Cover Page for ClinicalTrials.gov

Informed Consent Form

Effects of Simulator Motion Fidelity on Pilot Performance while using a Mixed-Reality Headset

NCT07129876

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National Aeronautics and Space Administration (NASA) IRB

HUMAN RESEARCH INFORMED CONSENT FORM

Title:

Effects of simulator motion fidelity on pilot performance while using a mixed-reality headset.

A. Purpose:

The purpose of this research is to investigate how different levels of simulator motion fidelity affect pilot performance in two demanding flight tasks while using a head mounted display (or mixed-reality headset) for out-the-window (OTW) visuals.

B. Investigators:

Principal Investigator: Peter M. T. Zaal, Ph.D. (Metis Technology Solutions, Inc.)
Co-Investigator and Simulator Operator: Matt L. Blanken (NASA Ames Research Center)
Co-Investigator and Simulator Operator: Sam P. Orth (Symvionics, Inc.)
Co-Investigator and Simulator Operator: Supreethi V. Penmetcha (NASA Ames Research Center)

Key Information

C. What is the key information needed to help me decide if I should participate in this voluntary study or not?

- **What am I being asked to do?** You will be flying a lift-plus-cruise electrical vertical takeoff and landing (eVTOL) vehicle and perform two flight tasks in the NASA Ames Vertical Motion Simulator (VMS), the world's largest vertical motion simulator. The out-the-window visual scene will be provided by a mixed-reality headset that you will be wearing while inside the simulator cockpit. The out-the-window visual scene will be overlayed on a camera passthrough of the real cockpit. This means you will see the actual head down displays (HDD) and inceptors in the cab. You will start each task with three training runs to get familiar with the task criteria and procedures. Both tasks will be repeated nine times after training and the simulator motion intensity might be different each time. You will complete a motion rating scale and a Simulator Sickness Questionnaire at the end of each run.

  In task 1, a roll-lateral sidestep maneuver will be performed from one landing pad to a second landing pad of a vertiport on the Fifth & Mission Parking Garage in San Francisco. During the maneuver, you should remain at a constant altitude. A positioning sight is placed in the visual scene at each landing pad to determine your positioning error precisely. You will be provided with lateral position and time criteria for desired and

adequate performance. You will press an event marker on the sidestick as soon as you acquire the station-keeping point at the landing pad. Turbulence will be present during the task.

In task 2, a precision landing will be performed at the same vertiport in San Francisco that is used in task 1. The task will start from level flight from a position that allows for a standard approach and landing. Landing position and time criteria for desired and adequate performance will be provided. You will press an event marker on the control inceptor as soon as you acquire the desired reference point on the landing pad. Turbulence will be present during the task.

Your participation in the experiment will start with a 60-minute briefing and walkaround. A run for each task will take no longer than 3 minutes including time for completing questionnaires. After the briefing, the first task session starts which will take no longer than 45 minutes (12 runs). This includes time for completing questionnaires and additional breaks. A 30-minute break is scheduled after the first session, after which the second 45-minute task session will commence. Finally, your participation concludes with a 30-minute debrief. The total experiment will not take longer than 3.5 hours.

- **What are the possible risks/discomforts?**
  There is a small risk of some motion sickness, including vomiting, due to the use of VR visuals with simulator motion. To minimize this discomfort:
  - You must request that we immediately end the simulation run verbally or by the push of a button on the sidestick when you start to feel nauseous.
  - We are monitoring motion sickness through a Simulator Sickness Questionnaire that you fill out at the end of each run and will stop the experiment when motion sickness is increasing.
  - We do not want anyone to vomit.

  There is a risk of claustrophobia (a fear of being in small, enclosed spaces) because you will be seated alone in the closed simulator cabin that is the size of an aircraft cockpit. If you know you have claustrophobia, you should not enroll in this study. If you discover once onboard that you are uncomfortable being alone in the cabin, ask immediately to be released from the cabin and stop your participation in this study.
  There is very small risk of simulator malfunction. This is managed by the simulator's standard operating and safety procedures. These procedures are always followed for all motion simulations. Remember that the simulator engineer and motion operator can stop the simulation whenever necessary.
- **What are the benefits for me?** None to you personally. However, your data will help inform the use of simulator motion in future simulation studies and training with mixed-reality headsets.
- **Is there any compensation for my time?** You will not receive any compensation for participating in the experiment. When participating while on duty, there will be no additional compensation beyond your normal work pay. You should always ask permission from your supervisor when participating while on duty.
- **How will my information and/or identity be protected?** No stored test data will contain identifiable information. All your study data will only be identified by a code that is assigned to you before data collection begins. The datasheet linking your name to this code will be stored on the Principal Investigator's password-protected NASA computer. Only summary data (such as participant group averages) or coded raw data will ever be

shared for any subsequent analyses or publication. All test data will be collected, stored, and analyzed on NASA equipment that is protected per NASA data security procedures. Your privacy and the confidentiality of the data we collect from you will be protected from unauthorized disclosure according to applicable federal law.

