

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT_SELECTION

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Cohort Selection

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

1.	Select appropriate response - Protocol version	01 DEC 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Dec/22/2020
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Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10911447]
2.	Birth Date:	(b) (6) 2005
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1091

Subject No: 10911447

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): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Dec/22/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:00

Site No: 1091

Subject No: 10911447

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): 10-Nov-2021 20:44

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1091

Subject No: 10911447

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): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation /Death	Dec/22/2020
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: 10911447

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): 10-Nov-2021 20:44

Form Comments

Medical History Details

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

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1091

Subject No: 10911447

Generated By: (b) (4)

Form: HIV STATUS

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1091) Aventiv Research Inc.

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

HIV Status

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Dec-2020 02:29

Site No: 1091

Subject No: 10911447

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): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Dec/22/2020
2.	Weight:	[48.1]
3.	Unit:	kg
4.	Height:	[158.8]
5.	Unit:	cm
6.	Body Mass Index:	[19.1]

Vital Signs Details

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

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1091

Subject No: 10911447

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1091) Aventiv Research Inc.

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Dec/22/2020
2.	Randomization Number:	[23767]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Dec/22/2020
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	[BS3FR1]
5.b	Sample ID	[BPYSGP]
5.c	Sample ID	[BPYSGN]

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Dec/22/2020
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	[BPYSGT]
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

eCRF Audit Trail History

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Dec/22/2020 10:41
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

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1091

Subject No: 10911447

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): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Reactogenicity Diary

1.	Select appropriate response - Reactogenicity diary collection	YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT
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Header Text: c4591001

Visit: V2_VAX2_L

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/14/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO
2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENERED JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP

Form Version: 14-Jan-2021 02:22

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Jan/14/2021
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[37.1]
	Unit:	C
	Temperature Location:	ORAL CAVITY

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/14/2021
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	[BRFGLS]
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090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1091

Subject No: 10911447

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1091) Aventiv Research Inc.

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

eCRF Audit Trail History

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/14/2021 11:25
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

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (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: 10911447 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/15/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 10-Dec-2020 02:30 **Form Status:** Data Complete, Locked, Frozen, Verified

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

Subject No: 10911447 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO
2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 10-Dec-2020 02:30 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENERED JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 10-Dec-2020 02:30 **Form Status:** Data Complete, Locked, Frozen, Verified

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

Subject No: 10911447 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

Subject No: 10911447 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Feb/15/2021
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	[BSGY42]
5.b	Sample ID	[BR1RZJ]
5.c	Sample ID	[BR1RZK]

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1091

Subject No: 10911447

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1091) Aventiv Research Inc.

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V4_MONTH6_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jul/8/2021
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	[BR1R7J]
5.b	Sample ID	[BNWWGB]
5.c	Sample ID	[BNWWG9]

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1091

Subject No: 10911447

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1091) Aventiv Research Inc.

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:03

Site No: 1091

Subject No: 10911447

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1091) Aventiv Research Inc.

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1091

Subject No: 10911447

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1091) Aventiv Research Inc.

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:03

Site No: 1091

Subject No: 10911447

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1091) Aventiv Research Inc.

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/16/2021

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/16/2021
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/16/2021

Form Version: 14-Jan-2021 02:23

Site No: 1091

Subject No: 10911447

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Status: Data Complete

Site Name: (1091) Aventiv Research Inc.

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Signs and Symptoms

1.	Date of Assessment:	Feb/16/2021
2.	Date of First Symptom Started:	Dec/22/2020
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Dec/22/2020

Symptoms

4.a	Symptoms:	FEVER
	Was symptom present?	NO
4.b	Symptoms:	NEW OR INCREASED COUGH
	Was symptom present?	NO
4.c	Symptoms:	NEW OR INCREASED SHORTNESS OF BREATH
	Was symptom present?	NO
4.d	Symptoms:	CHILLS
	Was symptom present?	NO
4.e	Symptoms:	NEW OR INCREASED MUSCLE PAIN
	Was symptom present?	NO

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/16/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

4.f	Symptoms:	NEW LOSS OF TASTE OR SMELL
	Was symptom present?	NO
4.g	Symptoms:	NEW OR INCREASED SORE THROAT
	Was symptom present?	NO
4.h	Symptoms:	DIARRHEA
	Was symptom present?	NO
4.i	Symptoms:	VOMITING
	Was symptom present?	YES
Symptoms - Other		
5.a	Symptoms - Other Text:	[fatigue]
5.b	Symptoms - Other Text:	[vomiting]

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Not Done	Not Done	Not Done	Not Done	Not Done	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/16/2021

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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[Form Comments](#)

[eCRF Audit Trail History](#)

Microbiology Specimen

1.	Actual Date of Collection:	Not Done _____ //	Comments
2.	Specimen Type:	Not Done _____	Comments
3.	Specimen Collection Location:	Not Done _____	Comments
4.	Assay Code and Description:	Not Done _____	Comments
5.	Device Type:	Not Done _____	Comments
6.	Trade Name:	Not Done _____	Comments
7.	Test Result:	Not Done _____	Comments
8.	Comments/Findings /Details:	Not Done _____ []	Comments
9.	Trade Name Other, Specify:	Not Done _____ []	Comments

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 -
Unscheduled Visit on Feb/16/2021**Form:** ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1091**Site Name:** (1091) Aventiv Research Inc.**Subject No:** 10911447**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 10-Nov-2021 20:44[eCRF Audit Trail History](#)**Electronic Sample Tracking**

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/16/2021

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/16/2021

Form: HEALTH CARE UTILIZATION

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Health Care Utilization

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

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/16/2021

Form: HEALTH CARE UTILIZATION

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

1.f	Physician or Healthcare Professional:	OTHER
	Occurrence of Visits or Contacts:	NO

Health Care Utilization Other

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

Health Care Utilization

3.	Has the subject been hospitalized due to potential COVID-19 illness?	NO
----	--	----

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

#	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Treatment	Start Date	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/16/2021

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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Respiratory Treatment

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

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/16/2021

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Illness Details

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

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

#	Category of Clinical Event:	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.					Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/16/2021

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Form Status: Not Started

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Illness Details

1.	Category of Clinical Event:	
2.	Subcategory of Clinical Event:	
3.	Was a diagnosis obtained?	
4.	Toxicity Grade:	

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 10-Dec-2020 02:24

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1.					Sponsor-Defined Identifier	Test:	Result:	Repeating Pages

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/16/2021

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY

Form Version: 10-Dec-2020 02:24

Form Status: Not Started

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Lab Chemistry Details

1.	Lab Panel:	
2.	Laboratory Name and Address	[]
3.	Collection Date:	//
4.	Specimen Type:	

Lab Result

5.	Sponsor ID:	[]
	Test:	
	Result:	[]
	Not Done:	
	LNMT	Low [] High [] Unit

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 10-Dec-2020 02:28

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date	Specimen Type	Lab Result			Form Instance
1.					Sponsor-Defined Identifier	Test:	Result:	Repeating Pages

