NASA INSTITUTIONAL REVIEW BOARD (IRB)
CONSENT TO BE A PART OF A RESEARCH STUDY

Determining the Dose Response Profile of the Headward Fluid Shift during Varying G-Levels
[Study 508]

NOTE: Any alterations to this consent document will invalidate the test subjects' consent unless the changes are approved in advance by the IRB.

ABOUT THIS RESEARCH CONSENT FORM

You may be eligible to take part in a research study.

A research study is carefully planned and designed to increase scientific knowledge.

This NASA IRB Consent form describes important information related to participation in a research study including the purpose, planned procedures, and potential risks.

Please take time to review this information carefully. Talk to the researchers about the study and ask any questions you have. **Make sure you fully understand what will be expected of you and the risks associated with participating in this study.** You may also wish to talk to others (for example, your friends, family, or doctors) about your participation in this study. If and when you decide to be a participant, you will be asked to sign this form, and you will be given a copy.

Taking part in this study is completely **voluntary**. The decision to participate is yours. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you.

This NASA IRB Consent form provides a detailed description regarding essential information including, but not limited to, **how, when, where**, and **by whom** a signed informed consent will be obtained.

Note: Failure to disclose pre-existing medical conditions may place you at greater risk for injury or other adverse events resulting from your participation in this study.

1. KEY INFORMATION

1.1 What am I being asked to do?

You are being asked to participate in a research study to determine how different gravity levels affect the distribution of fluids in the body (e.g., blood). To accomplish this, the investigators will use ultrasound to measure the size, flow characteristics, and pressure of the veins in your neck (internal jugular vein) while you are seated in a chair on a plane that is performing parabolic maneuvers (up and down like a rollercoaster). Experienced pilots will guide the plane through different shapes of parabolas to simulate multiple gravity levels varying from no gravity (weightlessness like in space) to ¾ (75%) of the Earth's gravity. The investigators will also be measuring your heart rate and blood pressure. You are being asked to participate in at least two parabolic flights for this study so that you experience each gravity level multiple times while the investigators obtain their measurements.

1.2 What are the possible risks/discomforts?

General risks associated with the facility: personal injury; slips, trips, and falls; fire.

General risks of participation in a parabolic flight: physical injury, motion sickness, emotional fatigue, stress, and harm to fetus, if pregnant. Parabolic flight does not comply with safety standards defined for public air transportation and may result in cancellation of guarantees for loans or insurance policies. It is recommended that you review your policies for exclusion clause related to flight aboard an aircraft without a standing Certificate of Airworthiness.

Risks of participation in this study: Skin irritation or allergic reaction due to application of electrodes (small adhesive patches)

1.3 What are the benefits for me?

There are no direct benefits to you associated with your participation of this study.

1.4 Is there any compensation for my time?

You will receive no direct compensation for your participation in this research study. However, your lodging and meal costs will be covered.

1.5 How will my information and/or identity be protected?

Your privacy and data confidentiality must be maintained in accordance with 1) NASA Policy Directive (NPD) 7100.8, "Protection of Human Research Subjects"; 2) NASA Procedural Requirements (NPR) 7100.1A, "Protection of Human Research Subjects"; and 3) to the extent allowed by Federal law.

All of your data, including electronically stored data and hard copies, will be labeled with your designated subject ID code and stored in a locked laboratory (Cardiovascular and Vision Laboratory at NASA JSC) and on secure NASA servers. Records linking your subject ID code to you directly will be retained by the Principal Investigator and will not be released without your consent, unless specifically required by law. Representatives of NASA and its medical contractors may review the research data for the purposes of medical safety or for verification of research data. Every effort will be made to maintain the confidentiality of your study records. The results from the study may be used by the research team and possibly be presented at scientific conferences and/or published in peer-reviewed scientific journals, with all identifiers removed from the data. The confidentiality of the data will be maintained within legal limits.

1.6 Are there any alternatives to participation in this study?

The alternative to your participation is to not participate in the study.

