

7a or before

<input checked="" type="checkbox"/>	Turn on chamber control deck
<input checked="" type="checkbox"/>	Assure MGA calibration every 2 weeks (maybe every other Tuesday?)
<input checked="" type="checkbox"/>	Power source for AliCats on
<input checked="" type="checkbox"/>	PAX oxygen source on, secondary reg tape pointing out, and connected (both MGA and O2 source)
<input checked="" type="checkbox"/>	Double check fresh PAX mask/MGA connection and SpO2 finger wrap
<input checked="" type="checkbox"/>	Place PAX on plastic hanger in chamber near Subject chair
<input checked="" type="checkbox"/>	Assure new breathing filter for PFT/Pneumotach
<input checked="" type="checkbox"/>	Blanket and towels check
<input checked="" type="checkbox"/>	Privacy curtain check

8a or before - begin

<input checked="" type="checkbox"/>	Place Nonin sensor for SpO2 and heart rate data collection
<input checked="" type="checkbox"/>	Review Health History: Medical
<input checked="" type="checkbox"/>	Read through Informed Consent document
<input checked="" type="checkbox"/>	Sign informed consent
<input checked="" type="checkbox"/>	Sign investigator's affirmation
<input checked="" type="checkbox"/>	Sign Audio/Video if agreeable
<input checked="" type="checkbox"/>	Phlebotomy and blood gas analysis (everyday stay ahead of consumables and schedule for swaps)
<input type="checkbox"/>	Respirations
<input checked="" type="checkbox"/>	Weight
<input checked="" type="checkbox"/>	Height
<input checked="" type="checkbox"/>	Place H10 heart rate sensor strap with conducting gel
<input checked="" type="checkbox"/>	Place Polar watch

9a or before (Blue Chamber entry)

<input checked="" type="checkbox"/>	Place Wellue thumb SpO2 (and assure IO also is instrumented with last 3)
<input checked="" type="checkbox"/>	Pneumotach heater on
<input checked="" type="checkbox"/>	Place HansR SpO2 finger sensor and finger splint w/ tape
<input checked="" type="checkbox"/>	Place chest/abdomen expansion straps
<input checked="" type="checkbox"/>	Insight program HansR software ON <input checked="" type="checkbox"/> LabVIEW ON time/ certain of accurate inputs
<input checked="" type="checkbox"/>	Pneumotach PFT - noseclip on, good mouth seal, comfortable - 7 tidal, 1 full, 3 tidal
<input checked="" type="checkbox"/>	PAX mask tutorial (fit, function, emergency, MGA tubing)
<input checked="" type="checkbox"/>	Thumbs up for good, sideways for feelin' effects of hypoxia, thumb down for there's a problem/ thumbs down might suggest descend a bit
<input checked="" type="checkbox"/>	On the ride from 30k' to 45k', keep thumb extended per your condition, do not lift arm/stay relaxed/ do not talk unless necessary
<input checked="" type="checkbox"/>	Expansion straps = respirations. Talking, repositioning, fidgeting interferes with that signal. Please stay still, focus on breathing slowly and relaxed.
<input checked="" type="checkbox"/>	Nonin SpO2 finger clamps in place for Subj and IO
<input checked="" type="checkbox"/>	MGAs from stdby to "on" and ready for altitude exposure

Flight

<input checked="" type="checkbox"/>	Insight and LabVIEW on (and recording) for PFT and 10k' and 14k' SpO2 baseline
<input checked="" type="checkbox"/>	Campbell enters chamber when door opened at GL to remove SpO2 and expansion strap connectors
<input checked="" type="checkbox"/>	IO or Campbell helps fit aviator's mask/helmet
<input checked="" type="checkbox"/>	Echo bike exercise prep (comfort, orient, hr target, watts, instruction)
<input checked="" type="checkbox"/>	Echo bike exercise execution
<input checked="" type="checkbox"/>	At timepoint 55min into the 100% oxygen pre-breathe, Campbell enters chamber/ leads minimal exercise portion
<input checked="" type="checkbox"/>	At timepoint 150min, pre-breathe and exercise portion are over, prep for ascent to 30k'
<input checked="" type="checkbox"/>	At 30k', begin 3.24LPM oxygen supply via PAX (just prior to mask swap)
<input checked="" type="checkbox"/>	Change PAX oxygen supply to 3.1LPM when SpO2 recovers to 85%
<input checked="" type="checkbox"/>	At start of descent to 35k', PAX mask oxygen flow 2.55L
	Transition to other sheet with oxygen flows per altitude

ANNEX A1

Health History Questionnaire

(completed by each participant, presented for PI/medical monitor prior to enrollment)

Subject ID#: AM631 CAMI # 9 Age (18 to 50): 24 F
 Height (in): 64 Weight (lbs): 116
nhlbi.nih.gov/health/educational/lose_wt/BMI/bmicalc.htm BMI = _____
 Circle one – 1st class medical 2nd class medical/ 3rd class medical/ no current medical
 Flight time (hrs/wk total & if pressurized) 5 week
 Exercise regimen hrs/wk, type 3 hrs week
 Are you able to run continuously for 20 minutes? Y / N Avg. pace? 10 minutes/mile
 Diver? (hrs/wk, depth, most recent dive) N/A
 Do you currently use tobacco? Y / N Type: _____ Frequency: _____
 Have you ever smoked/vaped? Y / N Quit when? _____ How long/how regularly? _____
 Any medical/clinical respiratory condition (e.g., asthma, chronic obstructive pulmonary disease [COPD], etc.) Lung injury/breathing illness? Y / N When _____ What _____
 Do you have a history of or now have peripheral vascular/neuromuscular disease, neuropathy (stroke/epilepsy), high blood pressure, or Raynaud's syndrome? Y / N
 Medical or physical limitations that would preclude a decompressive experience? Y / N
 Have you, in the past or at present, experienced discomfort in confined spaces? Y / N
 Have you donated blood, platelets or plasma in the past 30 days or have a known anemia? Y / N
 Do you have any of the following: respiratory ailments such as asthma or emphysema; pregnancy; hypo/hypertension; diagnosed heart problems; chest pains, difficulty breathing; serious bodily disability, deformity, or dismemberment; spells of severe dizziness; diabetes requiring medication; claustrophobia; recent surgery; or any other chronic disease? Circle 1
 Any chronic medical condition not listed previously? N/A
 Taking prescribed medications? Y / N Amount/type/reason: _____
 Use nutrition/herbal supplement? Y / N Amount/type/reason: _____
 Use otc medication (e.g., Tylenol/Advil) routinely? Y / N Amount/type/reason: _____
 Sensitive to other's touch or uncomfortable in enclosed environments? Y / N
 Please list any other comments regarding your medical history that might affect your ability to participate in this protocol.