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/16/2021

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Version: 10-Dec-2020 02:28

Form Status: Not Started

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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Laboratory Data Hematology

1.	Lab Panel:	
2.	Laboratory Name and Address	[]
3.	Collection Date:	//
4.	Specimen Type:	

Lab Result

5.	Sponsor ID:	[]
	Test:	
	Result:	[]
	Not Done:	
	LNMT	Low [] High [] Unit

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 10-Dec-2020 02:25

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

#	Date:	Vital Signs Details			Form Instance
1.		Record Identifier:	Systolic:	Diastolic:	Repeating Pages

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/16/2021

Form: VITAL SIGNS - COVID

Form Version: 10-Dec-2020 02:25

Form Status: Not Started

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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Vital Signs

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

Vital Signs Details

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

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 10-Dec-2020 02:31

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

#	Date:	Vital Signs Details		Form Instance
1.		Record Identifier:	Oxygen Saturation	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/16/2021

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 10-Dec-2020 02:31

Form Status: Not Started

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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Vital Signs

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

Vital Signs Details

2.	Record Identifier:	
	SPO2 Pulse Oximetry %	[]

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.				Repeating Pages

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/16/2021

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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Oxygenation Parameters

1.	Date Time of Assessment:	//
2.	Arterial Blood Gases PaO2 (mmHg):	[]
3.	FiO2 (Fraction of Inhaled Oxygen):	[]

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: CONCOMITANT MEDICATIONS -
VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/16/2021

Form Version: 06-Jul-2020 21:55

Site No: 1091

Subject No: 10911447

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS -
VASOPRESSORS

Form Status: Not Started

Site Name: (1091) Aventiv Research Inc.

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

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Concomitant Medications

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

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.					Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/16/2021

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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Imaging

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

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Apr/01/2021

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Date of Visit

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

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_A1
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Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Apr/01/2021

Form Version: 22-Apr-2020 21:03

Site No: 1091

Subject No: 10911447

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

Site Name: (1091) Aventiv Research Inc.

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR1SCH]
5.b	Sample ID	[BLG1GS]
5.c	Sample ID	[BLG1GT]

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

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

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

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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: 10911447 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: Unplanned - New Unscheduled **Form:** DATE OF VISIT
Visit

Form Version: 22-Apr-2020 21:02 **Form Status:** Not Started

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

Subject No: 10911447 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit **Form:** UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04 **Form Status:** Not Started

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

Subject No: 10911447 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

Unplanned Assessments

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

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: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: VITAL SIGNS - TEMP

Form Version: 30-Apr-2021 01:41

Form Status: Not Started

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Vital Signs

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

Vital Signs Details

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

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Vaccination

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

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (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: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Contact Outcome

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

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: CONTACT OUTCOME - MONTH 6

Form Version: 10-Oct-2020 16:01

Form Status: Not Started

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Contact Outcome

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - **Form:** DATE OF VISIT
Unscheduled

Form Version: 22-Apr-2020 21:02 **Form Status:** Not Started

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

Subject No: 10911447 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: INFORMED CONSENT - ASYMPTOMATIC
SURVEILLANCE

Form Version: 14-Jan-2021 02:29

Form Status: Not Started

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Informed Consent - Asymptomatic Surveillance

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

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: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: 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: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

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

Form Version: 10-Dec-2020 02:29 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Feb/15/2021
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

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

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

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

Subject No: 10911447 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Mar/16/2021
2.	Erroneous Visit	

Header Text: c4591001

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

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

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

Subject No: 10911447 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

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

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53

Form Status: Not Started

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Disposition - Follow-Up

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

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: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1. DELETED	ADVERSE EVENT	1	fatigue	Dec/22/2020 11:05	NO End Date Time: Dec/22/2020 20:00	Repeating Pages
2. DELETED	ADVERSE EVENT	2	vomiting	Dec/22/2020 11:20	NO End Date Time: Dec/22/2020 11:25	Repeating Pages
3.	ADVERSE EVENT	3	Appendicitis	Jul/10/2021 03:00	NO End Date Time: Jul/10/2021 08:00	Repeating Pages

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Deleted

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

***** THIS REPEATING FORM HAS BEEN DELETED *****

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[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[±]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[fatigue]
4.	Start Date Time:	Dec/22/2020 11:05
5.	Is the adverse event still ongoing?	NO End Date Time: Dec/22/2020 20:00
6.	Toxicity Grade:	2

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Deleted

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

***** THIS REPEATING FORM HAS BEEN DELETED *****

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:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [vasovagal with blood draw]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Deleted

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

***** THIS REPEATING FORM HAS BEEN DELETED *****

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	[]

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Deleted

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

***** THIS REPEATING FORM HAS BEEN DELETED *****

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[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[vomiting]
4.	Start Date Time:	Dec/22/2020 11:20
5.	Is the adverse event still ongoing?	NO End Date Time: Dec/22/2020 11:25
6.	Toxicity Grade:	2

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Deleted

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

***** THIS REPEATING FORM HAS BEEN DELETED *****

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:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [vasovagal with blood draw]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Deleted

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

***** THIS REPEATING FORM HAS BEEN DELETED *****

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	[]

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1091

Subject No: 10911447

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Queries, Frozen

Site Name: (1091) Aventiv Research Inc.

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Appendicitis]
4.	Start Date Time:	Jul/10/2021 03:00
5.	Is the adverse event still ongoing?	NO End Date Time: Jul/10/2021 08:00
6.	Toxicity Grade:	2

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1091**Subject No:** 10911447**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, Queries, Frozen**Site Name:** (1091) Aventiv Research Inc.**Subject Initials:** ---**Generated Time (GMT):** 10-Nov-2021 20:44

7.	<p>Is the adverse event serious?</p> <p>If Yes, NOTIFY PFIZER IMMEDIATELY.</p> <p>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).</p>	<p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect? NO</p> <p>Did this serious event result in death? NO</p> <p>Did this serious event require or prolong hospitalization? YES</p> <p>Did this serious event result in persistent or significant disability/incapacity? NO</p> <p>Is this serious event life threatening? NO</p> <p>Other medically important serious event NO</p>
8.	<p>Is this adverse event the result of a study Medication Error?</p> <p>If Yes, record the type of medication error on the Medication Error Log.</p>	NO
9.	<p>Is this event related to study treatment:</p>	<p>NOT RELATED</p> <p>If Not Related to study treatment(s), this event is due to: OTHER</p> <p>If Other, specify: [Appendicitis]</p>
10.	<p>Latest Action Taken with Study Treatment:</p>	NOT APPLICABLE

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Queries, Frozen

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	YES
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	[2021881783]

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

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: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Form Status: Not Started

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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Medication Error

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

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (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: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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Concomitant Medications

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

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (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: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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Concomitant Medications

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

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (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: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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Radiation Treatment

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

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

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: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

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

Header Text: c4591001

Visit:
UNPLANNED_BOOSTER_CONTACT
- 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: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit:
UNPLANNED_BOOSTER_CONTACT
- Unscheduled

Form: BOOSTER DOSE TRIGGER FORM

Form Version: 13-Apr-2021 01:26

Form Status: Not Started

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Booster Dose Trigger Form

- | | | |
|----|--|--|
| 1. | Select appropriate response
- Will the participant return
for consent/eligibility
assessment for the booster
dose visit? | |
|----|--|--|

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED

Form Version: 10-Dec-2020 02:27

Form Status: Data Complete, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Mar/17/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Feb/15/2021

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: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Casebook Signature Form

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

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: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Audit Trail](#)

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA -
Comments

Form Version: 10-Oct-2020 16:00

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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Item	Date	User	Comment
Form	Dec-22-2020 12:14:00 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	all criteria met <hr/> Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1091

Subject No: 10911447

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1091) Aventiv Research Inc.