2. GENERAL INFORMATION

2.1 The study title is: Determining the Dose Response Profile of the Headward Fluid Shift During Varying G-Levels

2.2 The study team includes a Principal Investigator, Co-Investigator, Key-Personnel (names, degrees, affiliations):

Principal Investigator: Stuart M. C. Lee, PhD, KBR, Houston, TX USA

Co-Investigators:
David Martin, MS, KBR, Houston, TX USA
Chris Miller, MS, KBR, Houston, TX USA
Jason Lytle, PhD, KBR, Houston, TX USA
Steven Laurie, PhD, KBR, Houston, TX USA
Brandon Macias, PhD, NASA, Houston, TX USA
Millennia Young, PhD, NASA, Houston, TX USA

Key Personnel:
Rebecca Cox, Aegis Aerospace
Monica Randall, KBR
Sondra Perez-Freeman, KBR
Matthew Poczatek, JES Tech
Annelise Miller, Aegis Aerospace
Stephanie Melvin, RN, JES Tech

Study Coordinator:
Lucinda Yu, MS, KBR, Houston, TX USA

2.3 This study is sponsored or funded by: National Aeronautics and Space Administration, Human Research Program

3. PURPOSE OF THIS STUDY

3.1 The purpose of this study is to determine whether exposures to partial gravity levels (G-levels), including those similar to those on the Moon and Mars, will provide protection against the excess fluid in the head that may be associated with the development of Spaceflight-Associated Neuro-ocular Syndrome (SANS). SANS refers to a range of changes in the eyes and surrounding structures of astronauts during long stays in weightlessness. This study will provide important data to inform NASA if artificial gravity (or similar concepts) will restore proper fluid flow in the upper body during spaceflight.

3.2 You are being asked to join this study, because you are apparently healthy with no known cardiovascular complications that might affect the data acquired during parabolic flight. You are being asked to participate solely for research purposes.

4. STUDY PARTICIPANTS

4.1 In order to be eligible to participate, you may be asked to undergo the following screening tests or procedures:

In coordination with the parabolic flight company, Novespace, healthy volunteers from the population that are 25-55 years old without a history cardiovascular disease will be recruited for this study. In order to participate, you must be able to follow instructions in English.

Participants must be age 18 years or older, hold a French or European Health Insurance Card, and provide medical certification of fitness for flight to Novespace (i.e., Novespace Parabolic Flight Medical Aptitude Certificate) completed by their medical doctor or an Authorized Medical Examiner.

Novespace exclusion criteria includes: Those with certain heart and lung conditions, dizziness, certain inner ear conditions, severe motor disability, impaired bone density, certain neurological diseases, debilitating anxiety and/or panic attacks, claustrophobia, women who are pregnant, certain gastrointestinal conditions, and those taking certain medications are ineligible to participate. An individual's overall medical fitness for flight is assessed and certified prior to enrollment by a medical doctor or Authorized Medical Examiner.

Pregnant women are not eligible to participate in this study. Women who could possibly become pregnant will be offered a pregnancy screening test and excluded with a positive test. Women who could possibly become pregnant should consult with their health care provider about contraception use until all study procedures are complete. The study may involve risks that are unforeseeable to both mother and baby.

4.2 You are one of 20 subjects.

5. STUDY PROCEDURES

5.1 Measurements

During this study, we will use ultrasound to measure the cross-sectional area (size) of the main veins in your neck (internal jugular veins), the pattern of blood flow within them, and the pressure within your veins during normal gravity and during reduced gravity produced by parabolic flight. When measuring cross-sectional area and flow in your neck veins, a small amount of gel will be placed on the end of an ultrasound probe and then placed gently on your neck. You will not experience any other sensations from this measurement beyond light pressure required to hold the probe in place. To measure the pressure in the veins of your neck, the ultrasound operator will press the probe firmly against your neck to briefly compress the neck vein. You will not experience any effects beyond the pressure of the probe. These measurements have been performed many times by our team in our laboratory, during parabolic flights, and by astronauts on the International Space Station.