Detailed Information

D. Nature of Tests or Experiment:

The aim of this study is to determine the effects of simulator motion fidelity on pilot performance in two demanding piloting tasks while wearing a mixed-reality headset for OTW visuals. You will be wearing a head mounted display (HMD) displaying mixed-reality visuals (Figure 1) meaning that the virtual OTW visual scene will be overlayed on an image of the real simulator cockpit and head down displays (HDD). Figure 2 shows an example of a location in the virtual OTW scene that will be displayed in the headset. You will fly two tasks in this experiment: 1) a roll-lateral sidestep maneuver, and 2) a precision landing. You will be provided with flight cards detailing the task criteria and procedures before the start of the experiment. Both tasks will be flown under different motion fidelity conditions representing motion ranging from small to larger simulators. Three repetitions of each motion condition will be flown for both tasks.

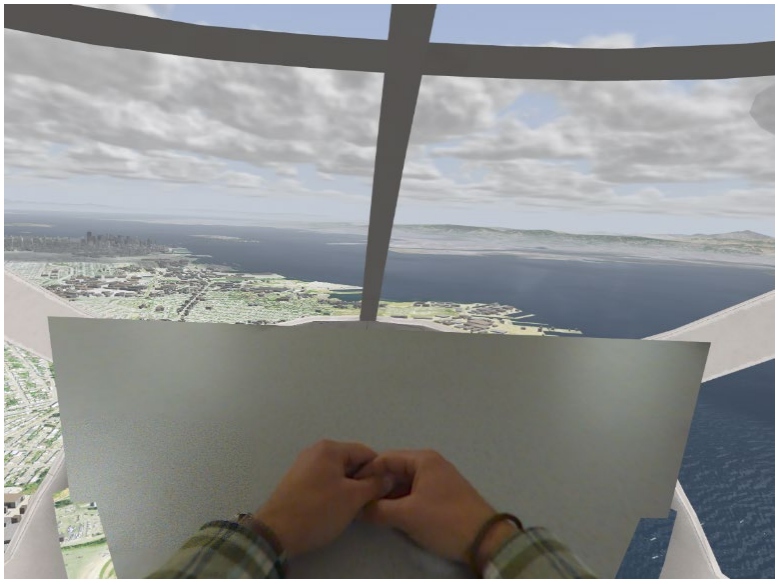

Figure 1 Example of the mixed-reality visuals showing the virtual out-the-window scene and a passthrough of the real environment.

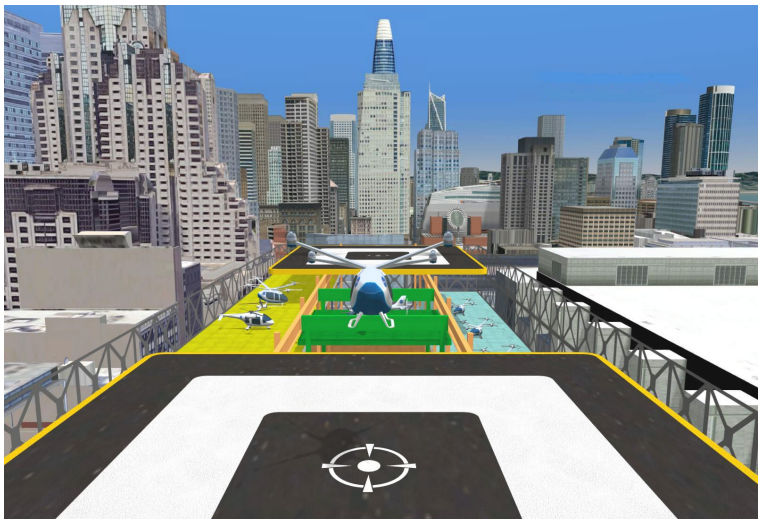

Figure 2 Virtual out-the-window scene showing the Fifth & Mission Parking Garage with vertiport in San Francisco.

Pilot performance in each task will be determined by several outcome-based variables, including the error between desired and actual aircraft position and attitude at specified locations, the intensity of control inputs, and task completion time. You will also complete a motion fidelity rating and a Simulator Sickness Questionnaire (SSQ) at the end of each run.

Data collection will take place in the VMS, the largest vertical motion simulator in the world. The VMS provides motion in all three rotational and all three translational degrees-of-freedom. Its vertical and lateral motion range are 60 ft and 40 ft, respectively. This study will use the Rotorcraft Cab (R-Cab) with a single seat. Two sidesticks, positioned on the left and right sides of the seat, will be used for controlling a lift-plus-cruise electrical vertical takeoff and landing (eVTOL) vehicle (Figure 3). HDDs are positioned in front of you providing primary flight and navigation information. OTW visuals will be provided by a Varjo XR-4 mixed-reality headset (Figure 4). You will wear David Clark noise-canceling headsets at all times allowing for direct communication with simulator operators and investigators.