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

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Item	Date	User	Comment
Form	Dec-22-2020 12:15:03 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [Redacted]	no medical history reported <hr/> Not Applicable

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/16/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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Item	Date	User	Comment
Form	Feb-16-2021 16:11:21 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/16/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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Item	Date	User	Comment
1	Feb-16-2021 16:11:21 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/16/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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Item	Date	User	Comment
2	Feb-16-2021 16:11:21 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/16/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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Item	Date	User	Comment
3	Feb-16-2021 16:11:21 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/16/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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Item	Date	User	Comment
4	Feb-16-2021 16:11:21 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/16/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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Item	Date	User	Comment
5	Feb-16-2021 16:11:21 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/16/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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Item	Date	User	Comment
6	Feb-16-2021 16:11:21 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/16/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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Item	Date	User	Comment
7	Feb-16-2021 16:11:21 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/16/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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Item	Date	User	Comment
8	Feb-16-2021 16:11:21 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/16/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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Item	Date	User	Comment
9	Feb-16-2021 16:11:21 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

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: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
(b) (6)	N/A	Apr-01-2021 17:19:34 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated

Affidavit:

N/A

Samir Arora	Approved	Mar-22-2021 16:29:24 (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.

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Dec-22-2020 12:12:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 01 DEC 2020	Initial Entry

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

Date	Location	User	Value	Reason
Dec-22-2020 12:12:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Consent Was:

Date	Location	User	Value	Reason
Dec-22-2020 12:13:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Dec/22/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Subject ID

Date	Location	User	Value	Reason
Dec-22-2020 12:12:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 10911447	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Dec-22-2020 12:12:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: (b) (6) 2005	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Dec-22-2020 12:13:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Dec-22-2020 12:13:26 (UTC-05:00) Eastern	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Data Entry: NOT HISPANIC OR LATI NO(A) OR OF SPANISH O	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Time (US & Canada)

RIGIN

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

Date	Location	User	Value	Reason
Dec-22-2020 12:13:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1091

Subject No: 10911447

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): 10-Nov-2021 20:44

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1. Date of Visit

Date	Location	User	Value	Reason
Dec-22-2020 12:13:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Dec/22/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Dec-22-2020 12:14:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Dec/22/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Dec-22-2020 12:14:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Dec-22-2020 12:14:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1091

Subject No: 10911447

Generated By: (b) (4)

Form: HIV STATUS - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1091) Aventiv Research Inc.

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

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

Date	Location	User	Value	Reason
Dec-22-2020 12:15:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: The subject is NOT known to be HIV POSITIVE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Date:

Date	Location	User	Value	Reason
Dec-22-2020 12:16:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Dec/22/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Dec-22-2020 12:16:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 48.1	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Dec-22-2020 12:16:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Dec-22-2020 12:16:48	ACV0PF EINFP60	(b) (4), (b) (6)	Data Entry: 158.8	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

(UTC-05:00) Eastern Time (US & Canada)	00			
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5. Unit:

Date	Location	User	Value	Reason
Dec-22-2020 12:16:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Dec-22-2020 12:16:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 19.1	Initial Entry

7.a

Date	Location	User	Value	Reason
Dec-22-2020 12:16:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Record Identifier: Temperature: 36.8 Temperature Unit: Temperature Location: ORAL CAVITY	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

7.a Record Identifier:

Date	Location	User	Value	Reason
Dec-22-2020 12:16:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Dec-22-2020 12:16:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 36.8	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Dec-22-2020 12:16:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Dec-22-2020 12:16:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1091

Subject No: 10911447

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): 10-Nov-2021 20:44

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1. Randomization Date :

Date	Location	User	Value	Reason
Dec-22-2020 12:17:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Dec/22/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Dec-22-2020 12:17:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 23767	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1091

Subject No: 10911447

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1091) Aventiv Research Inc.

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

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1. Data Origin

Date	Location	User	Value	Reason
Dec-22-2020 12:17:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-22-2020 12:17:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-28-2020 11:45:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-23-2020 07:12:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (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: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

				correct as appropriate.
Dec-22-2020 12:17:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-22-2020 12:17:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Dec/22/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-28-2020 11:45:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BS3FR1	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Dec-28-2020 11:45:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BS3FR1	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (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: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

5.b

Date	Location	User	Value	Reason
Dec-28-2020 14:25:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BPYSGP	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Dec-28-2020 14:25:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BPYSGP	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-28-2020 14:45:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BPYSGN	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Dec-28-2020 14:45:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BPYSGN	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (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: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Data Origin

Date	Location	User	Value	Reason
Dec-22-2020 12:17:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-22-2020 12:17:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-28-2020 14:55:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-23-2020 07:12:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (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: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

				correct as appropriate.
Dec-22-2020 12:17:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-22-2020 12:17:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Dec/22/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-28-2020 14:55:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BPYSGT	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Dec-28-2020 14:55:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BPYSGT	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Dec-2020 02:26

Site No: 1091

Subject No: 10911447

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): 10-Nov-2021 20:44

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Dec-22-2020 12:18:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Dec-22-2020 12:18:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Dec-22-2020 12:18:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Dec-22-2020 12:18:23 (UTC-05:00) Eastern	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Dec/22/2020 10:41	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Time (US & Canada)

5. Anatomical Location:

Date	Location	User	Value	Reason
Dec-22-2020 12:18:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Dec-22-2020 12:18:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Dec-22-2020 12:18:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Dec-22-2020 12:18:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIE D OBSERVATION PERIOD	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

Date	Location	User	Value	Reason
Dec-22-2020 12:18:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Dec-22-2020 12:18:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES - REACTOGENICITY E-DIARY COLLECTED F OR THIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1091

Subject No: 10911447

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): 10-Nov-2021 20:44

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-14-2021 16:50:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jan/14/2021	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-14-2021 16:51:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Jan-14-2021 16:51:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: FE V ER Were fever or systemi c symptoms present o n the last day the Subj ect Diary was complet ed?: N O	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Jan-14-2021 16:51:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-14-2021 16:51:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Jan-14-2021 16:51:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: FA TI GU E Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

2.b Symptom:

Date	Location	User	Value	Reason
Jan-14-2021 16:51:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: FATIGUE	Initial Entry

