INFORMED CONSENT DOCUMENT
AGREEMENT TO BE IN A RESEARCH STUDY
AND
AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

Sponsor / Study Title:	**Kalogon / "Effect of the Kalogon AF Prototype Smart Cushion on B52 Pilot Fatigue and Comfort"**
Protocol Number:	**605.019**
Principal Investigator:	**Evan Call, MS, CSM-NRM**
Telephone:	**(801) 296-0451** **(801) 231-6499 (24 Hours)**
Address:	**Kalogon** **2401 S Harbor City Blvd** **Melbourne, FL 32901**

KEY INFORMATION

You are invited to take part in a research study. This research study is studying the effect seat cushions play in the comfort and fatigue (extremely tired) of airline pilots. This study is being sponsored by the company Kalogon, with funding from the Department of Defense.

1. The main reasons you will want to join this study may include an opportunity to participate in increasing our knowledge of how to help pilots be comfortable and reduce fatigue.
2. The main reasons you may not want to join this study may include playing video games, the length of visits (up to 12 hours), and sitting essentially in the same spot with little breaks.
3. The main research question is to see if the new cushion made by Kalogon (the study sponsor) will improve pilot comfort and reduce pilot fatigue compared to the standard airplane cushion. This is relevant to anyone who travels on an airplane. The comfort and ability of a pilot to perform their tasks effectively and safely is vital to the safety of everyone on the aircraft.
4. You likely have not taken a psychomotor vigilance task (PVT) test before which is a focus and reaction time test taken on a tablet. You will receive training on how to perform this test prior to participation if you proceed as a subject. You will also be asked to wear a flight suit during each trial.
5. Since our target population for the application of this study are pilots, we are screening individuals using the health standards that certain pilots are expected to meet. As such, subjects will undergo a health screening of yes and no questions about certain health conditions, outlined later in this informed consent, that may disqualify a subject from participating. We also are screening for medications that are not ok for pilots to take and/or will influence the outcome of the study. We also will be collecting your responses to the 3 surveys and the 2 trials of the PVT. All subject information will be stored electronically on a Health Insurance Portability and Accountability Act (HIPAA)-compliant, secured server.
6. Subjects will be asked to either play video games, fly a flight-simulator, or solve simple puzzles during their trials. A break will be given to eat and short, minimal bathroom breaks are allowed as well.

7. The most-likely, foreseeable impact this research will have on subjects outside of this study is the potential for subjects to experience muscle fatigue, pain, and stiffness from prolonged sitting. These side effects are expected to be mild and to resolve in a day or two, no more than typical soreness from travel or a workout at a gym.
8. As far as the study staff and investigators have found, this study has not been performed in a similar way anywhere else, combining different seat cushions with subjects taking a PVT test and multiple surveys for up to a 12-hour period.

INTRODUCTION

You are being invited to volunteer for a human subject research study. You must read and sign this form before you agree to take part in this study. This form will give you more information about this study. Please ask as many questions as you need to before you decide if you want to be in the study. You should not sign this form if you have any questions that have not been answered.

The investigator is being paid by the sponsor (the company paying for this study) to conduct this research study.

You must be honest with the investigator about your health history or you may harm yourself by participating in this study.

An investigator on this study has an ownership interest in Kalogon, the company sponsoring this research study. As a result, the investigator may benefit financially from a successful study. Please speak with the investigator if you have questions about this.

PURPOSE OF THE STUDY

This study is designed to evaluate the Kalogon AF prototype smart cushion and the affect it has on fatigue and comfort. This study will measure response time during a Psychomotor Vigilance Task (PVT) and a subjective comfort/discomfort survey on healthy subjects. The PVT testing and survey will both occur before and after each trial, with an additional third survey administered in the middle of the trial. Order of testing will be randomized (like the flip of a coin).

HOW LONG THE STUDY WILL LAST AND HOW MANY PEOPLE WILL BE IN THE STUDY

The study will be conducted via 2 visits for each subject. Each visit will last up to 12 hours. There will be at least 22 subjects in the study, between ages 18 and 35.

TO BE IN THIS STUDY

To be in this study you must have signed the Informed Consent and Photo Release forms. You must be between the ages of 18 to 35, ambulatory, able to sit for up to 12 hours with minimal breaks, and weigh between 91 - 250 lbs. You cannot participate in this study if you are pregnant or have traveled across time zones in the last 7 days. You cannot be taking any of the medications not allowed by the Federal Aviation Administration (FAA) including: opiates, muscle relaxants, anticholinergics (scopolamine, oxybutynin, Spiriva, etc.), sedating antihistamines (Benadryl, promethazine, hydroxyzine, etc.), anti-psychotics, or Over-the-Counter (OTC) active dietary supplements. Diagnosis of any of the following will prevent your participation as well:

- Chronic pain
- Asthma or other bronchospasm diagnoses

- Abnormalities of the heart valves, major vessels, heart rate or rhythm, any condition leading to poor circulation, increased risk of blood clots
- Chronic diseases of abdominal organs including hepatitis and inflammatory bowel disease
- Un-united fractures, instability of a major joint, retained orthopedic fixation devices, severe scoliosis, or disorder of the skeletal muscles
- Psoriasis
- Psychosis, schizophrenia, or other severe mental health disorder
- Seizure disorders
- Sleeping disorders

Subject Responsibilities:

While participating in this research study, you will need to:

- Be willing and able to follow the study directions and procedures
- Tell the study staff about any side effects or problems
- Ask questions as you think of them
- Tell the investigator or the study staff if you change your mind about staying in the study

WHAT WILL HAPPEN DURING THE STUDY

Screening:

Before the study starts, you will be asked to sign this consent form, give your health history, and tell study staff if you take any over-the-counter or prescription medicines, vitamins or herbs.

Study Procedures:

Upon arrival you will be asked to dress in a provided flight suit and be strapped into the simulated cockpit test rig. You will be provided a tablet to perform the pre-trial PVT. You will also have the start-trial survey administered to you. You will be asked to play video games during your study time. At a designated time in the middle of the trial, you will have the mid-trial survey administered to you. At the end of your trial time, you will have the end-trial survey administered to you and perform the post-trial PVT. This will be repeated a second time for a total of 2 trials per person.

POSSIBLE SIDE EFFECTS AND RISKS

If you do not understand what any of these side effects or risks mean, please ask the investigator, medical staff, or study staff to explain these terms to you.

You will also be asked to sit on a cushion for up to 12 hours with minimal breaks to use the restroom. Sitting for long periods of time can lead to pain and discomfort, muscle strains, pressure injuries, and blood clots. To minimize this risk, you are allowed to have a few, short bathroom breaks and we are recruiting healthy subjects who are less likely to experience one of these side effects.

Staring at screens for extended periods of time can lead to eye strain and mental fatigue. The screen has been placed at an appropriate distance and at an appropriate height to minimize eye strain. Short breaks to look away from the screen are permissible to help mitigate this risk.

Your health and safety are our top priority. We will do everything in our power to ensure your safety while maintaining the integrity of the study. If you experience any of these side effects, the trial will terminate immediately and appropriate medical treatment will be sought out.

If any anxiety or discomfort arises, please inform study staff immediately.

ADDITIONAL RISKS OR DISCOMFORTS

There may be other risks that are unknown. Frequent and open communication with study staff is vital to maintaining your safety and assists us in avoiding these unforeseen risks.

POSSIBLE BENEFITS OF THE STUDY

You will get no medical benefit from this study. Benefits of this study may include:

- A valuable contribution to the knowledge and understanding of how to keep pilots (and thereby their passengers and crew) safe, especially during long flights.

ALTERNATIVES TO PARTICIPATING IN THE STUDY

Since this study is for research only, the only alternatives would be not to participate or to withdraw your participation in the study.

CONFIDENTIALITY

Your provided personal health information and data gathered during the study will be kept private except when ordered by law. The following people will have access to your study records:

- The investigator
- Sponsor company and/or research institution [including monitor(s) and auditor(s)]
- State or federal regulatory agencies
- Advarra Institutional Review Board

The Institutional Review Board (IRB), Advarra, and accrediting agencies may inspect and copy your records, which may have your name on them. Therefore, total confidentiality cannot be guaranteed. If the study results are presented at meetings or printed in publications, your name will not be used. While every effort will be made to protect the confidentiality of your information, absolute confidentiality cannot be guaranteed.

Identifiers might be removed from your identifiable private information or identifiable biospecimens collected during this study and **could then be used for future research studies or distributed to another investigator for future research studies** without additional informed consent.

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

IN CASE OF STUDY RELATED INJURY

In the event of physical injury resulting from your participation in this research, you will be directed to receive the necessary medical treatment. Costs not covered by your health care insurer will be your responsibility. Also, it is your responsibility to determine the extent of your health care coverage. There is no program in place for other monetary compensation for such injuries. However, you are not giving up any legal rights or benefits to which you are otherwise entitled. If you are participating in research that is not conducted at a medical facility, you will be responsible for seeking medical care and for the expenses associated with any care received.

Please be aware that some insurance plans may not pay for research-related injuries. You should contact your insurance company for more information.

LEGAL RIGHTS

You will not lose any of your legal rights by signing this consent form.

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study such as:

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research subject;
- Eligibility to participate in the study;
- The investigator's or study site's decision to withdraw you from participation;
- Results of tests and/or procedures;

Please contact the investigator at the telephone number listed on the first page of this consent document.

If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, contact:

- By **mail**:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00073477.