N/A

ANNEX A2

PRE-flight Subject Exam and Instructions

(Completed morning of Subject experimentation after informed consent for confirmation of Subject qualification to participate)

Subject ID #: Am 631 Cam 1 9 Age (18 to 50): 24

4 DAYS BEFORE CHAMBER FLIGHT

- 1) Review informed consent and OFOS protocol documents
- 2) Avoid gas-producing foods (beans, spicy foods, etc.) for at least 3 days prior to experimentation. Each Subject knows his/her own gastrointestinal fortitude – Do not exceed. If you do exceed, then report and postpone. Let someone else attend that day.
- 3) Limit alcohol for 3 days prior to chamber flight. Dehydration will undoubtedly occur. Do not further contribute to this impending dehydration.
- 4) No self-medication for flu, cold, etc. If you become ill, please inform the contract company (employer), that will in turn notify the government immediately upon discovery of symptoms.
- 5) No diving for 72 hours prior to hypobaric chamber exposure.
- 6) Get a good night's rest prior to participation.
- 7) Limit cardiovascular exercise for 12 hours prior, resistance training 4 days prior and do not perform exercise that is not part of your regular routine for 2 weeks prior.
- 8) Begin to ween yourself off caffeine at least one week prior to participation.

DAY OF CHAMBER FLIGHT (checklist)

- 1) Once again, no self-medication for flu, cold, etc. If you become ill, please inform your employer immediately upon discovery of symptoms.
- 2) No or very low caffeine intake as it is a vasoconstrictor and dehydrating agent. If a headache is expected with no consumption, then take as little as possible to avoid a headache.
- 3) Eat a breakfast low in fats and protein. Cereal, pancakes, waffles, toast are suggested with no butter or syrup. High triglyceride (fats) blood levels are known to interfere with hematocrit tests. Sorbitol, fructose, raffinose (carbohydrate found in beans) all increase the incidence of gas production, so please try to avoid.
- 4) Avoid exercise that is not protocol-related.
- 5) Use the restroom before entering hypobaric chamber. This will limit experimentation interruptions to use the urinal/potty in the hypobaric chamber.
- 6) Wear comfortable clothing. Females are suggested to wear a sports bra. Sensor placement may demand optimal access to skin on the upper torso.
- 7) Wear comfortable tennis shoes that do not stink. Shower using deodorant soap to wash every square inch of your body before arrival. You will be in a confined space. Respect others and save yourself the hours of discomfort.
- 8) BE ON TIME, please!
- 9) Reiteration - if you must cancel for any reason, please spread the word immediately to your employer. Many people prepare for one Subject's participation. Notification 24 hours prior or sooner is requested.

Physical Qualification/Inclusion Criteria

Hct ($>12.0\text{g/dl}$): 46 Hgb ($\geq 37\%$): 16.3 SpO₂ (> 94): 98 % rest HR: 95 bpm

Resp: 13 /min Temperature (< 100.0): 97.4 deg F

Height: 64 " Weight: 118 lbs BMI (≤ 40): ✓

Present your 3rd class or greater medical certificate for record of validity and non-expired status. GTG Y / N

Non-smoker/non-vaper? Y / N

History of injury (sports, hobby, accident)?

Location Pain level Frequency

Location Pain level Frequency

Location Pain level Frequency

Exclusion Criteria review (all "NO" answers get a pass on the day of experimentation)

Facial hair? Y / N

Any cold, acute upper respiratory infection (URI), or respiratory issue within two (2) weeks prior to study participation? Y / N

Not able to exercise at the marathon pace level for 15 minutes? Y / N

Personal items with you? Y / N

Currently taking any medication or drug which may impair physical or cognitive activity, or which precludes the operation of heavy machinery/driving? Y / N

Additional questions

Have you taken any medications/caffeine/alcohol within 24 hrs prior? Y / N

Amount and Type: Reason:

Recent illness? Y / N Symptoms/Severity 1-5/days? Recover Y/N

of hours slept last night? 7 Do you feel well rested/was sleep sufficient? Y / N

STAT Profile PrimePlus

Full Panel

Blood Results

05-30-2025 08:42

alyzed On 05-30-2025 08:39

alyzer ID

erator ID

ometric Pressure 729.6 mmHg

Patient ID AM631CAM19

FIO₂% 20.9 %

Patient Temperature °C 37.0

AM631CAM19 - Syringe - Venous

Test	Value	Units
pH	7.361	
pCO ₂	45.9	mmHg
pO ₂	21.2	mmHg
SO ₂	<30	%
Hct	46	%
tHb	16.3	g/dL
	136.8	mmol/L
	4.04	mmol/L
	104.0	mmol/L
	1.30	mmol/L
	0.51	mmol/L
	90	mg/dL
	0.7	mmol/L
tb	26.5	%
Hb	0.5	%
tHb	0.4	%
tb	>40.0	%
CO ₂	27.6	mmol/L

Calculated

Test	Value	Units
BE-ecf	0.6	mmol/L
BE-b	0.8	mmol/L
SBC	23.4	mmol/L
HCO ₃	26.24	mmol/L
O ₂ Cap	22.7	mL/dL
O ₂ Ct	7.4	mL/dL
A	87.6	mmHg
A-aDO ₂	66.5	mmHg
a/A	0.2	
a ₁	3.1	
a ₁ O ₂	101.2	
	1.27	mmol/L
	0.50	mmol/L
	0.6	mmol/L
		mol/mol

Investigator

Principal Investigator:

I have fully explained this study to the subject or his/her representative to the best of my ability. As a representative of this study, I have explained the purpose, the procedures, the possible benefits and risks that are involved in this research study. I have answered the subject's questions to his/her satisfaction before requesting the signature(s) above. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily. There are no blanks in this document. A copy of this form has been given to the subject or his/her representative.

