User	Value	Reason
Aug-26-2020 10:09:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 2 : Medical History T seasonal aller erm: gies Start Date: UNK/UNK/1 973 Ongoing: YES	Initial Entry

1.b Line/MH Number:

Date	Location	User	Value	Reason
Aug-26-2020 10:09:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Aug-26-2020 10:09:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: seasonal allergies	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Aug-26-2020 10:09:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1973	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Aug-26-2020 10:09:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.c

090177e196ae3d16\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: 10911170

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

Date	Location	User	Value	Reason
Aug-26-2020 10:11:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3 Medical History: torn meniscus (Term: right) Start Date: UNK/UNK/20 15 Ongoing: NO End Date: UNK/UNK/ 2015	Initial Entry

090177e196ae3d16\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: 10911170

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
Aug-26-2020 10:11:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Aug-26-2020 10:11:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: torn meniscus (right)	Initial Entry

1.c Start Date:

Date	Location	User	Value	Reason
Aug-26-2020 10:11:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2015	Initial Entry

1.c Ongoing:

Date	Location	User	Value	Reason
Aug-26-2020 10:11:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2015	Initial Entry

1.d

Date	Location	User	Value	Reason
Aug-26-2020 10:12:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: er: Medical History: torn meniscus (left) Term: Start Date: UNK/UNK/2017	Initial Entry

090177e196ae3d16\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: 10911170

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

			Ongoing:	NO End Date: UNK/UNK/ 2017
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1.d Line/MH Number:

Date	Location	User	Value	Reason
Aug-26-2020 10:12:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

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

Date	Location	User	Value	Reason
Aug-26-2020 10:12:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: torn meniscus (left)	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Aug-26-2020 10:12:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2017	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Aug-26-2020 10:12:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2017	Initial Entry

1.e

Date	Location	User	Value	Reason
Aug-26-2020 10:19:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 5 :	Initial Entry

090177e196ae3d16\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: 10911170

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

			Medical History T tibia break (left) Form: tibia break (left) Start Date: Dec/28/2019 Ongoing: NO End Date: Dec/28/2019	
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1.e Line/MH Number:

Date	Location	User	Value	Reason
Aug-26-2020 10:19:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

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

Date	Location	User	Value	Reason
Aug-26-2020 10:19:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: tibia break (left)	Initial Entry

1.e Start Date:

Date	Location	User	Value	Reason
Aug-26-2020 10:19:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/28/2019	Initial Entry

1.e Ongoing:

Date	Location	User	Value	Reason
Aug-26-2020 10:19:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Dec/28/2019	Initial Entry

1.f

Date	Location	User	Value	Reason
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090177e196ae3d16\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: 10911170

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

Aug-26-2020 10:19:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 6 mber: Medical Histo bilateral osteoarth ry Term: ritis of knees Start Date: UNK/UNK/2015 Ongoing: YES	Initial Entry
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1.f Line/MH Number:

Date	Location	User	Value	Reason
Aug-26-2020 10:19:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

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

Date	Location	User	Value	Reason
Aug-26-2020 10:19:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: bilateral osteoarthritis of knees	Initial Entry

1.f Start Date:

Date	Location	User	Value	Reason
Aug-26-2020 10:19:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2015	Initial Entry

1.f Ongoing:

Date	Location	User	Value	Reason
Aug-26-2020 10:19:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.g

Date	Location	User	Value	Reason
Aug-26-2020 10:22:35 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Nu 7	Transcription Error

090177e196ae3d16\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: 10911170

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

Time (US & Canada)		(b) (4), (b) (6)	Number: Medical History Term: meniscus repair (right) Start Date: UNK/UNK/2015 Ongoing: NO End Date: UNK/UNK/2015	
Aug-26-2020 10:21:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 7 Medical History Term: meniscus tear (right) Start Date: UNK/UNK/2015 Ongoing: NO End Date: UNK/UNK/2015	Initial Entry

090177e196ae3d16\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: 10911170

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
Aug-26-2020 10:21:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

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

Date	Location	User	Value	Reason
Aug-26-2020 10:22:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: meniscus repair (right)	Transcription Error
Aug-26-2020 10:21:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: meniscus tear (right)	Initial Entry

1.g Start Date:

Date	Location	User	Value	Reason
Aug-26-2020 10:21:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2015	Initial Entry

1.g Ongoing:

Date	Location	User	Value	Reason
Aug-26-2020 10:21:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2015	Initial Entry

1.h

Date	Location	User	Value	Reason
Aug-26-2020 10:22:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 8 Medical History Term: meniscus repair (left)	Initial Entry