PAYMENT FOR BEING IN THE STUDY

You may receive up to $150 per day for being in the study. If you choose to leave or are withdrawn from the study for any reason before finishing, you will be paid for the time spent (pro-rated at $20.00 per hour). You will receive payment within 4 weeks after your last study visit.

COSTS

There will be no charge to you for your participation in this study.

VOLUNTEERING TO BE IN THE STUDY

It is your choice if you want to be in the study. No one can force you to be in the study. You may not want to be in this study or you may leave the study at any time without penalty or loss of benefits to which you are otherwise entitled.

The investigator, or the sponsor company, may take you out of the study without your permission, at any time, for the following reasons:

- If you do not follow the investigator's instructions
- If we find out you should not be in the study
- If the study is stopped
- If it becomes harmful to your health

If information generated from this study is published or presented, your identity will not be revealed. If you leave the study, no more information about you will be collected for this study. However, all of the information you gave us before you left the study can still be used.

NEW FINDINGS

If there is new information or any significant new findings that could relate to your willingness to continue participation, we will tell you. You can then decide if you still want to be in the study.

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

If you decide to be in this study, the investigator and study staff will use and share health data about you to conduct the study. Health data may include:

- Your name.
- Address.
- Phone number.
- Date of birth.
- Medical history.
- Information from your study visits, including all test results.

Health data may come from your study records or from existing records kept by your doctor or other health care workers.

For this study, the study staff may share health data about you with authorized users. Authorized users

may include:

- Representatives of Kalogon.
- Representatives of EC Service, Inc.
- Representatives of Advarra IRB (an Institutional Review Board that reviews this study).
- The Food and Drug Administration (FDA) and other US federal and state agencies.
- Government agencies to whom certain diseases (like HIV, hepatitis, and STDs) must be reported.
- Governmental agencies of other countries.
- Outside individuals and companies, such as laboratories and data storage companies, that work with the researchers and sponsor and need to access your information to conduct this study.
- Other investigators and medical centers participating in this study, if applicable.
- A data safety monitoring board which oversees this study, if applicable.

Your health data will be used to conduct and oversee the research, including for instance:

- To see if the study device works and is safe.
- To compare the study device to other devices.
- For other research activities related to the study device.

Once your health data has been shared with authorized users, it may no longer be protected by federal privacy law and could possibly be used or disclosed in ways other than those listed here.

Your permission to use and share health data about you will end in 50 years unless you revoke it (take it back) sooner.

You may revoke (take back) your permission to use and share health data about you at any time by writing to the investigator at the address listed on the first page of this form. If you do this, you will not be able to stay in this study. No new health data that identifies you will be gathered after your written request is received. However, health data about you that has already been gathered may still be used and given to others as described in this form.

Your right to access your health data in the study records will be suspended during the study to keep from changing the study results. When the study is over, you can access your study health data.

If you decide not to sign this form, you will not be able to take part in the study.

AGREEMENT TO BE IN THE STUDY

This consent form contains important information to help you decide if you want to be in the study. If you have any questions that are not answered in this consent form, ask one of the study staff.

Please answer **YES** or **NO** to the following questions:

A. Is this document in a language you understand? _____

B. Do you understand the information in this consent form? _____

C. Have you been given enough time to ask questions and talk about the study? _____

D. Have all of your questions been answered to your satisfaction? _____

E. Do you think you received enough information about the study? _____

F. Do you volunteer to be in this study of your own free will and without being pressured by the investigator or study staff? _____

G. Do you know that you can leave the study at any time without giving a reason and without affecting your health care? _____

H. Do you know that your health records from this study may be reviewed by the sponsor company and by government authorities? _____

IF YOU ANSWERED "NO" TO ANY OF THE ABOVE QUESTIONS, OR YOU ARE UNABLE TO ANSWER ANY OF THE ABOVE QUESTIONS, YOU SHOULD NOT SIGN THIS CONSENT FORM.

_____

Printed Name of Adult Study Subject

_____

Signature of Adult Study Subject Date

_____

Printed Name of Person Explaining Consent Form

_____

Signature of Person Explaining Consent Form Date

PHOTO RELEASE FORM

You give the company paying for this research study the right to use, copy, and give out the pictures taken.

Your pictures may be used for advertising or in scientific journals or magazines.

Your pictures may be used as part of a larger presentation, along with other pictures, videotapes or things like that. Your pictures may also be edited.

The company paying for this research study may give other people or companies permission to use your pictures.

We will try to hide your identity. Your name will not be on the pictures. You have the right to review your pictures and cancel this Photo Release Form.

Statement of Consent:

I have read this release and understand its meaning. I understand I do not need to sign this Photo Release Form in order to be in the study.

_____
Printed Name of Adult Study Subject

_____
Signature of Adult Study Subject Date

_____
Printed Name of Person Explaining Release Form

_____
Signature of Person Explaining Release Form Date

You will be given a signed and dated copy of this release consent form to keep.