JAMES E. Campbell

Printed name of Principal Investigator or designee

J.E. Campbell

Signature of Principal Investigator or designee

30 May 2025

Date

Time

* About Intestinal Gas Expansion

OFOS 000 for AM631 PI

Subj: AM 631 Cami # 10

Date: _____

7a or before

- ☒ Turn on chamber control deck
- ☒ Assure MGA calibration every 2 weeks (maybe every other Tuesday?)
- ☒ Power source for AliCats on
- ☒ PAX oxygen source on, secondary reg tape pointing out, and connected (both MGA and O2 source)
- ☒ Double check fresh PAX mask/MGA connection and SpO2 finger wrap
- ☒ Place PAX on plastic hanger in chamber near Subject chair
- ☒ Assure new breathing filter for PFT/Pneumotach
- ☒ Blanket and towels check
- ☒ Privacy curtain check

8a or before - begin

- ☒ Place Nonin sensor for SpO2 and heart rate data collection
- ☒ Review Health History: Medical
- ☒ Read through Informed Consent document
- ☒ Sign informed consent
- ☒ Sign investigator's affirmation
- ☒ Sign Audio/Video if agreeable
- ☒ Phlebotomy and blood gas analysis (everyday stay ahead of consumables and schedule for swaps)
- ☒ Respirations
- ☒ Weight
- ☒ Height
- ☒ Place H10 heart rate sensor strap with conducting gel
- ☒ Place Polar watch

9a or before (Blue Chamber entry)

- ☒ Place Wellue thumb SpO2 (and assure IO also is instrumented with last 3)
- ☒ Pneumotach heater on
- ☒ Place HansR SpO2 finger sensor and finger splint w/ tape
- ☒ Place chest/abdomen expansion straps
- ☒ Insight program HansR software ON ☐ LabVIEW ON time/ certain of accurate inputs
- ☒ Pneumotach PFT - noseclip on, good mouth seal, comfortable - 7 tidal, 1 full, 3 tidal
- ☒ PAX mask tutorial (fit, function, emergency, MGA tubing)
- ☒ Thumbs up for good, sideways for feelin' effects of hypoxia, thumb down for there's a problem/
thumbs down might suggest descend a bit
- ☒ On the ride from 30k' to 45k', keep thumb extended per your condition, do not lift arm/stay relaxed/
do not talk unless necessary
- ☒ Expansion straps = respirations. Talking, repositioning, fidgeting interferes with that signal.
Please stay still, focus on breathing slowly and relaxed.
- ☒ Nonin SpO2 finger clamps in place for Subj and IO
- ☒ MGAs from stdby to "on" and ready for altitude exposure

Flight

- ☒ Insight and LabVIEW on (and recording) for PFT and 10k' and 14k' SpO2 baseline
- ☒ Campbell enters chamber when door opened at GL to remove SpO2 and expansion strap connectors
- ☒ IO or Campbell helps fit aviator's mask/helmet
- ☒ Echo bike exercise prep (comfort, orient, hr target, watts, instruction)
- ☒ Echo bike exercise execution
- ☒ At timepoint 55min into the 100% oxygen pre-breathe, Campbell enters chamber/
leads minimal exercise portion
- ☒ At timepoint 150min, pre-breathe and exercise portion are over, prep for ascent to 30k'
- ☒ At 30k', begin 3.24LPM oxygen supply via PAX (just prior to mask swap)
- ☒ Change PAX oxygen supply to 3.1LPM when SpO2 recovers to 85%
- ☒ At start of descent to 35k', PAX mask oxygen flow 2.55L
- Transition to other sheet with oxygen flows per altitude

Subj: AM 631 Cami 10 Aborted
 PI: J Campbell
 IO: L. Kennedy
 Chief Flight Engineer: EZ Dwyer, Jimmy Shaver
 Date: 13 Jun 2025

Intestinal
 Gas
 won,
 OFOL ZERO

OFOS sequence and LabVIEW log entries	PAX oxygen NLPM	Subj SpO2	Data time	Notes
---------------------------------------	-----------------	-----------	-----------	-------

04 HR →	09:20	20+ breaths/min	none	87	10m	Big breath @ 8min. Prior 3m avg: 86.85 87.2%
compensating to 18	10A definite	16 breaths/min	none	74	10m	@ 8m = 3m avg: 74
	Bike Start	none		✓		
	Sub 77% Start	none		✓		
	Sub End	none		✓		
	Sub 85%	none		✓		
	IO 77% Start	none		✓		
	IO End	none		✓		
	IO 85%	none		✓		
	LTA at 55	10:55	none	✓		
	LTA at 65		none	✓		
	LTA at 75		none	✓		
	LTA at 85		none	✓		
Handwritten re-instrument @ 12:15	Ascend to 30K	12:30	none	12:33:50 actual		
	30K Arrive and don PAX	3.24				

Instructions:

PAX o2 flow "steps" occur after SpO2 stabilizes

At 97%-100%, this can occur within 1 minute

At 96% and below, SpO2 stability is +/- 1% (2-tailed) for the better part of 3 minutes

1 minute and 3 minute average in LabVIEW helps BUT unstable breathing patterns devalue this info

Ascend 45k peak and Descend to 40k	3.24			Abmt @ 44k'. Intestinal Gas not expelled
40k Arrive	"			
40k Subj achieves 85% SpO2	"			
40k 3.1 Step	3.10			
Start of descent from 40K	2.55			
35k 1.9 Step	1.90			
35k 1.28 Step	1.28			
35k 0.64 Step	0.64			

ANNEX A1

Health History Questionnaire

(completed by each participant, presented for PI/medical monitor prior to enrollment)

✓
11/04/24
11/04/25

Subject ID#: AM 631 Cam # 10 Age (18 to 50): 35 F
 Height (in): 62 inches Weight (lbs): 177 lbs
nhlbi.nih.gov/health/educational/lose_wt/BMI/bmicalc.htm BMI = 32
 Circle one – 1st class medical/ 2nd class medical/ 3rd class medical/ no current medical
 Flight time (hrs/wk total & if pressurized) 16 hrs / wk - pressurized
 Exercise regimen hrs/wk, type 5 hrs / wk - yoga & walking
 Are you able to run continuously for 20 minutes? Y / (N) Avg. pace? 15 minutes/mile
 Diver? (hrs/wk, depth, most recent dive) No.
 Do you currently use tobacco? Y / (N) Type: _____ Frequency: _____
 Have you ever smoked/vaped? Y / (N) Quit when? _____ How long/how regularly? _____
 Any medical/clinical respiratory condition (e.g., asthma, chronic obstructive pulmonary disease [COPD], etc.) Lung injury/breathing illness? Y / (N) When _____ What _____
 Do you have a history of or now have peripheral vascular/neuromuscular disease, neuropathy (stroke/epilepsy), high blood pressure, or Raynaud's syndrome? Y / (N)
 Medical or physical limitations that would preclude a decompressive experience? Y / (N)
 Have you, in the past or at present, experienced discomfort in confined spaces? Y / (N)
 Have you donated blood, platelets or plasma in the past 30 days or have a known anemia? Y / (N)
 Do you have any of the following: respiratory ailments such as asthma or emphysema; pregnancy; hypo/hypertension; diagnosed heart problems; chest pains, difficulty breathing; serious bodily disability, deformity, or dismemberment; spells of severe dizziness; diabetes requiring medication; claustrophobia; recent surgery; or any other chronic disease? Circle 1 NO.
 Any chronic medical condition not listed previously? NO.
 Taking prescribed medications? (Y) / N Amount/type/reason: Semaglutide. 1 mg every 10 days.
 Use nutrition/herbal supplement? Y / (N) Amount/type/reason: Weight loss.
 Use otc medication (e.g., Tylenol/Advil) routinely? Y / (N) Amount/type/reason: _____
 Sensitive to other's touch or uncomfortable in enclosed environments? Y / (N)
 Please list any other comments regarding your medical history that might affect your ability to participate in this protocol.
None.