During these tests, you also will have adhesive pads (electrodes) placed on your chest, and these will be connected to cables so that we can measure heart rate (electrocardiogram). A small cuff will be placed around your finger to measure blood pressure continuously during the experiment. We will also record your blood pressure at your upper arm with an automated blood pressure measurement device that uses a standard inflatable cuff like that used at a doctor's office.

Before the Plane Takes Off

Before the day of the flight, you are required to participate in safety briefings by the parabolic flight company, which may take up to 2 hours.

Prior to the flight, ultrasound measurements will be taken both while you are seated and while you are lying down. It should take approximately 1 hour to obtain these preflight measures. The ultrasound operator will identify the proper location for ultrasound measurement on both sides of your neck and mark these locations on your neck with a marker. This will make it easier to find the proper location for the measurements during the flight. We will record your heart rhythm, finger blood pressure and upper arm blood pressure during this time, but you will be disconnected from the hardware (except for the electrodes on your chest) during take-off.

During the Parabolic Flight

You will board the plane for the parabolic flight, during which you will be exposed to normal gravity (plane flying straight and level), periods of increased gravity, and varying levels of partial gravity (0.25, 0.5, and 0.75-G) and zero-gravity (0-G). The plane will take-off and land normally, but will perform parabolic flight maneuvers during the experimental portion of the flight.

The aircraft will fly in parabolas that initially produce increased gravity (1.8-G, "hypergravity"), followed by ~20-50 second periods of partial or 0-G. After that, there will be another pull-up (hypergravity) to complete the parabola. The plane then will fly in normal horizontal flight for a few minutes before repeating the parabolic flight path again. The pilots will perform this sequence of maneuvers many times. The number of times, the level of reduced gravity, and the order of reduced gravity exposures will depend upon the flight plan for that day. You will be informed of the flight plan in the pre-mission briefing conducted by Novespace. Flights generally consist of 31 parabolas, one "practice" parabola to ensure that the experiment hardware is functioning correctly and then 6 sets of 5 parabolas. During the 0-G flights, your responses will be measured during at least 10 parabolas. When you are not being tested, you will be instructed by Novespace personnel to remain within a designated area. During flights which produce partial gravity, your responses will be measured for at least 10 parabolas at each of the gravity levels (0.25-, 0.50-, and 0.75-G). The total flight time from take-off to landing is approximately 2-3 hours.

During the flight, you will be seated in a specially designed chair with a seatbelt, and the ultrasound operator will be seated in front of you. Measurements will be taken multiple times during partial gravity or weightlessness and during level flight. We request that you stay relaxed and minimize any movements during the ultrasound measurements so that we may get accurate measurements. Also, it is a good idea to minimize any movements during periods of increased gravity ("pull-out", "pull-up") in order to prevent motion sickness. During takeoff and landing, you will be in a seated with a seatbelt in a standard airline seat in the back of the aircraft.

After the data collection is completed, we will disconnect you from the hardware and remove the electrodes. While you may experience fatigue, tiredness, and motion sickness from participating in parabolic flight, there will be no direct effects from the ultrasound measurements, except for perhaps skin irritation from the electrodes.

<u>Time Commitment</u>

Per Flight:

Preflight:	1-2 hours
Inflight:	2-3 hours
Postflight:	None, unless we are unable to acquire preflight measurements (e.g., due to scheduling constraints)

Total time:

You will be asked to participate in at least two flights during this study. One flight will include periods of weightlessness (0-G) and one will include periods of partial gravity (0.25-G, 0.50-G, 0.75-G).

Two flights	8-10 hours

<u>Photography</u>

Centre National D'Etudes (CNES), European Space Agency (ESA), Deutsches-Zentrum für Luft-und Raumfahrt (DLR), and Novespace will photograph or film you in Novespace facilities, including the aircraft, and use those images for the purposes of promotion and communication. These images also are for use by the investigator team to verify data acquisition practices and for communication in presentations and publications.

5.2 The study you are joining includes one of the following categories:

☐ *"Randomized"* means that you are put into a group by chance (e.g., like flipping a coin). Neither you nor the principal investigator will choose what group you will be in. You will have a chance of being placed in any group.