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-14-2021 16:51:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Jan-14-2021 16:51:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: HE AD AC HE Were fever or system ic symptoms present on the last day the Su bject Diary was com pleted?: NO	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

2.c Symptom:

Date	Location	User	Value	Reason
Jan-14-2021 16:51:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: HEADACHE	Initial Entry

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-14-2021 16:51:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Jan-14-2021 16:51:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: C HI LL S Were fever or systemi N c symptoms present o O n the last day the Subj ect Diary was complet ed?:	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

2.d Symptom:

Date	Location	User	Value	Reason
Jan-14-2021 16:51:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-14-2021 16:51:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Jan-14-2021 16:51:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: VO MI TIN G Were fever or system NO ic symptoms present on the last day the Su bject Diary was com pleted?:	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

2.e Symptom:

Date	Location	User	Value	Reason
Jan-14-2021 16:51:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-14-2021 16:51:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Jan-14-2021 16:51:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: DI AR RH EA Were fever or system ic symptoms present on the last day the Su bject Diary was comp leted?: NO	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

2.f Symptom:

Date	Location	User	Value	Reason
Jan-14-2021 16:51:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-14-2021 16:51:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Jan-14-2021 16:51:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: NEW O R WOR SENED MUSCL E PAIN Were fever or sy NO stemic symptoms present on the la st day the Subjec t Diary was com pleted?:	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

2.g Symptom:

Date	Location	User	Value	Reason
Jan-14-2021 16:51:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NEW OR WORSENERD M USCLE PAIN	Initial Entry

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-14-2021 16:51:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Jan-14-2021 16:51:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: NEW O R WOR SENERD JOINT PAIN Were fever or sys NO temic symptoms present on the las t day the Subject Diary was compl eted?:	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

2.h Symptom:

Date	Location	User	Value	Reason
Jan-14-2021 16:51:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NEW OR WORSENERD JOI NT PAIN	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-14-2021 16:51:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Jan-14-2021 16:51:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Jan-14-2021 16:51:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

5.a

Date	Location	User	Value	Reason
Jan-14-2021 16:51:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Injection Site Reaction: RES DN ES S Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Jan-14-2021 16:51:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: REDNESS	Initial Entry

5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-14-2021 16:51:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.b

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Jan-14-2021 16:51:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Injection Site Reaction: SW ELL ING Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Jan-14-2021 16:51:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: SWELLING	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-14-2021 16:51:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
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090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Jan-14-2021 16:51:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Injection Site Reaction: PAIN AT INJECTION SITE Were injection site reactions present on the last day the Subject Diary was completed?:	Initial Entry
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5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Jan-14-2021 16:51:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

5.c Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-14-2021 16:51:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 14-Jan-2021 02:22

Site No: 1091

Subject No: 10911447

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): 10-Nov-2021 20:44

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1. Date:

Date	Location	User	Value	Reason
Jan-14-2021 16:51:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jan/14/2021	Initial Entry

2.a

Date	Location	User	Value	Reason
Jan-14-2021 16:51:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Record Identifi er:: Temperature: 37.1 Temperature U C nit: Temperature L ORAL CA ocation:: VITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Jan-14-2021 16:51:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Temperature:

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:22

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Jan-14-2021 16:51:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 37.1	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Jan-14-2021 16:51:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: C	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Jan-14-2021 16:51:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (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: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Data Origin

Date	Location	User	Value	Reason
Jan-14-2021 16:51:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-14-2021 16:51:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-14-2021 16:52:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-14-2021 16:51:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (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: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Jan-14-2021 16:51:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/14/2021	Initial Entry
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5.a

Date	Location	User	Value	Reason
Jan-14-2021 16:52:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BRFGLS	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-14-2021 16:52:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BRFGLS	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1091

Subject No: 10911447

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): 10-Nov-2021 20:44

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jan-14-2021 16:52:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jan-14-2021 16:52:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-14-2021 16:52:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Jan-14-2021 16:52:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jan/14/2021 11:25	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-14-2021 16:52:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Jan-14-2021 16:52:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Jan-14-2021 16:52:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-14-2021 16:52:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIE D 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
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090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Jan-14-2021 16:52:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted]	Data Entry: YES	Initial Entry
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Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** DATE OF VISIT - eCRF Audit Trail History

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

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

Subject No: 10911447 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-15-2021 12:28:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Feb/15/2021	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30 **Form Status:** Data Complete, Locked, Frozen, Verified

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

Subject No: 10911447 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

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1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-15-2021 12:29:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Feb-15-2021 12:29:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: FE V ER Were fever or systemi c symptoms present o n the last day the Subj ect Diary was complet ed?: N O	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Feb-15-2021 12:29:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30 **Form Status:** Data Complete, Locked, Frozen, Verified

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

Subject No: 10911447 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-15-2021 12:29:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Feb-15-2021 12:29:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: FA TI GU E Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30 Form Status: Data Complete, Locked, Frozen, Verified

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

Subject No: 10911447 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

2.b Symptom:

Date	Location	User	Value	Reason
Feb-15-2021 12:29:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: FATIGUE	Initial Entry

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-15-2021 12:29:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Feb-15-2021 12:29:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: HE AD AC HE Were fever or system ic symptoms present on the last day the Su bject Diary was com pleted?: NO	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30 Form Status: Data Complete, Locked, Frozen, Verified

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

Subject No: 10911447 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

2.c Symptom:

Date	Location	User	Value	Reason
Feb-15-2021 12:29:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: HEADACHE	Initial Entry

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-15-2021 12:29:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Feb-15-2021 12:29:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: C HI LL S Were fever or systemi N c symptoms present o O n the last day the Subj ect Diary was complet ed?:	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30 Form Status: Data Complete, Locked, Frozen, Verified

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

Subject No: 10911447 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

2.d Symptom:

Date	Location	User	Value	Reason
Feb-15-2021 12:29:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-15-2021 12:29:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Feb-15-2021 12:29:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: VO MI TIN G Were fever or system NO ic symptoms present on the last day the Su bject Diary was com pleted?:	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30 Form Status: Data Complete, Locked, Frozen, Verified

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

Subject No: 10911447 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

2.e Symptom:

Date	Location	User	Value	Reason
Feb-15-2021 12:29:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-15-2021 12:29:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Feb-15-2021 12:29:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: DI AR RH EA Were fever or system ic symptoms present on the last day the Su bject Diary was comp leted?: NO	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30 Form Status: Data Complete, Locked, Frozen, Verified

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

Subject No: 10911447 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

2.f Symptom:

Date	Location	User	Value	Reason
Feb-15-2021 12:29:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-15-2021 12:29:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Feb-15-2021 12:29:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: NEW O R WOR SENED MUSCL E PAIN Were fever or sy NO stemic symptoms present on the la st day the Subjec t Diary was com pleted?:	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30 Form Status: Data Complete, Locked, Frozen, Verified

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

Subject No: 10911447 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

2.g Symptom:

Date	Location	User	Value	Reason
Feb-15-2021 12:29:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NEW OR WORSENERD M USCLE PAIN	Initial Entry