ANNEX A2

PRE-flight Subject Exam and Instructions

(Completed morning of Subject experimentation after informed consent for confirmation of Subject qualification to participate)

Subject ID #: Am 631 Cam. #10

Age (18 to 50): 35

4 DAYS BEFORE CHAMBER FLIGHT

- 1) Review informed consent and OFOS protocol documents
- 2) Avoid gas-producing foods (beans, spicy foods, etc.) for at least 3 days prior to experimentation. Each Subject knows his/her own gastrointestinal fortitude – Do not exceed. If you do exceed, then report and postpone. Let someone else attend that day.
- 3) Limit alcohol for 3 days prior to chamber flight. Dehydration will undoubtedly occur. Do not further contribute to this impending dehydration.
- 4) No self-medication for flu, cold, etc. If you become ill, please inform the contract company (employer), that will in turn notify the government immediately upon discovery of symptoms.
- 5) No diving for 72 hours prior to hypobaric chamber exposure.
- 6) Get a good night's rest prior to participation.
- 7) Limit cardiovascular exercise for 12 hours prior, resistance training 4 days prior and do not perform exercise that is not part of your regular routine for 2 weeks prior.
- 8) Begin to wean yourself off caffeine at least one week prior to participation.

DAY OF CHAMBER FLIGHT (checklist)

- 1) Once again, no self-medication for flu, cold, etc. If you become ill, please inform your employer immediately upon discovery of symptoms.
- 2) No or very low caffeine intake as it is a vasoconstrictor and dehydrating agent. If a headache is expected with no consumption, then take as little as possible to avoid a headache.
- 3) Eat a breakfast low in fats and protein. Cereal, pancakes, waffles, toast are suggested with no butter or syrup. High triglyceride (fats) blood levels are known to interfere with hematocrit tests. Sorbitol, fructose, raffinose (carbohydrate found in beans) all increase the incidence of gas production, so please try to avoid.
- 4) Avoid exercise that is not protocol-related.
- 5) Use the restroom before entering hypobaric chamber. This will limit experimentation interruptions to use the urinal/potty in the hypobaric chamber.
- 6) Wear comfortable clothing. Females are suggested to wear a sports bra. Sensor placement may demand optimal access to skin on the upper torso.
- 7) Wear comfortable tennis shoes that do not stink. Shower using deodorant soap to wash every square inch of your body before arrival. You will be in a confined space. Respect others and save yourself the hours of discomfort.
- 8) BE ON TIME, please!
- 9) Reiteration - if you must cancel for any reason, please spread the word immediately to your employer. Many people prepare for one Subject's participation. Notification 24 hours prior or sooner is requested.

Physical Qualification/Inclusion Criteria

Hct (≥ 12.0 g/dl): 44 Hgb ($\geq 37\%$): 14.9 SpO2 (> 94): 98 % rest HR: 80 bpm

Resp: 18 /min Temperature (< 100.0): 98 deg F

Height: 64 " Weight: 180 lbs BMI (≤ 40): ✓

Present your 3rd class or greater medical certificate for record of validity and non-expired status. GTG Y / N

Non-smoker/non-vaper? Y / N

History of injury (sports, hobby, accident)?

Location Ankle Pain level None Frequency All good

Location _____ Pain level _____ Frequency _____

Location _____ Pain level _____ Frequency _____

Exclusion Criteria review (all "NO" answers get a pass on the day of experimentation)

Facial hair? Y / N

Any cold, acute upper respiratory infection (URI), or respiratory issue within two (2) weeks prior to study participation Y / N

Not able to exercise at the marathon pace level for 15 minutes? Y / N

Personal items with you? Y / N

Currently taking any medication or drug which may impair physical or cognitive activity, or which precludes the operation of heavy machinery/driving? Y / N

Additional questions

Have you taken any medications/caffeine/alcohol within 24 hrs prior? Y / N

Amount and Type: _____ Reason: _____

Recent illness? Y / N Symptoms/Severity 1-5/days? _____ Recover Y/N

of hours slept last night? 6 Do you feel well rested/was sleep sufficient? Y / N

STAT Profile PrimePlus

Full Panel

Blood Results

06-13-2025 08:35

lyzed On 06-13-2025 08:30

lyzer ID

erator ID

ometric Pressure 724.0 mmHg

ient ID AM631CAM110

FIO2% 20.9 %

Patient Temperature °C 37.0

AM631CAM110 - Syringe - Venous

Test	Value	Units
pH	7.443	
pCO ₂	42.5	mmHg
pO ₂	30.9	mmHg
SO ₂	55	%
Hct	44	%
tHb	14.9	g/dL
Na	140.0	mmol/L
K	3.57	mmol/L
Cl	106.5	mmol/L
iCa	1.21	mmol/L
iMg	0.71	mmol/L
Glu	94	mg/dL
Lac	1.3	mmol/L
O ₂ Hb	54.9	%
COHb	0.5	%
MetHb	0.4	%
Hb	>40.0	%
TCO ₂	30.7	mmol/L

Calculated

Test	Value	Units
BE-ecf	5.1	mmol/L
BE-b	5.2	mmol/L
SBC	28.0	mmol/L
HCO ₃	29.36	mmol/L
O ₂ Cap	20.7	mL/dL
O ₂ Ct	11.5	mL/dL
iO ₂	90.5	mmHg
	59.6	mmHg
	0.3	mmHg
	29.7	mmHg
	1.9	mmHg
=IO ₂	147.8	mmol/L
	1.24	mmol/L
K)	0.73	mmol/L
iMg	7.7	mmol/L
	1.7	mmol/mol

Investigator

Principal Investigator:

I have fully explained this study to the subject or his/her representative to the best of my ability. As a representative of this study, I have explained the purpose, the procedures, the possible benefits and risks that are involved in this research study. I have answered the subject's questions to his/her satisfaction before requesting the signature(s) above. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily. There are no blanks in this document. A copy of this form has been given to the subject or his/her representative.