☐ *"Blinded"* means you (blinded) will not know what group you are in.

☐ *"Double-Blinded"* means that neither you nor the Principal Investigator (double-blinded) will know what group you are in.

☐ *"Placebo"* means a pill with no medicine. In a placebo-controlled study, you may be given a study medication and it will contain either (name of drug) or placebo (pills with no medicine).

☐ *"Observational"* means a chart or record-based study that examines previously collected data.

☒ None of the above: You are one of member of a group of normal, healthy subjects who have volunteered to participate in this study. Both men and women may participate.

6. DRUGS, BIOLOGICS, and MEDICAL DEVICES

6.1 Is a study drug or biologic used?

☒ No

☐ Yes, the study drug or biologic is N/A.

☐ This drug or biologic is FDA approved.

☐ This is an investigational drug or biologic, with the FDA IND number:
Click or tap here to enter text.

6.2 Is a medical device used?

☐ No

☒ Yes, the study medical devices are an ultrasound system, a finger blood pressure measurement device, and an electrocardiograph (to monitor your heart rhythm with standard electrodes (small adhesive patches) attached to your chest.

☒ These medicals device are FDA approved or CE marked.

☐ This is an investigational medical device, with the FDA IDE number _____.

☐ This device is IDE exempt as *[provide rationale/support]*.

☐ This is an investigational non-significant risk device, with IRB approval for use. A document providing full and informed disclosure is provided for your review.

7. INFORMATION ABOUT RISKS AND HAZARDS

7.1 You are joining a study that is:

___ "Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the research is not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

__x_ "Greater than minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the research is greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests, but that the risks of harm or discomfort are considered to be acceptable when weighed against the anticipated benefits and the importance of the knowledge to be gained from the research.

7.2 The risks/hazards of joining the study and the steps taken to protect against harm include:

Risks related to Parabolic Flight:

•Physical injury during parabolic flight. Trips, falls, or impact from equipment and other people during parabolic flight.

•Motion sickness during parabolic flight.

•Financial/insurance risk. Participation in a flight without a standard Certificate of Airworthiness may result in cancellation of insurance policies or guarantees for loans.

Parabolic Flight risk minimization:

•Physical injury during parabolic flight. -- The aircraft used is adapted and maintained specifically for parabolic flight and flown by experienced, trained pilots. Instructors and safety personnel are onboard the aircraft to aid in avoiding collisions, trips, and falls. The walls, ceiling and floor of the cabin are padded.

•Motion sickness during parabolic flight. – Novespace provides motion sickness medication, Participants are advised by Novespace to avoid alcohol, obtain proper sleep the night before the flight, and eat a regular breakfast the morning of the flight.

•Insurance/financial risk. Participants are advised to check personal insurance for clauses/provisions/restrictions related to participation in a flight without a standard Certificate of Airworthiness. Novespace provides insurance up to €1,000,000 for all passengers on the Air Zero G flight.

Pregnant women are not eligible to participate in this study. If you are a female of child-bearing age who could possibly become pregnant, you will be offered a pregnancy screening test and excluded with a positive test. If you could possibly become pregnant, you should consult with your health care provider about contraception use until all study procedures are complete. Currently there are no known risks to a pregnant female and a fetus for this protocol, but the study may involve risks that are unforeseeable to both mother and baby. Unknown adverse fetal events may occur, even in the absence of maternal symptoms.

General Risks Associated with Facility

1. Potential Hazard: Personal Injury
    a. Causes: Contact with sharp edges and points; impact from other equipment.
    b. Protection to Minimize Risks: Sharp edges, etc. are identified and controlled to prevent injury.
2. Potential Hazard: Slips, trips, or falls
    a. Causes: Trip hazards in testing area
    b. Protection to Minimize Risks: Trip hazards that cannot be removed will be marked. You will be directed to walk through cord-free zones.
3. Potential Hazard: Fire
    a. Causes: Electrical Faults
    b. Protection to Minimize Risks: Smoke/ fire alarm and sprinkler systems within building to protect occupants. Test operators that are building occupants will direct you to the safe meeting location.