090177e196ae3d16\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: 10911170

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

			Start Date:	UNK/UNK/2017
			Ongoing:	NO
			End Date:	UNK/UNK/2017

1.h Line/MH Number:

Date	Location	User	Value	Reason
Aug-26-2020 10:22:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 8	Initial Entry

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

Date	Location	User	Value	Reason
Aug-26-2020 10:22:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> meniscus repair (left)	Initial Entry

1.h Start Date:

Date	Location	User	Value	Reason
Aug-26-2020 10:22:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> UNK/UNK/2017	Initial Entry

1.h Ongoing:

Date	Location	User	Value	Reason
Aug-26-2020 10:22:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO End Date: UNK/UNK/2017	Initial Entry

1.i

Date	Location	User	Value	Reason
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090177e196ae3d16\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: 10911170

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

Aug-26-2020 10:23:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 9 : Medical History T anxiety erm: Start Date: UNK/UNK/1 983 Ongoing: YES	Initial Entry
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1.i Line/MH Number:

Date	Location	User	Value	Reason
Aug-26-2020 10:23:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 9	Initial Entry

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

Date	Location	User	Value	Reason
Aug-26-2020 10:23:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: anxiety	Initial Entry

1.i Start Date:

Date	Location	User	Value	Reason
Aug-26-2020 10:23:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1983	Initial Entry

1.i Ongoing:

Date	Location	User	Value	Reason
Aug-26-2020 10:23:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.j

Date	Location	User	Value	Reason
Aug-26-2020 10:24:05	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

090177e196ae3d16\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: 10911170

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

(UTC-05:00) Eastern Time (US & Canada)		(autocalc)	Line/MH Number: 10	
			Medical History Term: osteoarthritis of bilateral hallux	
			Start Date: UNK/UNK/2018	
			Ongoing: YES	

1.j Line/MH Number:

Date	Location	User	Value	Reason
Aug-26-2020 10:24:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10	Initial Entry

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

Date	Location	User	Value	Reason
Aug-26-2020 10:24:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: osteoarthritis of bilateral hallux	Initial Entry

090177e196ae3d16\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: 10911170

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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1.j Start Date:

Date	Location	User	Value	Reason
Aug-26-2020 10:24:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2018	Initial Entry

1.j Ongoing:

Date	Location	User	Value	Reason
Aug-26-2020 10:24:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.k

Date	Location	User	Value	Reason
Aug-26-2020 10:25:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Numbe 11 r: Medical History sulfa drugs all Term: ergy Start Date: UNK/UNK/1 990 Ongoing: YES	Initial Entry

090177e196ae3d16\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: 10911170

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.k Line/MH Number:

Date	Location	User	Value	Reason
Aug-26-2020 10:25:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11	Initial Entry

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

Date	Location	User	Value	Reason
Aug-26-2020 10:25:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: sulfa drugs allergy	Initial Entry

1.k Start Date:

Date	Location	User	Value	Reason
Aug-26-2020 10:25:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1990	Initial Entry

1.k Ongoing:

Date	Location	User	Value	Reason
Aug-26-2020 10:25:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.l

Date	Location	User	Value	Reason
Aug-26-2020 10:25:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 12 : Medical History T iodine allerg erm: y Start Date: UNK/UNK/1 990 Ongoing: YES	Initial Entry

090177e196ae3d16\Final\Final On: 01-Apr-2021 04:25 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1091

Subject No: 10911170

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

1.1 Line/MH Number:

Date	Location	User	Value	Reason
Aug-26-2020 10:25:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12	Initial Entry

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

Date	Location	User	Value	Reason
Aug-26-2020 10:25:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: iodine allergy	Initial Entry

1.1 Start Date:

Date	Location	User	Value	Reason
Aug-26-2020 10:25:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1990	Initial Entry

1.1 Ongoing:

Date	Location	User	Value	Reason
Aug-26-2020 10:25:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.m

Date	Location	User	Value	Reason
Aug-26-2020 10:26:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 13 : Medical History T latex allergy erm: Start Date: UNK/UNK/1 990 Ongoing: YES	Initial Entry

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Header Text: c4591001

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Subject No: 10911170

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
Aug-26-2020 10:26:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 13	Initial Entry

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

Date	Location	User	Value	Reason
Aug-26-2020 10:26:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> latex allergy	Initial Entry

1.m Start Date:

Date	Location	User	Value	Reason
Aug-26-2020 10:26:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> UNK/UNK/1990	Initial Entry

1.m Ongoing:

Date	Location	User	Value	Reason
Aug-26-2020 10:26:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