James E. Campbell

Printed name of Principal Investigator or designee

J. E. Campbell

Signature of Principal Investigator or designee

13 JUNE 2025

Date

Time

7a or before

- ☒ Turn on chamber control deck
- ☒ Assure MGA calibration every 2 weeks (maybe every other Tuesday?)
- ☒ Power source for AliCats on
- ☒ PAX oxygen source on, secondary reg tape pointing out, and connected (both MGA and O2 source)
- ☒ Double check fresh PAX mask/MGA connection and SpO2 finger wrap
- ☒ Place PAX on plastic hanger in chamber near Subject chair
- ☒ Assure new breathing filter for PFT/Pneumotach
- ☒ Blanket and towels check
- ☒ Privacy curtain check

8a or before - begin

- ☒ Place Nonin sensor for SpO2 and heart rate data collection
- ☒ Review Health History: Medical
- ☒ Read through Informed Consent document
- ☒ Sign informed consent
- ☒ Sign investigator's affirmation
- ☒ Sign Audio/Video if agreeable
- ☒ Phlebotomy and blood gas analysis (everyday stay ahead of consumables and schedule for swaps)
- ☒ Respirations
- ☒ Weight
- ☒ Height
- ☒ Place H10 heart rate sensor strap with conducting gel
- ☒ Place Polar watch

9a or before (Blue Chamber entry)

- ☒ Place Wellue thumb SpO2 (and assure IO also is instrumented with last 3)
- ☒ Pneumotach heater on
- ☒ Place HansR SpO2 finger sensor and finger splint w/ tape
- ☒ Place chest/abdomen expansion straps
- ☒ Insight program HansR software ON ☒ LabVIEW ON time/ certain of accurate inputs
- ☒ Pneumotach PFT - noseclip on, good mouth seal, comfortable - 7 tidal, 1 full, 3 tidal
- ☒ PAX mask tutorial (fit, function, emergency, MGA tubing)
- ☒ Thumbs up for good, sideways for feelin' effects of hypoxia, thumb down for there's a problem/
thumbs down might suggest descend a bit
- ☒ On the ride from 30k' to 45k', keep thumb extended per your condition, do not lift arm/stay relaxed/
do not talk unless necessary
- ☒ Expansion straps = respirations. Talking, repositioning, fidgeting interferes with that signal.
Please stay still, focus on breathing slowly and relaxed.
- ☒ Nonin SpO2 finger clamps in place for Subj and IO
- ☒ MGAs from stdby to "on" and ready for altitude exposure

Flight

- ☒ Insight and LabVIEW on (and recording) for PFT and 10k' and 14k' SpO2 baseline
- ☒ Campbell enters chamber when door opened at GL to remove SpO2 and expansion strap connectors
- ☒ IO or Campbell helps fit aviator's mask/helmet
- ☒ Echo bike exercise prep (comfort, orient, hr target, watts, instruction)
- ☒ Echo bike exercise execution
- ☒ At timepoint 55min into the 100% oxygen pre-breathe, Campbell enters chamber/
leads minimal exercise portion
- ☒ At timepoint 150min, pre-breathe and exercise portion are over, prep for ascent to 30k'
- ☒ At 30k', begin 3.24LPM oxygen supply via PAX (just prior to mask swap)
- ☒ Change PAX oxygen supply to 3.1LPM when SpO2 recovers to 85%
- ☒ At start of descent to 35k', PAX mask oxygen flow 2.55L
Transition to other sheet with oxygen flows per altitude

ANNEX A1

Health History Questionnaire

(completed by each participant, presented for PI/medical monitor prior to enrollment)

Subject ID#: An 631 Cam. #11 Age (18 to 50): 46 F
 Height (in): 64 inches Weight (lbs): 152.5
 nhlbi.nih.gov/health/educational/lose_wt/BMI/bmicalc.htm BMI = 26.2
 Circle one – 1st class medical/ 2nd class medical/ (3rd class medical) no current medical
 Flight time (hrs/wk total & if pressurized) 46.3
 Exercise regimen hrs/wk, type swim 1-2 wk / skate 1-wk / walk 2-wk
 Are you able to run continuously for 20 minutes? Y/(N) Avg. pace? 13/14 minutes/mile
 Diver? (hrs/wk, depth, most recent dive) no
 Do you currently use tobacco? Y/(N) Type: _____ Frequency: _____
 Have you ever smoked/vaped? Y/(N) Quit when? _____ How long/how regularly? _____
 Any medical/clinical respiratory condition (e.g., asthma, chronic obstructive pulmonary disease [COPD], etc.) Lung injury/breathing illness? Y/(N) When _____ What _____
 Do you have a history of or now have peripheral vascular/neuromuscular disease, neuropathy (stroke/epilepsy), high blood pressure, or Raynaud's syndrome? Y/(N)
 Medical or physical limitations that would preclude a decompressive experience? Y/(N)
 Have you, in the past or at present, experienced discomfort in confined spaces? Y/(N)
 Have you donated blood, platelets or plasma in the past 30 days or have a known anemia? Y/(N)
 Do you have any of the following: respiratory ailments such as asthma or emphysema; pregnancy; hypo/hypertension; diagnosed heart problems; chest pains, difficulty breathing; serious bodily disability, deformity, or dismemberment; spells of severe dizziness; diabetes requiring medication; claustrophobia; recent surgery; or any other chronic disease? Circle 1 no
 Any chronic medical condition not listed previously? psoriasis
 Taking prescribed medications? (Y)/N Amount/type/reason: daily Acrolimus ointment/ psoriasis
 Use nutrition/herbal supplement? (Y)/N Amount/type/reason: shot/ zepbound/ weight weekly
 Use otc medication (e.g., Tylenol/Advil) routinely? Y/(N) Amount/type/reason: spray/daily/ clobetasol/ psoriasis
 Sensitive to other's touch or uncomfortable in enclosed environments? Y/(N)
 Please list any other comments regarding your medical history that might affect your ability to participate in this protocol.