Risks Associated with Parabolic Flight

- Potential Risk: Physical injury during parabolic flight
    - Causes: Tripping, falling, or impacting equipment or other people while moving around the plane
    - Protection to Minimize Risks: Aircraft used is adapted and maintained specifically for parabolic flight and flown by experienced, trained pilots. You will be required to participate in safety briefings conducted by the parabolic flight company (Novespace) and follow all inflight safety protocols. All equipment will be secured during the flight. Edges of shelves and chairs are lined with soft foam, and the cabin is padded. You will be required to wear a seat belt while seated during take-off and landing and while seated in a specially designed chair during the experimental portion of the flight.
- Potential Risk: Motion sickness during parabolic flight
    - Causes: Alternating periods of hypergravity (more than normal Earth gravity) and partial or zero gravity
    - Protection to Minimize Risks: At the discretion of the on-site physician (provided by Novespace), you may be offered anti-nausea medication to reduce the chance of motion sickness. Additionally, we recommend that you minimize movement during periods of altered gravity. Participants are advised by Novespace to avoid alcohol, obtain proper sleep, and eat a regular breakfast before the flight.
- Potential Risk: Harm to fetus if pregnant
    - Causes: Altered gravity, potential for physical harm
    - Protection to Minimize Risks: If you are a female of child-bearing age capable of becoming pregnant, we recommend that you take a pregnancy test and/or consult with your physician before participating in this study.
- Potential Risk: Insurance and financial risk
    - Causes: Participation in a flight without a standard Certificate of Airworthiness

- Protection to Minimize Risks: Participants are advised to check personal insurance for clauses, provisions, and restrictions related to participation in a flight without a standard Certificate of Airworthiness. Novespace provides insurance up to €1,000,000 for all test subjects on the Air Zero G flight.

Risks Associated with Investigational Procedures

- Potential Risk: Skin irritation or allergic reaction
  - Causes: Application of electrocardiogram electrodes or ultrasound gel.
  - Protection to Minimize Risks: Only standard medically approved electrodes and gel are used. You will be encouraged to wash off ultrasound gel, electrode gel and adhesive with soap and water.

Risk of participation in data collection activities

- Potential Hazard: Breach of subject confidentiality
  - Causes: Improper handling of data or data reporting
  - Protection to Minimize Risks: All data, including electronically stored data and hard copies, will be labeled with your designated subject ID code and stored in a locked laboratory (Cardiovascular and Vision Laboratory at NASA JSC) and on secure servers. Records linking your subject ID code to your identity will be retained by the Principal Investigator and will not be released without your consent, unless specifically required by law. The results from the study may be used by the research team and possibly be presented at scientific conferences and/or published in peer-reviewed scientific journals, with all identifiers removed from the data. The confidentiality of the data will be maintained within legal limits.

8. TREATMENT, INJURY AND COMPENSATION INFORMATION

8.1 Even though researchers have taken steps to minimize the risks, you may experience problems or side effects. In the event of physical injury resulting from this study, NASA will provide or cause to be provided, the necessary immediate action or treatment. NASA will pay for any claims of injury, loss of life or property damage to the extent required by the Federal Employees Compensation Act or the Federal Tort Claims Act. Your agreement to participate shall not be construed as a release of NASA or any third party from any future liability, which may arise from, or in connection with, the test procedures.

8.2 Novespace and the European Space Agency (ESA) are unable to offer financial compensation nor absorb the costs of medical treatment should you be injured as a result of participating in this research. However, per Novespace policy, as a passenger on an Air Zero G flight, you are insured with a Limit of Coverage of €1,000,000. Additional insurance coverage may be available at your own expense. Please contact Novespace with questions, concerns, or claims.

9. BENEFITS INFORMATION

9.1 Participation in NASA studies generally result in no direct benefit to you as an individual. It is hoped that the information gained from this research study will help NASA learn more about human physiological changes during space flight missions and how to prevent any deleterious adaptations.