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Header Text: c4591001

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Form Version: 21-Aug-2020 02:51

Site No: 1091

Subject No: 10911170

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: ---

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1. Date:

Date	Location	User	Value	Reason
Aug-26-2020 10:41:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Aug/25/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-26-2020 10:41:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 105.9	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-26-2020 10:41:53 (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
Aug-26-2020 10:41:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 171.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-26-2020 10:41:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-26-2020 10:41:53	ACV0PFEINFP6000	auto calc	<u>Data Entry:</u>	Initial Entry

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Header Text: c4591001

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Form Version: 21-Aug-2020 02:51

Site No: 1091

Subject No: 10911170

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

(UTC-05:00) Eastern Time (US & Canada)		(autocalc)	36.2	
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7.a

Date	Location	User	Value	Reason
Aug-26-2020 10:41:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier 1 :: Temperature: 36.8 Temperature Unit: Temperature Location: ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-26-2020 10:41:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-26-2020 10:41:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.8	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-26-2020 10:41:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-26-2020 10:41:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1091

Subject No: 10911170

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: ---

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Time (US & Canada)

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

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Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:49**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1091**Site Name:** (1091) Aventiv Research Inc.**Subject No:** 10911170**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:31[Back to Form](#)**1. Lab Panel:**

Date	Location	User	Value	Reason
Aug-26-2020 10:42:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Aug-26-2020 10:42:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Aug-26-2020 10:42:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/25/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Aug-26-2020 10:42:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Aug-26-2020 10:42:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

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Form Status: Data Complete, Locked, Frozen, Verified

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Site Name: (1091) Aventiv Research Inc.

Subject No: 10911170

Subject Initials: ---

Generated By: (b) (4)

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Aug-26-2020 10:42:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Choriogonadotropin Beta_PX113 Result:: NEGATIVE Not Done::	Initial Entry
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Aug-26-2020 10:42:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Aug-26-2020 10:42:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Aug-26-2020 10:42:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1091

Subject No: 10911170

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
Aug-26-2020 10:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/25/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-26-2020 10:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 238310	Initial Entry

090177e196ae3d16\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:** 10911170**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:31[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Aug-26-2020 10:45:35 (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
Aug-26-2020 10:45:35 (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
Aug-27-2020 06:49:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-27-2020 00:41:07 (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.
Aug-26-2020 10:45:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES Date of Collection: Aug/25/2020	Transcription Error
Aug-26-2020 10:45:35 (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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911170

Subject Initials: ---

Generated By: (b) (4)

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				as appropriate.
Aug-26-2020 10:45:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/26/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-27-2020 06:49:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP8M5B	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-27-2020 06:49:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP8M5B	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-27-2020 06:49:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP8M5C	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-27-2020 06:49:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP8M5C	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-27-2020 06:52:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP8M59	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911170

Subject Initials: ---

Generated By: (b) (4)

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

5.c Sample ID

Date	Location	User	Value	Reason
Aug-27-2020 06:52:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP8M59	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-27-2020 06:53:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BPR4FN	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-27-2020 06:53:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BPR4FN	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-27-2020 06:53:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BPR4FP	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-27-2020 06:53:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BPR4FP	Initial Entry

090177e196ae3d16\Final\Final On: 01-Apr-2021 04:25 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911170

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
Aug-26-2020 10:46:46 (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
Aug-26-2020 10:46:46 (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
Aug-27-2020 16:28:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-27-2020 00:41:07 (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.
Aug-26-2020 10:46:46 (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.
Aug-26-2020 10:46:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES Date of Collection:	Initial Entry

090177e196ae3d16\Final\Final On: 01-Apr-2021 04:25 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911170

Subject Initials: ---

Generated By: (b) (4)

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

			Aug/25/2020	
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5.a

Date	Location	User	Value	Reason
Aug-27-2020 16:28:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP8M4T	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-27-2020 16:28:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP8M4T	Initial Entry

090177e196ae3d16\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: 10911170

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-26-2020 10:47:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-26-2020 10:47:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-26-2020 10:47:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Aug-26-2020 10:47:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/25/2020 11:24	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-26-2020 10:47:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Aug-26-2020 10:47:41	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae3d16\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: 10911170

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

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	LEFT	
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7. Route:

Date	Location	User	Value	Reason
Aug-26-2020 10:47:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-26-2020 10:47:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Aug-26-2020 10:47:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3d16\Final\Final On: 01-Apr-2021 04:25 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1091

Subject No: 10911170

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
Aug-26-2020 10:47:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO - REACTOGENICITY E-DI ARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1091

Subject No: 10911170

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-17-2020 07:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/16/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1091