ANNEX A2

PRE-flight Subject Exam and Instructions

(Completed morning of Subject experimentation after informed consent for confirmation of Subject qualification to participate)

Subject ID #: Am 631 Com 1 B 11 Age (18 to 50): 46

4 DAYS BEFORE CHAMBER FLIGHT

- 1) Review informed consent and OFOS protocol documents
- 2) Avoid gas-producing foods (beans, spicy foods, etc.) for at least 3 days prior to experimentation. Each Subject knows his/her own gastrointestinal fortitude – Do not exceed. If you do exceed, then report and postpone. Let someone else attend that day.
- 3) Limit alcohol for 3 days prior to chamber flight. Dehydration will undoubtedly occur. Do not further contribute to this impending dehydration.
- 4) No self-medication for flu, cold, etc. If you become ill, please inform the contract company (employer), that will in turn notify the government immediately upon discovery of symptoms.
- 5) No diving for 72 hours prior to hypobaric chamber exposure.
- 6) Get a good night's rest prior to participation.
- 7) Limit cardiovascular exercise for 12 hours prior, resistance training 4 days prior and do not perform exercise that is not part of your regular routine for 2 weeks prior.
- 8) Begin to ween yourself off caffeine at least one week prior to participation.

DAY OF CHAMBER FLIGHT (checklist)

- 1) Once again, no self-medication for flu, cold, etc. If you become ill, please inform your employer immediately upon discovery of symptoms.
- 2) No or very low caffeine intake as it is a vasoconstrictor and dehydrating agent. If a headache is expected with no consumption, then take as little as possible to avoid a headache.
- 3) Eat a breakfast low in fats and protein. Cereal, pancakes, waffles, toast are suggested with no butter or syrup. High triglyceride (fats) blood levels are known to interfere with hematocrit tests. Sorbitol, fructose, raffinose (carbohydrate found in beans) all increase the incidence of gas production, so please try to avoid.
- 4) Avoid exercise that is not protocol-related.
- 5) Use the restroom before entering hypobaric chamber. This will limit experimentation interruptions to use the urinal/potty in the hypobaric chamber.
- 6) Wear comfortable clothing. Females are suggested to wear a sports bra. Sensor placement may demand optimal access to skin on the upper torso.
- 7) Wear comfortable tennis shoes that do not stink. Shower using deodorant soap to wash every square inch of your body before arrival. You will be in a confined space. Respect others and save yourself the hours of discomfort.
- 8) BE ON TIME, please!
- 9) Reiteration - if you must cancel for any reason, please spread the word immediately to your employer. Many people prepare for one Subject's participation. Notification 24 hours prior or sooner is requested.

Physical Qualification/Inclusion Criteria

Hct (≥ 12.0 g/dl): 44 Hgb ($\geq 37\%$): 14.5 SpO2 (> 94): 100% rest HR: 68 bpm

Resp: 13/min Temperature (< 100.0): 97.9deg F

Height: 5'5" Weight: 154 lbs BMI (≤ 40): 24.5

Present your 3rd class or greater medical certificate for record of validity and non-expired status. GTG Y/N

Non-smoker/non-vaper? Y/N

History of injury (sports, hobby, accident)?

Location clavicle Pain level — Frequency no

Location wrist Pain level — Frequency no

Location — Pain level — Frequency —

Exclusion Criteria review (all "NO" answers get a pass on the day of experimentation)

Facial hair? Y / NO

Any cold, acute upper respiratory infection (URI), or respiratory issue within two (2) weeks prior to study participation Y / NO

Not able to exercise at the marathon pace level for 15 minutes? Y / NO

Personal items with you? Y / NO

Currently taking any medication or drug which may impair physical or cognitive activity, or which precludes the operation of heavy machinery/driving? Y / NO

Additional questions

Have you taken any medications/caffeine/alcohol within 24 hrs prior? Y/N

Amount and Type: caffeine Reason: very very 1. HRE

Recent illness? Y / NO Symptoms/Severity 1-5/days? — Recover Y/N

of hours slept last night? 6.5 Do you feel well rested/was sleep sufficient? Y/N

STAT Profile PrimePlus

Full Panel

Blood Results

06-23-2025 08:34

Analyzed On 06-23-2025 08:32

Analyzer ID

Operator ID

Systolic Pressure 729.5 mmHg

Patient ID AM631CAM111

FIO2% 20.9%

Patient Temperature °C 37.0

AM631CAM111 - Syringe - Venous

Test	Value	Units
pH	7.388	
pCO ₂	44.8	mmHg
SO ₂	<30	%
Hct	44	%
Hb	14.5	g/dL
Na	139.2	mmol/L
K	4.19	mmol/L
Cl	105.1	mmol/L
iCa	1.26	mmol/L
iMg	0.61	mmol/L
Glu	57	mg/dL
Lac	0.6	mmol/L
O ₂ Hb	17.8	%
COHb	0.5	%
MetHb	0.5	%
Hb	>40.0	%
TCO ₂	28.6	mmol/L

Calculated

Test	Value	Units
anion gap	2.1	mmol/L
base deficit	2.3	mmol/L
base excess	27.26	mmol/L
base deficit	20.2	mL/dL
base excess	3.6	mL/dL
base deficit	88.9	mmHg
base excess	1.25	mmol/L
base deficit	0.60	mmol/L
base excess	11.0	mmol/L
base deficit	2.1	mmol/mol

Investigator

Principal Investigator:

I have fully explained this study to the subject or his/her representative to the best of my ability. As a representative of this study, I have explained the purpose, the procedures, the possible benefits and risks that are involved in this research study. I have answered the subject's questions to his/her satisfaction before requesting the signature(s) above. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily. There are no blanks in this document. A copy of this form has been given to the subject or his/her representative.