10. NEW FINDINGS

10.1 If new information is obtained during the study after you have joined, you will not be informed. You may change your mind about continuing in the study. You may be asked to sign a new consent form that includes the new information.

In the course of your participation in this investigation, if the test operators performing the study observe what they perceive to be an anatomical abnormality or a potential medical issue in your ultrasound images, a medical monitor on the parabolic flight (physician) and/or the Institutional Review Board Protocol Compliance Officer (physician) will be notified. The physician will review the images and contact you if they believe that a medical condition exists. The Cardiovascular and Vision Laboratory personnel cannot provide medical diagnoses but can provide you with still images and/or short video loops from the ultrasound for the purpose of follow-up with your personal physician.

11. STUDY WITHDRAWAL and/or TERMINATION

11.1 You may withdraw from the study at any time. If you decide to leave before the study is finished, please tell the investigator or study staff. Your refusal will be honored. In cases when the responsible physician's opinion is that study termination could have undesired consequences for your health and/or the health of other subjects, you will be told if there could be any harm to you if you decide to leave before the study is finished. If you tell the researchers your reasons for leaving the study, that information will be part of the study record.

NOTE: Because this is a parabolic flight on which other experiments also are flying, if you decide not to participate in the experiment after the plane takes off, except in case of medical emergency, you will have to experience the entirety of the parabolic flight from the airline seat you use during take-off and landing.

11.2 Your withdrawal or refusal to participate in the study will not result in any penalty or loss of benefits to which you are otherwise entitled.

11.3 If you decide <u>not</u> to join the study, you may be eligible to participate in other studies.

11.4 Researchers may need to stop your participation in the study even if you want to continue participation. Some examples of this scenario include: (Check applicable boxes)

☒ The researcher believes that it is not in your best interest to stay in the study

☒ There is any problem with following study related instructions

☒ There is any problem with following hospital, clinic, or laboratory policies and procedures

☒ There is any serious complication during the study

☒ There is inappropriate behavior

☒ The study is suspended or canceled

☒ The subject's information is or becomes unusable for any reason

☒ Events beyond NASA's control occur, for example: fire, explosion, disease, weather, floods, terrorism, wars, insurrection, civil strife, riots, government action, or failure of utilities

☐ Existing data reveal answers earlier than expected

12. COST and FINANCIAL INFORMATION

12.1 There are no costs or bills to you for participation in this study.

13. PAYMENT and REIMBURSEMENT

13.1 You will not be paid to participate in the study.

14. DATA PRIVACY AND CONFIDENTIALITY

14.1 Subject privacy and data confidentiality must be maintained in accordance with 1) NASA Policy Directive (NPD) 7100.8, "Protection of Human Research Subjects"; 2) NASA Procedural Requirements (NPR) 7100.1A, "Protection of Human Research Subjects"; and 3) to the extent allowed by Federal law.

All data, including electronically stored data and hard copies, will be labeled with your designated subject ID code and stored in a locked laboratory (Cardiovascular and Vision Laboratory at NASA JSC) and on secure servers. Records linking your code to your identity will be retained by the Principal Investigator and will not be released without your consent, unless specifically required by law. Representatives of NASA and its medical contractors may review the research data for the purposes of medical safety or for verification of research data. Every effort will be made to maintain the confidentiality of study records. The results from the study may be used by the research team and possibly be presented at scientific conferences and/or published in peer-reviewed scientific journals, with all identifiers removed from the data. The confidentiality of the data will be maintained within legal limits.

14.2 Your privacy and the confidentiality of data collected as a part of this research study will be protected from unauthorized disclosure according to applicable federal law.

14.3 If applicable, your protected health information may be used or shared with others during the research for your safety. This may include:

- Existing medical records;
- Video and photographic materials;
- New information created from study-related tests, procedures, visits, and/or questionnaires.