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-15-2021 12:29:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Feb-15-2021 12:29:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: NEW O R WOR SENERD JOINT PAIN Were fever or sys NO temic symptoms present on the las t day the Subject Diary was compl eted?:	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30 Form Status: Data Complete, Locked, Frozen, Verified

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

Subject No: 10911447 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

2.h Symptom:

Date	Location	User	Value	Reason
Feb-15-2021 12:29:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NEW OR WORSENERD JOI NT PAIN	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-15-2021 12:29:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Feb-15-2021 12:29:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Feb-15-2021 12:29:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30 Form Status: Data Complete, Locked, Frozen, Verified

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

Subject No: 10911447 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

5.a

Date	Location	User	Value	Reason
Feb-15-2021 12:29:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Injection Site Reaction: RE DN ES S Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Feb-15-2021 12:29:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: REDNESS	Initial Entry

5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-15-2021 12:29:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.b

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30 Form Status: Data Complete, Locked, Frozen, Verified

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

Subject No: 10911447 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Feb-15-2021 12:29:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Injection Site Reaction: SW ELL ING Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Feb-15-2021 12:29:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: SWELLING	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-15-2021 12:29:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
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090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30 Form Status: Data Complete, Locked, Frozen, Verified

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

Subject No: 10911447 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

Feb-15-2021 12:29:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Injection Site Reaction: PAIN AT INJECTION SITE Were injection site reactions present on the last day the Subject Diary was completed?:	Initial Entry
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5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Feb-15-2021 12:29:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

5.c Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-15-2021 12:29:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (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: 10911447 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

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1. Data Origin

Date	Location	User	Value	Reason
Feb-15-2021 12:29:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-15-2021 12:29:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-15-2021 13:35:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-15-2021 12:29:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (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: 10911447 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

				correct as appropriate.
Feb-15-2021 12:29:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/15/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-15-2021 13:35:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BSGY42	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-15-2021 13:35:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BSGY42	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-15-2021 13:35:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BR1RZJ	Initial Entry

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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: 10911447 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

5.b Sample ID

Date	Location	User	Value	Reason
Feb-15-2021 13:35:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BR1RZJ	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-15-2021 13:35:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BR1RZK	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Feb-15-2021 13:35:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BR1RZK	Initial Entry

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Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1091

Subject No: 10911447

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1091) Aventiv Research Inc.

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

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1. Date of Visit

Date	Location	User	Value	Reason
Jul-08-2021 15:05:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jul/8/2021	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, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Data Origin

Date	Location	User	Value	Reason
Jul-08-2021 15:06:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jul-08-2021 15:06:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jul-08-2021 16:44:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jul-08-2021 15:06:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (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, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Jul-08-2021 15:06:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jul/8/2021	Initial Entry
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5.a

Date	Location	User	Value	Reason
Jul-08-2021 16:44:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BR1R7J	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jul-08-2021 16:44:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BR1R7J	Initial Entry

5.b

Date	Location	User	Value	Reason
Jul-08-2021 16:44:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BNWWGB	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, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

5.b Sample ID

Date	Location	User	Value	Reason
Jul-08-2021 16:44:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BNWWGB	Initial Entry

5.c

Date	Location	User	Value	Reason
Jul-08-2021 16:44:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BNWWG9	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Jul-08-2021 16:44:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BNWWG9	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/16/2021

Form Version: 22-Apr-2020 21:03

Site No: 1091

Subject No: 10911447

Generated By: (b) (4)

Form: DATE OF VISIT - ILLNESS ONSET - eCRF
Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1091) Aventiv Research Inc.

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

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1. Date of Visit

Date	Location	User	Value	Reason
Apr-09-2021 04:13:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Apr-05-2021 05:08:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 3: Reissued:Candida te	PDQ RQ1: As per Query response, CONVA visit will be checked after 5Apr21.
Apr-01-2021 14:30:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 3: Answered	Visit is scheduled for today and will be entered upon completion.
Apr-01-2021 06:07:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 3: Opened	PDQ: Convalescent visit is missing and 35+ days (44) have passed since COVID Illness Visit. If visit occurred record data as a matching

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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/16/2021

Form Version: 22-Apr-2020 21:03

Site No: 1091

Subject No: 10911447

Generated By: (b) (4)

Form: DATE OF VISIT - ILLNESS ONSET - eCRF
Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1091) Aventiv Research Inc.

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

				CONVA visit; if visit did not occur attempt to schedule visit even if OOW and obtain the CONVA sample else clarify.
Feb-24-2021 02:31:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	As per site confirmation - updated PD tracker
Feb-23-2021 14:27:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Answered	A nasal swab was not collected for this visit. Subject was present on site for study visit when vasovagal response occurred. Originally reported as AEs but was later changed and an ill visit added to capture symptoms.
Feb-17-2021 05:20:16	ACV0PF EINFP60	(b) (4), (b) (6)	Query 1: Opened	PDQ: Date of Visit is

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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/16/2021

Form: DATE OF VISIT - ILLNESS ONSET - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

(UTC-05:00) Eastern Time (US & Canada)	00			completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Feb-16-2021 16:14:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Data Entry: Feb/16/2021	Changed Information
Feb-16-2021 16:10:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Feb-16-2021 16:08:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Feb-16-2021	ACV0PF	auto query	Query 1: Candidate	Date of Visit is

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/16/2021

Form: DATE OF VISIT - ILLNESS ONSET - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

16:08:28 (UTC-05:00) Eastern Time (US & Canada)	EINFP60 00	(autoquery)		completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Feb-16-2021 16:08:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Data Entry: Dec/22/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Feb-16-2021 16:08:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: COVID_A	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/16/2021

Form Version: 14-Jan-2021 02:23

Site No: 1091

Subject No: 10911447

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1091) Aventiv Research Inc.

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

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1. Date of Assessment:

Date	Location	User	Value	Reason
Feb-16-2021 16:15:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-16-2021 16:15:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Feb/16/2021	Changed Information
Feb-16-2021 16:14:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Opened	Date of assessment is not same as Date Visit. Please check and correct.
Feb-16-2021 16:10:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Dec/22/2020	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Feb-16-2021 16:10:31 (UTC-05:00) Eastern	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Dec/22/2020	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/16/2021

Form Version: 14-Jan-2021 02:23

Site No: 1091

Subject No: 10911447

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1091) Aventiv Research Inc.

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

Time (US & Canada)

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Feb-16-2021 16:11:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-16-2021 16:11:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO Date of Last Symptom Re solved: Dec/22/2020	Transcription Error
Feb-16-2021 16:10:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Opened	Last Symptom Resolved date is a future date compared to when it was entered. Please correct.
Feb-16-2021 16:10:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO Date of Last Symptom Re solved: Dec/22/2021	Initial Entry

4.a

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/16/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Feb-16-2021 16:10:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptoms: FEVE R Symptom Present NO :	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Feb-16-2021 16:10:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Feb-16-2021 16:10:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Feb-16-2021 16:10:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom NEW OR INCR s: EASED COUG H	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/16/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

			Symptom NO Present:	
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4.b Symptoms:

Date	Location	User	Value	Reason
Feb-16-2021 16:10:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED CO UGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Feb-16-2021 16:10:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.c

Date	Location	User	Value	Reason
Feb-16-2021 16:10:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sympt NEW OR INCRE oms: ASED SHORTNE SS OF BREATH Sympt NO om Pre sent:	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/16/2021

Form Version: 14-Jan-2021 02:23

Site No: 1091

Subject No: 10911447

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1091) Aventiv Research Inc.