JAMES E. Campbell

Printed name of Principal Investigator or designee

J. E. Campbell

Signature of Principal Investigator or designee

23 Jun 2025

Date

Time

AM 631, Cam #11

7a or before

- | | |
|-------------------------------------|---|
| <input checked="" type="checkbox"/> | Turn on chamber control deck |
| <input checked="" type="checkbox"/> | Assure MGA calibration every 2 weeks (maybe every other Tuesday?) |
| <input checked="" type="checkbox"/> | Power source for AliCats on |
| <input checked="" type="checkbox"/> | PAX oxygen source on, secondary reg tape pointing out, and connected (both MGA and O2 source) |
| <input checked="" type="checkbox"/> | Double check fresh PAX mask/MGA connection and SpO2 finger wrap |
| <input checked="" type="checkbox"/> | Place PAX on plastic hanger in chamber near Subject chair |
| <input checked="" type="checkbox"/> | Assure new breathing filter for PFT/Pneumotach |
| <input checked="" type="checkbox"/> | Blanket and towels check |
| <input checked="" type="checkbox"/> | Privacy curtain check |

8a or before - begin

- | | |
|-------------------------------------|---|
| <input checked="" type="checkbox"/> | Place Nonin sensor for SpO2 and heart rate data collection |
| <input checked="" type="checkbox"/> | Review Health History: Medical |
| <input checked="" type="checkbox"/> | Read through Informed Consent document |
| <input checked="" type="checkbox"/> | Sign informed consent |
| <input checked="" type="checkbox"/> | Sign investigator's affirmation |
| <input checked="" type="checkbox"/> | Sign Audio/Video if agreeable |
| <input checked="" type="checkbox"/> | Phlebotomy and blood gas analysis (everyday stay ahead of consumables and schedule for swaps) |
| <input checked="" type="checkbox"/> | Respirations |
| <input checked="" type="checkbox"/> | Weight |
| <input checked="" type="checkbox"/> | Height |
| <input checked="" type="checkbox"/> | Place H10 heart rate sensor strap with conducting gel |
| <input checked="" type="checkbox"/> | Place Polar watch |

9a or before (Blue Chamber entry)

- | | |
|-------------------------------------|--|
| <input checked="" type="checkbox"/> | Place Wellue thumb SpO2 (and assure IO also is instrumented with last 3) |
| <input checked="" type="checkbox"/> | Pneumotach heater on |
| <input checked="" type="checkbox"/> | Place HansR SpO2 finger sensor and finger splint w/ tape |
| <input checked="" type="checkbox"/> | Place chest/abdomen expansion straps |
| <input checked="" type="checkbox"/> | Insight program HansR software ON <input checked="" type="checkbox"/> LabVIEW ON time/ certain of accurate inputs |
| <input checked="" type="checkbox"/> | Pneumotach PFT - noseclip on, good mouth seal, comfortable - 7 tidal, 1 full, 3 tidal |
| <input checked="" type="checkbox"/> | PAX mask tutorial (fit, function, emergency, MGA tubing) |
| <input checked="" type="checkbox"/> | Thumbs up for good, sideways for feelin' effects of hypoxia, thumb down for there's a problem/
thumbs down might suggest descend a bit |
| <input checked="" type="checkbox"/> | On the ride from 30k' to 45k', keep thumb extended per your condition, do not lift arm/stay relaxed/
do not talk unless necessary |
| <input checked="" type="checkbox"/> | Expansion straps = respirations. Talking, repositioning, fidgeting interferes with that signal.
Please stay still, focus on breathing slowly and relaxed. |
| <input checked="" type="checkbox"/> | Nonin SpO2 finger clamps in place for Subj and IO |
| <input checked="" type="checkbox"/> | MGAs from stdby to "on" and ready for altitude exposure |

Flight

- | | |
|-------------------------------------|---|
| <input checked="" type="checkbox"/> | Insight and LabVIEW on (and recording) for PFT and 10k' and 14k' SpO2 baseline |
| <input checked="" type="checkbox"/> | Campbell enters chamber when door opened at GL to remove SpO2 and expansion strap connectors |
| <input checked="" type="checkbox"/> | IO or Campbell helps fit aviator's mask/helmet |
| <input checked="" type="checkbox"/> | Echo bike exercise prep (comfort, orient, hr target, watts, instruction) |
| <input checked="" type="checkbox"/> | Echo bike exercise execution |
| <input checked="" type="checkbox"/> | At timepoint 55min into the 100% oxygen pre-breathe, Campbell enters chamber/
leads minimal exercise portion |
| <input checked="" type="checkbox"/> | At timepoint 150min, pre-breathe and exercise portion are over, prep for ascent to 30k' |
| <input checked="" type="checkbox"/> | At 30k', begin 3.24LPM oxygen supply via PAX (just prior to mask swap) |
| <input checked="" type="checkbox"/> | Change PAX oxygen supply to 3.1LPM when SpO2 recovers to 85% |
| <input checked="" type="checkbox"/> | At start of descent to 35k', PAX mask oxygen flow 2.55L |
| | Transition to other sheet with oxygen flows per altitude |

ANNEX A1

Health History Questionnaire

(completed by each participant, presented for PI/medical monitor prior to enrollment)

Subject ID#: Am631 Cami #12 Age (18 to 50): 32 F
 Height (in): 62 Weight (lbs): 138
nhlbi.nih.gov/health/educational/lose_wt/BMI/bmicalc.htm BMI = 25.2
 Circle one – 1st class medical/ 2nd class medical/ 3rd class medical/ no current medical
 Flight time (hrs/wk total & if pressurized) 1, non pressurized
 Exercise regimen hrs/wk, type 20/week farm chores
 Are you able to run continuously for 20 minutes? Y/N Avg. pace? 8 minutes/mile
 Diver? (hrs/wk, depth, most recent dive) NO
 Do you currently use tobacco? Y/N Type: _____ Frequency: _____
 Have you ever smoked/vaped? Y/N Quit when? _____ How long/how regularly? _____
 Any medical/clinical respiratory condition (e.g., asthma, chronic obstructive pulmonary disease [COPD], etc.) Lung injury/breathing illness? Y/N When _____ What _____
 Do you have a history of or now have peripheral vascular/neuromuscular disease, neuropathy (stroke/epilepsy), high blood pressure, or Raynaud's syndrome? Y/N
 Medical or physical limitations that would preclude a decompressive experience? Y/N
 Have you, in the past or at present, experienced discomfort in confined spaces? Y/N
 Have you donated blood, platelets or plasma in the past 30 days or have a known anemia? Y/N
 Do you have any of the following: respiratory ailments such as asthma or emphysema; pregnancy; hypo/hypertension; diagnosed heart problems; chest pains, difficulty breathing; serious bodily disability, deformity, or dismemberment; spells of severe dizziness; diabetes requiring medication; claustrophobia; recent surgery; or any other chronic disease? Circle 1
 Any chronic medical condition not listed previously? NO
 Taking prescribed medications? Y/N Amount/type/reason: _____
 Use nutrition/herbal supplement? Y/N Amount/type/reason: _____
 Use otc medication (e.g., Tylenol/Advil) routinely? Y/N Amount/type/reason: _____
 Sensitive to other's touch or uncomfortable in enclosed environments? Y/N
 Please list any other comments regarding your medical history that might affect your ability to participate in this protocol.