14.4 Your protected information may be used or shared by NASA offices of research oversight or quality assurance, medical monitors, and researchers for the reasons below:

- To conduct and oversee the present research;
- To make sure the research meets NASA requirements;
- To conduct monitoring activities (including situations where you or others may be at risk of harm or reporting of adverse events);
- To become part of your medical record, if necessary, for your medical care;
- To review the safety of the research.
- To support "NASA Clinical Summit" activities where clinical experts evaluate relevant medical and research data to recommend clinical practice guidelines specifically for astronauts. These data will not include names or other information that explicitly link the information to you.

14.5 Every effort will be made to maintain the confidentiality of your study records. There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- NASA and other government officials may need the information to make sure that the study is done in a safe and proper manner. These agencies may include the Department of Health and Human Services (DHHS), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and/or the Office for Human Research Protections (OHRP) or other domestic or foreign government bodies if required by law and/or necessary for oversight purposes.
- The FDA may need to review the information if the study involves the use of an experimental drug or device.
- Safety monitors, medical personnel, or safety committees may review your research data, stored biospecimens, and/or medical records for the purposes of medical safety or for verification of research procedures.
- A data and safety monitoring board (DSMB) may oversee the research, if applicable.
- The results may be used by the research team and possibly be presented/published at scientific conferences and/or in an article, but would not include information that would identify you without your consent.

14.6 You have the right to withdraw your consent for the researchers to use or share your research data. The researchers will not be able to withdraw all the information that already has been used or shared with others to carry out related activities such as oversight, or to ensure quality of the study. To withdraw your consent, you must do so in writing by contacting the researcher.

14.7 You have the right to request access to your study records after the study is completed. To request this information, you must do so in writing by contacting the researcher.

14.8 If physiologic data (including but not limited to standard measures, laboratory data, psychological, or physiological measurements) are obtained from you for this study, they may become the property of NASA's Life Science Data Archive. All federal regulations concerning the privacy and confidentiality of these data will be followed. Records stored in this archive will not include names, registration numbers, or other information that explicitly links the information to you.

14.9 After your private identifiers have been removed, the remaining information or biospecimens could also be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

14.10 A blank informed consent form will be made available on Regulations.gov. This website will not include any information that can identify you. You can search this website at any time.

15. CONTACT INFORMATION

15.1 You may contact the Principal Investigator to:

- Obtain more information about the study;
- Ask a question about the study procedures;
- Report an illness, injury, or other problem;
- Leave the study before it is finished;
- Express a concern about the study.

Principal Investigator:	Stuart M. C. Lee, PhD
Email Address:	stuart.lee-1@nasa.gov
Mailing Address:	2400 NASA Parkway, Houston, TX 77058

Study Coordinator:	Lucinda Yu
Email Address:	lucinda.m.yu@nasa.gov
Mailing Address:	2101 NASA Parkway, Houston, TX 77058
Telephone:	281-704-9071

You may express a concern about this study by contacting the NASA Institutional Review Board (IRB) listed below:

Office of Research Assurance: Research Integrity & Protection of Human Subjects
2101 NASA Parkway
Mail Code SA
Houston, Texas 77058
Visit: https://irb.nasa.gov/contact

16. RECORD of INFORMATION PROVIDED

16.1 Your signature in the next section means that you have received copies of all of the following documents:

___ This NASA IRB "Consent to be Part of a Research Study" document

___ Other (specify): _____

17. SIGNATURES

Research Subject:

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with _____. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact the study team. I understand that I will receive a copy of this form at the time I sign it and later upon request.

Signature of Subject: _____ Date: _____

Name (Print legal name): _____

___ Check here if the study will NOT utilize video, audio or still photography

Research Subject Release for Video, Audio, and/or Photo:

I understand that this study will utilize video, audio and/or still photography to analyze study results and I consent for the use of these materials.

___ I accept

___ I do not accept

Signature: _____

Principal Investigator (or Designee):

I have relayed detailed information to this subject about this study. I believe it to be accurate and complete. The subject has indicated that he or she understands the nature of the risks and benefits of participating in this study.

Name: _____ Title: _____

Signature: _____ Date: _____

Witness (optional):

I observed the above subject sign this consent document.

Name: _____

Signature: _____ Date: _____