CONSENT TO BE A PART OF A RESEARCH PROJECT

ABOUT THIS RESEARCH CONSENT FORM

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

This project is not under the purview of the NASA IRB because the NASA IRB determined the project does not meet the Federal definition of "research" or "human subject" as defined in 14CFR1230.

Please take time to review this information carefully. Talk to the researchers about the project 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 project.**

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

1. GENERAL INFORMATION

The project title is: Sample Size Requirements for Human-In-the-Loop Testing

The project team includes: Ian Robertson, PhD, Principle Investigator, KBR
Kritina Holden, PhD, Co-investigator, Leidos
Tyler Duke, MS, Co-investigator, Leidos
Ryan Lange, PhD, Co-investigator, Aegis Aerospace

This project is sponsored or funded by: The Human Research Program

Brief Summary: The purpose of this study is to understand how varying the number of participants used to evaluate a system affects the observed outcomes.

2. PROJECT PROCEDURES

As part of this study, you will complete two sessions. Each session is estimated to about 90 to 150 minutes in length. It is necessary to complete both sessions.

In Session One you will complete the following activities:

- Gain familiarization with the systems involved in the study.
- Complete up to two flight-like tasks with high-fidelity, flight-like systems ranging from 25 minutes to 35 minutes in length.
- Complete surveys (usability, workload, feedback etc.) and answer questions about your experience with the systems.

In Session Two you will complete the following activities:

- Complete a review of what you learned in Session One.
- Complete up to two flight-like tasks with high-fidelity, flight-like systems ranging from 25 minutes to 35 minutes in length.
- Complete surveys (usability, workload, feedback etc.) and answer questions about your experience with the systems.

3. INFORMATION ABOUT RISKS AND HAZARDS

The risks and hazards of joining the project and the steps taken to protect against harm include:

Risk	**Mitigation Strategy**
Fatigue	Participants can cease involvement at any time without penalty, participants can take breaks as needed and test moderators will inquire if a break is needed between segments of the study (e.g., in between the familiarization session and the tasks).
Physical injury	Participants will be completing tasks with a high-fidelity space vehicle mockup that approximates crew-like activities (interacting with a screen, pressing buttons, twisting knobs etc.). The risk of physical injury is no greater than what you may encounter in daily life (e.g., working on a desktop computer). However, to minimize risk, the test area will be inspected before every session for potential hazards, and participants may stop activity at any time if they feel there is potential for harm. Any perceived hazard will be addressed immediately before research protocol is continued.
Privacy	Participants' data will be coded and assigned to an anonymous ID. Identifying information (e.g., informed consent form) will not be tied to this ID. Data will be stored in secure locations only accessible to the research team.

Please note, this risk level was not determined by the NASA IRB.

4. TREATMENT, INJURY AND COMPENSATION INFORMATION

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 project, 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.

5. BENEFITS INFORMATION

Participation in NASA projects/studies generally result in no direct benefit to you as an individual. It is hoped that the information learned from this research project will help NASA learn more about human physiological and psychological changes for future space flight missions.

Some participants will be paid to participate in the study as follows:

- You will not receive payment if you are a NASA civil servant, other federal civil servant employee, contractor, or International Partner crewmember participating in ESA, JAXA, CSA, or NASA-sponsored studies.
- Eligible participants from the Human Subjects Test Facility will be paid $10 per hour.
- Eligible NASA contractors will be provided a charge number for their time.

6. SUBJECT RECORD CONFIDENTIALITY AND AUTHORIZATION TO RELEASE PROTECTED HEALTH INFORMATION

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

Your protected health information may be used or shared with others during the research. This may include:

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

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.

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

- The researchers may need the information to make sure you can take part in the project.
- NASA may need the information to make sure that the project is done in a safe and proper manner.
- 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.
- 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.

You have the right to withdraw your consent for the researchers to use or share your protected health information. 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 project. To withdraw your consent, you must do so in writing by contacting the researcher.

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

If physiologic data (including but not limited to standard measures, laboratory data, psychological, or physiological measurements) are obtained from you for this project, they may become the property of NASA's Life Science Data Archive. These data may be used in this project, may be used in other research, and may be shared with other organizations. 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.

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.

7. CONTACT INFORMATION

If you have any questions you may contact the Project Lead, Ian Robertson, at ian.w.robertson@nasa.gov or 618-521-7670.

8. AFFIRMATION

I have reviewed all of the above materials and consent to participation in this activity as detailed in this form, including the recording of audio, video, and/or digital data.

Signature_____

Date_____