ANNEX A2

PRE-flight Subject Exam and Instructions

(Completed morning of Subject experimentation after informed consent for confirmation of Subject qualification to participate)

Subject ID #: AM631 Cam. # 12 Age (18 to 50): 32

4 DAYS BEFORE CHAMBER FLIGHT

- 1) Review informed consent and OFOS protocol documents
- 2) Avoid gas-producing foods (beans, spicy foods, etc.) for at least 3 days prior to experimentation. Each Subject knows his/her own gastrointestinal fortitude – Do not exceed. If you do exceed, then report and postpone. Let someone else attend that day.
- 3) Limit alcohol for 3 days prior to chamber flight. Dehydration will undoubtedly occur. Do not further contribute to this impending dehydration.
- 4) No self-medication for flu, cold, etc. If you become ill, please inform the contract company (employer), that will in turn notify the government immediately upon discovery of symptoms.
- 5) No diving for 72 hours prior to hypobaric chamber exposure.
- 6) Get a good night's rest prior to participation.
- 7) Limit cardiovascular exercise for 12 hours prior, resistance training 4 days prior and do not perform exercise that is not part of your regular routine for 2 weeks prior.
- 8) Begin to wean yourself off caffeine at least one week prior to participation.

DAY OF CHAMBER FLIGHT (checklist)

- 1) Once again, no self-medication for flu, cold, etc. If you become ill, please inform your employer immediately upon discovery of symptoms.
- 2) No or very low caffeine intake as it is a vasoconstrictor and dehydrating agent. If a headache is expected with no consumption, then take as little as possible to avoid a headache.
- 3) Eat a breakfast low in fats and protein. Cereal, pancakes, waffles, toast are suggested with no butter or syrup. High triglyceride (fats) blood levels are known to interfere with hematocrit tests. Sorbitol, fructose, raffinose (carbohydrate found in beans) all increase the incidence of gas production, so please try to avoid.
- 4) Avoid exercise that is not protocol-related.
- 5) Use the restroom before entering hypobaric chamber. This will limit experimentation interruptions to use the urinal/potty in the hypobaric chamber.
- 6) Wear comfortable clothing. Females are suggested to wear a sports bra. Sensor placement may demand optimal access to skin on the upper torso.
- 7) Wear comfortable tennis shoes that do not stink. Shower using deodorant soap to wash every square inch of your body before arrival. You will be in a confined space. Respect others and save yourself the hours of discomfort.
- 8) BE ON TIME, please!
- 9) Reiteration - if you must cancel for any reason, please spread the word immediately to your employer. Many people prepare for one Subject's participation. Notification 24 hours prior or sooner is requested.

Physical Qualification/Inclusion Criteria

Hct (≥ 12.0 g/dl): 42 Hgb ($\geq 37\%$): 14.6 SpO₂ (> 94): 100 % rest HR: 74 bpm

Resp: 12 /min Temperature (< 100.0): 97.7 deg F

Height: 5-3 1/2 " Weight: 147 lbs BMI (≤ 40): ✓

Present your 3rd class or greater medical certificate for record of validity and non-expired status. GTG Y / N

Non-smoker/non-vaper? Y / N

History of injury (sports, hobby, accident)?

Location _____ Pain level _____ Frequency _____

Location _____ Pain level _____ Frequency _____

Location _____ Pain level _____ Frequency _____

Exclusion Criteria review (all "NO" answers get a pass on the day of experimentation)

Facial hair? Y / N

Any cold, acute upper respiratory infection (URI), or respiratory issue within two (2) weeks prior to study participation Y / N

Not able to exercise at the marathon pace level for 15 minutes? Y / N

Personal items with you? Y / N

Currently taking any medication or drug which may impair physical or cognitive activity, or which precludes the operation of heavy machinery/driving? Y / N

Additional questions

Have you taken any medications/caffeine/alcohol within 24 hrs prior? Y / N

Amount and Type: _____ Reason: _____

Recent illness? Y / N Symptoms/Severity 1-5/days? _____ Recover Y/N

of hours slept last night? 8 Do you feel well rested/was sleep sufficient? Y / N

STAT Profile PrimePlus

Full Panel

Blood Results

07-02-2025 08:34

Printed On 07-02-2025 08:31

Printer ID

Operator ID

Barometric Pressure 727.2 mmHg

Patient ID AM631CAM112

SpO₂ 20.9 %

Patient Temperature °C 37.0

AM631CAM112 - Syringe - Venous

Test	Value	Units
pH	7.380	
pCO ₂	42.3	mmHg
SO ₂	<30	%
Hct	42	%
tHb	14.6	g/dL
Na	137.3	mmol/L
K	4.06	mmol/L
Cl	104.0	mmol/L
iCa	1.21	mmol/L
iMg	0.67	mmol/L
Glu	84	mg/dL
Lac	0.6	mmol/L
O ₂ Hb	18.7	%
COHb	0.3	%
MethHb	0.3	%
H+H	>40.0	%
	26.6	mmol/L

Calculated

Units	Value	Units
mmol/L	0.0	
mmol/L	0.6	
mmol/L	25.28	
mL/dL	20.2	
mL/dL	3.8	
mmHg	91.5	
mmol/L	1.20	
mmol/L	0.66	
mmol/L	12.1	
mol/mol	1.8	

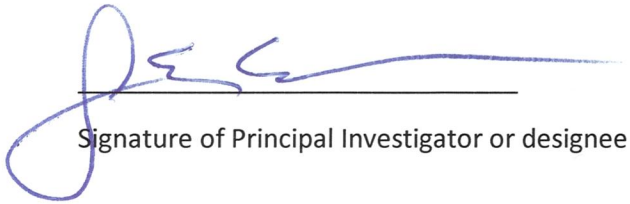
Investigator

Principal Investigator:

I have fully explained this study to the subject or his/her representative to the best of my ability. As a representative of this study, I have explained the purpose, the procedures, the possible benefits and risks that are involved in this research study. I have answered the subject's questions to his/her satisfaction before requesting the signature(s) above. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily. There are no blanks in this document. A copy of this form has been given to the subject or his/her representative.



Printed name of Principal Investigator or designee



Signature of Principal Investigator or designee



Date

Time