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

4.c Symptoms:

Date	Location	User	Value	Reason
Feb-16-2021 16:10:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SH ORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Feb-16-2021 16:10:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Feb-16-2021 16:10:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptoms: CHILL S Symptom Present NO :	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/16/2021

Form Version: 14-Jan-2021 02:23

Site No: 1091

Subject No: 10911447

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1091) Aventiv Research Inc.

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

4.d Symptoms:

Date	Location	User	Value	Reason
Feb-16-2021 16:10:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Feb-16-2021 16:10:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Feb-16-2021 16:10:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom: NEW OR INCREASED MUSCLE PAIN Symptom Present: NO	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/16/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

4.e Symptoms:

Date	Location	User	Value	Reason
Feb-16-2021 16:10:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED M USCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Feb-16-2021 16:10:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Feb-16-2021 16:10:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom: NEW LOSS OF TASTE OR SMO LL Symptom Present: NO	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/16/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

4.f Symptoms:

Date	Location	User	Value	Reason
Feb-16-2021 16:10:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Feb-16-2021 16:10:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Feb-16-2021 16:10:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom: NEW OR INCRE ASED SORE TH ROAT Symptom Present: NO	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/16/2021

Form Version: 14-Jan-2021 02:23

Site No: 1091

Subject No: 10911447

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1091) Aventiv Research Inc.

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

4.g Symptoms:

Date	Location	User	Value	Reason
Feb-16-2021 16:10:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SO RE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Feb-16-2021 16:10:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.h

Date	Location	User	Value	Reason
Feb-16-2021 16:10:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptoms: DIARRH EA Symptom Present: NO	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/16/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

4.h Symptoms:

Date	Location	User	Value	Reason
Feb-16-2021 16:10:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Feb-16-2021 16:10:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Feb-16-2021 16:10:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptoms: VOMITI NG Symptom Present: YES	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/16/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

4.i Symptoms:

Date	Location	User	Value	Reason
Feb-16-2021 16:10:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Feb-16-2021 16:10:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-16-2021 16:10:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptoms - Other fatigue	Initial Entry

5.a Symptoms - Other Text:

Date	Location	User	Value	Reason
Feb-16-2021 16:10:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: fatigue	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/16/2021

Form Version: 14-Jan-2021 02:23

Site No: 1091

Subject No: 10911447

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1091) Aventiv Research Inc.

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

5.b

Date	Location	User	Value	Reason
Feb-23-2021 13:58:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Data Entry: Symptoms - Other: vomiting	Transcription Error (DELETED)
Feb-18-2021 15:37:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Data Entry: Symptoms - Other: vomiting	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/16/2021

Form Version: 14-Jan-2021 02:23

Site No: 1091

Subject No: 10911447

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1091) Aventiv Research Inc.

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

5.b Symptoms - Other Text:

Date	Location	User	Value	Reason
Feb-23-2021 15:06:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-23-2021 13:58:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: vomiting	Transcription Error (DELETED)
Feb-23-2021 13:58:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-19-2021 11:16:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	CLIQUERY: The symptom VOMITING is already reported above in the predefined list. Please update.
Feb-18-2021 15:37:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: vomiting	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/16/2021

Form: MICROBIOLOGY SPECIMEN - eCRF Audit
Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Actual Date of Collection:

Date	Location	User	Value	Reason
Feb-16-2021 16:11:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Feb-16-2021 16:11:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Feb-16-2021 16:11:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Feb-16-2021 16:11:21	ACV0PF EINFP60	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/16/2021

Form: MICROBIOLOGY SPECIMEN - eCRF Audit
Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

(UTC-05:00) Eastern Time (US & Canada)	00			
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5. Device Type:

Date	Location	User	Value	Reason
Feb-16-2021 16:11:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Feb-16-2021 16:11:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
Feb-16-2021 16:11:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Feb-16-2021 16:11:21	ACV0PF EINFP60	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/16/2021

Form: MICROBIOLOGY SPECIMEN - eCRF Audit
Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

(UTC-05:00) Eastern Time (US & Canada)	00			
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9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Feb-16-2021 16:11:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted]	Data Entry: Not Done	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/16/2021

Form Version: 22-Apr-2020 21:03

Site No: 1091

Subject No: 10911447

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1091) Aventiv Research Inc.

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

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1. Data Origin

Date	Location	User	Value	Reason
Feb-16-2021 16:13:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-16-2021 16:13:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-16-2021 16:13:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-16-2021	ACV0PF	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/16/2021

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

16:13:03 (UTC-05:00) Eastern Time (US & Canada)	EINFP60 00	(b) (4), (b) (6)	Not collected for ill visit.	
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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/16/2021

Form Version: 22-Apr-2020 21:03

Site No: 1091

Subject No: 10911447

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1091) Aventiv Research Inc.

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Feb-16-2021 16:13:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-16-2021 16:13:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-16-2021 16:13:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-16-2021	ACV0PF	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/16/2021

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

16:13:17 (UTC-05:00) Eastern Time (US & Canada)	EINFP60 00	(b) (4), (b) (6)	Not collected for ill visit	
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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/16/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1.a

Date	Location	User	Value	Reason
Feb-16-2021 16:14:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Type of Practition SPECI er: ALIST Occurrence of Vis NO its or Contacts:	Initial Entry

1.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Feb-16-2021 16:14:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: SPECIALIST	Initial Entry

1.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-16-2021 16:14:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.b

Date	Location	User	Value	Reason
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090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/16/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Feb-16-2021 16:14:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Type of Practitioner: EMERGE NCY ROO M Occurrence of Visits or Contacts: NO	Initial Entry
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1.b Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Feb-16-2021 16:14:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: EMERGENCY ROOM	Initial Entry

1.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-16-2021 16:14:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.c

Date	Location	User	Value	Reason
Feb-16-2021 16:14:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Type of Practitioner: PRIMARY CARE PHY SICIAN	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/16/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

			Occurrence NO of Visits or C ontacts:	
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1.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Feb-16-2021 16:14:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: PRIMARY CARE PHYSICI AN	Initial Entry

1.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-16-2021 16:14:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.d

Date	Location	User	Value	Reason
Feb-16-2021 16:14:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Type of Practitio URGEN ner: T CARE Occurrence of V NO isits or Contacts:	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/16/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Feb-16-2021 16:14:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: URGENT CARE	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-16-2021 16:14:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.e

Date	Location	User	Value	Reason
Feb-16-2021 16:14:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Type of Prac TELEPHON titioner: E CONSULT ATION Occurrence NO of Visits or C ontacts:	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/16/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