Subject No: 10911170

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

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1. Date:

Date	Location	User	Value	Reason
Sep-17-2020 07:44:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/16/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-17-2020 07:44:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier 1 :: Temperature: 36.7 Temperature Uni C t: Temperature Loc ORAL CAV ation:: ITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-17-2020 07:44:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Sep-17-2020 07:44:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.7	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-17-2020 07:44:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

090177e196ae3d16\Final\Final On: 01-Apr-2021 04:25 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1091

Subject No: 10911170

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

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-17-2020 07:44:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> ORAL CAVITY	Initial Entry

Header Text: c4591001**Visit:** V2_VAX2_L**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:49**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1091**Site Name:** (1091) Aventiv Research Inc.**Subject No:** 10911170**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:31[Back to Form](#)**1. Lab Panel:**

Date	Location	User	Value	Reason
Sep-17-2020 07:51:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-17-2020 07:51:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-17-2020 07:51:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/16/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-17-2020 07:51:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-17-2020 07:51:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911170

Subject Initials: ---

Generated By: (b) (4)

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

Sep-17-2020 07:51:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Choriogonadotropin Beta_PX113 Result:: NEGATIVE Not Done::	Initial Entry
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-17-2020 07:51:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-17-2020 07:51:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-17-2020 07:51:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

090177e196ae3d16\Final\Final On: 01-Apr-2021 04:25 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911170

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
Sep-17-2020 07:51:21 (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-17-2020 07:51:21 (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-21-2020 15:05:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-18-2020 03:36:46 (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-17-2020 07:51:21 (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-17-2020 07:51:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES Date of Collection: Sep/16/2020	Initial Entry

090177e196ae3d16\Final\Final On: 01-Apr-2021 04:25 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911170

Subject Initials: ---

Generated By: (b) (4)

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

5.a

Date	Location	User	Value	Reason
Sep-21-2020 15:05:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPYSV0	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-21-2020 15:05:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPYSV0	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1091

Subject No: 10911170

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-17-2020 07:55:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-17-2020 07:55:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-17-2020 07:55:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-17-2020 07:55:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/16/2020 11:58	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-17-2020 07:55:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-17-2020 07:55:11	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae3d16\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: 10911170

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

(UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	LEFT
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7. Route:

Date	Location	User	Value	Reason
Sep-17-2020 07:55:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-17-2020 07:55:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION 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-17-2020 07:55:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3d16\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: 10911170

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
Oct-19-2020 14:39:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/14/2020	Initial Entry

090177e196ae3d16\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: 10911170

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
Oct-19-2020 14:39:47 (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
Oct-19-2020 14:39:47 (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
Oct-21-2020 02:31:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	V3 DOV updated
Oct-20-2020 10:02:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-20-2020 10:02:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Oct-20-2020 10:02:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES Date of Collection: Oct/14/2020	Transcription Error
Oct-20-2020 08:14:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	PDQ : Date of Collection is not equal to Date of Visit. Please clarify or correct.

090177e196ae3d16\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: 10911170

Subject Initials: ---

Generated By: (b) (4)

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

Oct-19-2020 14:39:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-19-2020 14:39:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/14/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-20-2020 10:02:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP8M1J	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-20-2020 10:02:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP8M1J	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-20-2020 10:02:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSGXSH	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-20-2020 10:02:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSGXSH	Initial Entry

5.c

090177e196ae3d16\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: 10911170

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Oct-20-2020 10:03:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSGXSG	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-20-2020 10:03:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSGXSG	Initial Entry

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1091

Subject No: 10911170

Generated By: (b) (4)

Form: DATE OF VISIT - 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. Date of Visit

Date	Location	User	Value	Reason
Mar-10-2021 13:48:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/10/2021	Initial Entry

090177e196ae3d16\Final\Final On: 01-Apr-2021 04:25 (GMT)

Header Text: c4591001**Visit:** V4_MONTH6_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1091**Subject No:** 10911170**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - 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[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Mar-10-2021 13:48:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-10-2021 13:48:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-10-2021 13:48:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-10-2021 13:48:34 (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.
Mar-10-2021 13:48:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Mar/10/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-10-2021 13:48:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSGYCC	Initial Entry

Header Text: c4591001

Visit: V4_MONTH6_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911170

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Mar-11-2021 16:04:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-11-2021 09:45:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Mar-10-2021 23:40:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW7668878; This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate.
Mar-10-2021 13:48:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry</u> : BSG YCC	Initial Entry

5.b

Date	Location	User	Value	Reason
Mar-10-2021 13:49:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry</u> : Sample ID: BSGYCB	Initial Entry