1.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Feb-16-2021 16:14:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: TELEPHONE CONSULTA TION	Initial Entry

1.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-16-2021 16:14:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.f

Date	Location	User	Value	Reason
Feb-16-2021 16:14:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Type of Practitioner OTH : ER Occurrence of Visits NO or Contacts:	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/16/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Feb-16-2021 16:14:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: OTHER	Initial Entry

1.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-16-2021 16:14:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-16-2021 16:14:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Feb/16/2021

Form: ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Feb-16-2021 16:16:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: POTENTIAL COVID-19 ILL NESS	Initial Entry

2. Was a diagnosis obtained for Potential COVID-19 Illness?

Date	Location	User	Value	Reason
Feb-16-2021 16:16:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-16-2021 16:16:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Apr/01/2021

Form: DATE OF VISIT - ILLNESS CONVALESCENT -
eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Date of Visit

Date	Location	User	Value	Reason
Apr-01-2021 17:19:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Apr/1/2021	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Apr-01-2021 17:19:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: COVID_A1	Initial Entry

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Apr/01/2021

Form Version: 22-Apr-2020 21:03

Site No: 1091

Subject No: 10911447

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1091) Aventiv Research Inc.

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

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1. Data Origin

Date	Location	User	Value	Reason
Apr-01-2021 17:19:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Apr-01-2021 17:19:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Apr-01-2021 17:39:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Apr-01-2021 17:19:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Apr/01/2021

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

				correct as appropriate.
Apr-01-2021 17:19:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Apr/1/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Apr-01-2021 17:39:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BR1SCH	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Apr-01-2021 17:39:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BR1SCH	Initial Entry

5.b

Date	Location	User	Value	Reason
Apr-01-2021 17:39:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BLG1GS	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Apr/01/2021

Form Version: 22-Apr-2020 21:03

Site No: 1091

Subject No: 10911447

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1091) Aventiv Research Inc.

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

5.b Sample ID

Date	Location	User	Value	Reason
Apr-01-2021 17:39:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BLG1GS	Initial Entry

5.c

Date	Location	User	Value	Reason
Apr-01-2021 17:39:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BLG1GT	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Apr-01-2021 17:39:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BLG1GT	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Feb-15-2021 12:29:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Feb/15/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Feb-15-2021 12:29:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Feb-15-2021 12:29:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** DATE OF VISIT - eCRF Audit Trail History
Unscheduled

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

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Date of Visit

Date	Location	User	Value	Reason
May-13-2021 08:02:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Balaji Prabu R (b) (4)	Query 1: Deleted	Query is invalid or does not apply
May-12-2021 03:17:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	Query 1: Candidate	Site to update the date and re vaccination confirmation CRF. Please check audit trail and close this candidate query once the updates are done.
Mar-17-2021 11:37:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted]	Data Entry: Mar/16/2021	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION -
Unscheduled eCRF Audit Trail History

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

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

Subject No: 10911447 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

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

Date	Location	User	Value	Reason
May-13-2021 08:02:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Balaji Prabu R (b) (4)	Query 2: Deleted	Query is invalid or does not apply
May-12-2021 03:19:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 2: Candidate	Site to update the date and re vaccination confirmation CRF. Please check audit trail and close this candidate query once the updates are done.
Mar-17-2021 11:38:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-17-2021 11:38:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION -
Unscheduled eCRF Audit Trail History

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

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

Subject No: 10911447 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

				UNBLINDED date is missing in the DISP visit. Please complete this date.
Mar-17-2021 11:38:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received orally placebo at Vaccination 1/2	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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Date	Location	User	Value	Reason
Feb-18-2021 15:38:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Changed Information
Feb-15-2021 12:32:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

***** THIS REPEATING FORM HAS BEEN DELETED *****

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Date	Location	User	Value	Reason
Feb-18-2021 15:35:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Changed Information
Feb-15-2021 12:34:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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Date	Location	User	Value	Reason
Jul-19-2021 15:00:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Deleted

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Category:

Date	Location	User	Value	Reason
Feb-15-2021 12:32:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Feb-15-2021 12:32:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-19-2021 20:06:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Feb-18-2021 15:38:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Answered	Changed Information

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Deleted

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

***** THIS REPEATING FORM HAS BEEN DELETED *****

Canada)				
Feb-18-2021 15:28:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Salim Bouguermouh (b) (4)	Query 1: Reissued:Opened	Clin: FATIGUE, one of the CDC-defined symptoms of COVID-19 (Prot Sect 8.3.7.) does not qualify as AE and please should be documented only on the COVID Illness CRF SOD form (already entered) and should not be captured on the AE CRF page
Feb-16-2021 16:18:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Answered	Covid ill visit forms were added.
Feb-16-2021 10:30:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Salim Bouguermouh (b) (4)	Query 1: Opened	Clin: Since FATIGUE is one of the CDC-defined symptoms of COVID-19 (Prot Sect 8.1), please

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Deleted

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

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				consider whether this symptom, could have been due to COVID-19 and should have triggered a potential COVID illness visit
Feb-15-2021 12:32:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Data Entry: fatigue	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-15-2021 12:32:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Data Entry: Dec/22/2020 11:05	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-15-2021 12:32:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Data Entry: NO End Date Time:	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Deleted

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

*** THIS REPEATING FORM HAS BEEN DELETED ***

Dec/22/2020 20:00

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-15-2021 12:32:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Feb-15-2021 12:32:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(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
Feb-15-2021 12:32:18	ACV0PF EINFP60	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Deleted

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

*** THIS REPEATING FORM HAS BEEN DELETED ***

(UTC-05:00) Eastern Time (US & Canada) 00

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-15-2021 12:32:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> vasovagal with blood draw	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-15-2021 12:32:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
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090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Deleted

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

*** THIS REPEATING FORM HAS BEEN DELETED ***

Feb-15-2021 12:32:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-15-2021 12:32:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-15-2021 12:32:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Feb-15-2021 12:32:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Deleted

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

*** THIS REPEATING FORM HAS BEEN DELETED ***

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1. Category:

Date	Location	User	Value	Reason
Feb-15-2021 12:34:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Feb-15-2021 12:34:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-19-2021 20:06:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Feb-18-2021 15:35:56 (UTC-05:00)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Answered	Changed Information

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Deleted

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

***** THIS REPEATING FORM HAS BEEN DELETED *****

Eastern Time (US & Canada)				
Feb-18-2021 15:27:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Salim Bouguermouh (b) (4)	Query 2: Closed	Response satisfies query
Feb-18-2021 15:27:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Salim Bouguermouh (b) (4)	Query 1: Reissued:Opened	Clin: Per Prot Sect 8.3.7., COVID-19 listed symptoms VOMITING does not qualify as AE and please should be documented only on the COVID-19 Illness CRF SOD form (already entered) and should not be captured on the AE CRF page
Feb-16-2021 16:17:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Answered	Changed data per query