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Header Text: c4591001

Visit: V4_MONTH6_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911170

Subject Initials: ---

Generated By: (b) (4)

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

5.b Sample ID

Date	Location	User	Value	Reason
Mar-10-2021 13:49:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BSGYCB	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-10-2021 15:28:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BR1S75	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Mar-10-2021 15:28:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BR1S75	Initial Entry

5.d

Date	Location	User	Value	Reason
Mar-11-2021 09:44:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BSGYCC	Transcription Error (DELETED)
Mar-10-2021 15:28:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BSGYCC	Initial Entry

090177e196ae3d16\Final\Final On: 01-Apr-2021 04:25 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911170

Subject Initials: ---

Generated By: (b) (4)

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

5.d Sample ID

Date	Location	User	Value	Reason
Mar-11-2021 16:04:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-11-2021 09:44:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry</u> : BSG YCC	Transcription Error (DELETED)
Mar-11-2021 09:44:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Mar-10-2021 23:40:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW7668879;This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate.
Mar-10-2021 15:28:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry</u> : BSG YCC	Initial Entry

090177e196ae3d16\Final\Final On: 01-Apr-2021 04:25 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911170

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-19-2020 14:40:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/14/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-19-2020 14:40:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-19-2020 14:40:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3d16\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: 10911170

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-17-2020 08:00:52 (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: 10911170

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

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1. Category:

Date	Location	User	Value	Reason
Sep-17-2020 08:00:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Sep-17-2020 08:00:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Sep-17-2020 08:00:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: enlarged left axillary lymph node	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-17-2020 08:00:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/3/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-19-2020 14:51:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Sep/30/2020 UNK:UNK	New Information
Sep-17-2020 08:00:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1091

Subject No: 10911170

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

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-17-2020 08:00:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Sep-17-2020 08:00:52 (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
Sep-17-2020 08:00:52 (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
Oct-06-2020 12:00:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Patricia Banchero (b) (4)	Query 1: Closed	Response satisfies query
Oct-06-2020 09:25:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Related. Reactionary as result of receiving vaccine.
Sep-18-2020 18:51:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Patricia Banchero (b) (4)	Query 1: Opened	GPDCLIN: Per protocol an investigator's causality

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1091

Subject No: 10911170

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

				assessment is the determination of whether there is a reasonable possibility that the IP caused or contributed to an AE. Please provide the facts or arguments to suggest a causal relationship.
Sep-17-2020 08:00:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-17-2020 08:00:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-17-2020 08:00:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-17-2020 08:00:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-19-2020 14:51:54 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1091

Subject No: 10911170

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

Time (US & Canada)				
Oct-19-2020 14:51:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	New Information
Oct-19-2020 14:51:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	For AE enlarged left axillary lymph node: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Sep-28-2020 01:23:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	As per the update
Sep-27-2020 16:46:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Sep-27-2020 16:46:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERING/RESOLVING	Initial Entry
Sep-18-2020 02:42:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: The response for "What was the outcome of this adverse event?" is missing? kindly review and update.

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Sep-17-2020 08:00:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3d16\Final\Final On: 01-Apr-2021 04:25 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911170

Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Mar-10-2021 13:50:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911170

Subject Initials: ---

Generated By: (b) (4)

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

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Mar-10-2021 13:50:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Mar-10-2021 13:50:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Mar-10-2021 13:50:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> NO	Initial Entry

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).

Date	Location	User	Value	Reason
Mar-10-2021 13:50:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Influenza vaccine	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Mar-10-2021 13:50:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Nov/UNK/2020	Initial Entry

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Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911170

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
Jan-11-2021 19:54:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/16/2020	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit
Trail History

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911170

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
Jan-11-2021 19:55:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-11-2021 19:54:55 (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.
Jan-11-2021 19:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willing to return f or Vaccination 3 Participant is: eligible and NOT confirmed to have received only placeb o at Vaccination 1/2	Initial Entry

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Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1091

Subject No: 10911170

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
Jan-11-2021 19:55:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/16/2020	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-11-2021 19:55:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILITY FOR A DDITIONAL VACCINATION	Initial Entry

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Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1091

Subject No: 10911170

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
Oct-19-2020 14:40:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-26-2020 10:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-26-2020 09:57:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Oct-19-2020 14:40:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/14/2020	Initial Entry
Aug-26-2020 10:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/25/2020	Initial Entry
Aug-26-2020 09:57:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/25/2020	Initial Entry

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Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911170

Subject Initials: ---

Generated By: (b) (4)

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

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1. Casebook Signature

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