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Deleted

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

***** THIS REPEATING FORM HAS BEEN DELETED *****

Feb-16-2021 16:17:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Query 2: Answered	Changed data per query
Feb-16-2021 11:32:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Salim Bouguermouh (b) (4)	Query 2: Opened	Clin: Despite telehealth visit was not done, please complete the potential COVID-19 Illness Visit CRF forms with all information available. Should be captured only on the SOD CRF form and a NASAL SWAB will not be collected
Feb-16-2021 10:31:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Salim Bouguermouh (b) (4)	Query 1: Opened	Clin: Per Prot Sect 8.1., COVID-19 listed symptom VOMITING, should have please triggered a potential COVID Illness

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Generated Time (GMT): 10-Nov-2021 20:44

*** THIS REPEATING FORM HAS BEEN DELETED ***

				Visit irrespective of perceived etiology or clinical significance and captured only on the CRF SOD form
Feb-15-2021 12:34:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: vomiting	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-15-2021 12:34:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Dec/22/2020 11:20	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-15-2021 12:34:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO End Date Time: Dec/22/2020 11:25	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Deleted

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

*** THIS REPEATING FORM HAS BEEN DELETED ***

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-15-2021 12:34:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Feb-15-2021 12:34:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(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
Feb-15-2021 12:34:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Deleted

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

*** THIS REPEATING FORM HAS BEEN DELETED ***

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-15-2021 12:34:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> vasovagal with blood draw	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-15-2021 12:34:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-15-2021 12:34:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Deleted

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

*** THIS REPEATING FORM HAS BEEN DELETED ***

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-15-2021 12:34:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-15-2021 12:34:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Feb-15-2021 12:34:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Queries, Frozen

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Category:

Date	Location	User	Value	Reason
Jul-19-2021 15:00:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Jul-19-2021 15:00:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 3	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Aug-30-2021 10:58:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 4: Opened	Clinical - please consider if SAE Event term should reflect a complication, as in Appendicitis with Peritonitis or Appendicitis with Perforated Appendix. If event term updated; please

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Header Text: c4591001

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Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Queries, Frozen

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

				report to INFORM and SAE together.
Aug-30-2021 10:56:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Query 3: Closed	Response satisfies query
Aug-27-2021 14:17:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Query 3: Opened	Clinical - Followup: have Med records been re-requested (3 tries) to report clinical course (presenting Sx, exam, eval including labs/imaging, medications other than pain meds, path)
Aug-26-2021 08:23:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Query 2: Closed	Response satisfies query
Aug-25-2021 10:30:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Query 2: Answered	SAE report was updated yesterday.

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Queries, Frozen

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Canada)				
Aug-17-2021 22:52:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Query 2: Opened	Clinical - Followup: please submit a SAE update to report clinical course (presenting Sx, exam, evaluation including labs/imaging, medications other than pain meds, pathology)
Aug-06-2021 19:59:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Query 1: Closed	Response satisfies query
Aug-05-2021 07:27:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Query 1: Answered	Pending medical records. They have been requested by the site.
Jul-19-2021 23:08:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Query 1: Opened	Clinical - please submit a SAE update to report clinical course (presenting Sx, exam, evaluation

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Queries, Frozen

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

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				including labs/imaging, medications other than pain meds, pathology)
Jul-19-2021 15:00:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Appendicitis	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Aug-30-2021 07:07:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	SAE RECON: AER#2021881783 ,onset date was recorded as 09Jul2021 in Safety database however, recorded as 10Jul2021 on AE CRF. Please confirm correct Onset Date. If safety update is required, please submit a follow-up SAE form.
Jul-19-2021	ACV0PF	(b) (4), (b) (6)	Data Entry:	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Queries, Frozen

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

15:00:17 (UTC-05:00) Eastern Time (US & Canada)	EINFP60 00	(b) (4), (b) (6)	Jul/10/2021 03:00	
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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jul-19-2021 15:00:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO End Date Time: Jul/10/2021 08:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jul-19-2021 15:00:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
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090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Queries, Frozen

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Aug-06-2021 19:58:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 2: Closed	Query closed; will follow for requested COVID test information.
Aug-05-2021 07:27:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 2: Answered	Pending medical records. They have been requested by the site.
Jul-20-2021 08:58:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jul-19-2021 23:06:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 2: Opened	Clinical COVID test status (yes/no) during Hosp was not reported in the SAE. Please submit a follow-up SAE form [#2021881783] to document if COVID testing was performed (YES/NO or info not available) and if yes, the date and results.

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Header Text: c4591001

Visit: Logs - Unscheduled

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Form Status: Data Complete, Queries, Frozen

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

<p>Jul-19-2021 15:00:17 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PF EINFP60 00</p>	<p>auto query (autoquery)</p>	<p>Query 1: Candidate</p>	<p>For AE Appendicitis: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.</p>
<p>Jul-19-2021 15:00:17 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PF EINFP60 00</p>	<p>(b) (4), (b) (6)</p>	<p>Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO</p>	<p>Initial Entry</p>

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Header Text: c4591001

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Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

			Is this serious event life threatening?	
			NO	
			Other medically important serious event	
			NO	

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Jul-19-2021 15:00:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Aug-06-2021 19:58:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Aug-05-2021 07:28:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Answered	Pending medical records. They have been

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Queries, Frozen

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Canada)				requested by the site.
Jul-19-2021 23:09:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	Clinical - Other cause (not study drug related) for SAE cannot be SAE itself. Please update to report other potential cause.
Jul-19-2021 15:00:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> Appendicitis	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jul-19-2021 15:00:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Queries, Frozen

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Jul-19-2021 15:00:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jul-19-2021 15:00:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Jul-19-2021 15:00:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Jul-19-2021 15:00:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Queries, Frozen

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Jul-20-2021 08:58:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 2021881783	Initial Entry

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:27

Form Status: Data Complete, Frozen, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Mar-17-2021 11:38:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Mar/17/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Mar-17-2021 11:38:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILITY FO R ADDITIONAL VACCIN ATION	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Subject Status

Date	Location	User	Value	Reason
Feb-15-2021 12:29:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Dec-22-2020 12:17:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Dec-22-2020 12:14:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Jul-19-2021 23:01:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jul-19-2021 15:00:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Answered	Changed data per query

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Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1091

Site Name: (1091) Aventiv Research Inc.

Subject No: 10911447

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Jul-16-2021 20:50:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	Clinical- SAE of Appendicitis (#2021881783) was submitted; however, no adverse event has been reported on the AE CRF. Please report the SAE of Appendicitis on the AE CRF
Feb-15-2021 12:29:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Feb/15/2021	Initial Entry
Dec-22-2020 12:17:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Dec/22/2020	Initial Entry
Dec-22-2020 12:14:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Dec/22/2020	Initial Entry

090177e19891a044\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

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Form: CASEBOOK SIGNATURE FORM - eCRF Audit
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1. Casebook Signature

Date	Location	User	Value	Reason
Mar-22-2021 16:29:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PF EINFP60 00	Samir Arora (b) (4)	Data Entry: Click Here to Enable	Initial Entry