Figure 3 Visual presentation of the simulated lift-plus-cruise electrical vertical takeoff and landing vehicle.

Figure 4 Varjo XR-4 mixed-reality headset.

E. Manner in Which Tests or Experiment Will Be Conducted:

After confirming you remain interested in participating in the study and meeting the inclusion/exclusion criteria listed in the study recruiting announcement, you will be emailed an electronic copy of this informed consent document. We will also send you a Motion Sickness Susceptibility Questionnaire which we ask you to complete and return to us. If you want to participate in this study after reading this document, and after having all your questions answered by the PI, we will schedule your participation in the experiment.

On the day of the experiment, you will receive an experiment briefing in the pilot ready room adjacent to the VMS. The briefing will include a detailed explanation of each task and the post-run questionnaires. You will be encouraged to discuss the protocol and details of the study with the investigators and ask questions. You will also be provided the opportunity to view the VMS facility and the R-Cab. After this, we ask you to give your informed consent by signing this informed consent document and returning it to the PI. You will also be asked to complete a short demographics questionnaire.

Before data collection starts, you will receive a safety walkaround by the simulator motion operator. When you are ready, you will be seated in the VMS cab. All communication with the study team will be through a headset you are required to always wear while seated in the cab. Once your seatbelt is fastened and the cabin door is closed, the simulator cab will move to the initial position for the first task.

You will start the session with three training runs for the first task. After training, you will complete 9 more runs of the task with varying simulator motion intensity. You will not be told the specifics of the motion condition. At the end of each run, including the training runs,

you will complete a motion fidelity rating and Simulator Sickness Questionnaire. A break is scheduled after completing the first task. The second session with the second task will commence after the break. Additional breaks will be scheduled during the sessions if needed. After the experiment, you will be debriefed and given an opportunity to provide any final comments. At this time, the specifics of the motion conditions can be discussed.

F. Duration and Location:

This research will be performed in the Simulation Research & Development Branch (Code AFS) at NASA Ames Research Center (ARC). Data collection will be conducted in the Vertical Motion Simulator (VMS) in building N-243 at ARC. The experiment will not take more than 3.5 hours to complete, including briefing time and breaks. A run for each task will take no longer than 3 minutes including time for completing questionnaires. The detailed schedule is as follows:

- Briefing and walkaround: 60 minutes.
- Task 1 – 12 runs of 3 minutes + 9 minutes for additional short breaks: 45 minutes.
- Main break: 30 minutes.
- Task 2 – 12 runs of 3 minutes + 9 minutes for additional short breaks: 45 minutes.
- Debriefing: 30 minutes.

G. Foreseeable Inconvenience, Discomfort, and/or Risks:

This study is minimal risk.

There is a small risk of some motion sickness, including vomiting, due to the use of VR visuals with simulator motion. *The following measures are taken to limit the risk and severity of motion sickness:*

- *You must request that we immediately end the simulation run verbally or by the push of a button on the sidestick when you start to feel nauseous.*
- *We are monitoring motion sickness through a Simulator Sickness Questionnaire that you fill out at the end of each run and will stop the experiment when motion sickness is increasing.*
- *We do not want anyone to vomit.*

There is a risk that terminating a study run due to motion sickness may cause some embarrassment or emotional discomfort. *If you feel any emotional discomfort or embarrassment, you are encouraged to let the investigators know. Please be aware that the investigators have completed ethics training and are aware of the need to make individuals feel comfortable and of the importance of maintaining discretion when discussing potentially embarrassing information.*

There is a small risk of claustrophobia. *If you know you have claustrophobia, you should not enroll in this study. If you discover once onboard that you are uncomfortable being enclosed alone in the VMS cabin, immediately ask the test monitor to be released from the cabin and stop your participation in the study.*

There is very small risk of VMS malfunction. *This risk is managed by the VMS's standard operating procedures, including all safety procedures. These procedures are always followed for all motion simulations. Remember, the simulator engineer and motion operator can stop the simulation whenever necessary.*

Although all stated precautions will be taken to protect confidentiality (Section I), there remains a small risk that confidentiality could be breached. A breach of confidentiality may cause some embarrassment or emotional discomfort depending on achieved task performance and experienced motion sickness during the experiment.

H. Benefits of Participation:

No benefits will accrue to you. However, your data will help inform the use of simulator motion in future simulation studies and training with mixed-reality headsets.

I. Data/Identity Security and Protection:

- All study data will only be identified by a unique code assigned to each participant prior to data collection. Therefore, no stored test data will contain identifiable information. All test data will be collected, stored, and analyzed on password-protected NASA computers that are protected per NASA data security procedures.
- A datasheet linking participant names with their codes will be stored on the Principal Investigator's password-protected NASA computer. This information will not be accessible to anyone other than the PI.
- Only aggregated summary data (for example, group averages) or coded raw data will ever be shared for any subsequent analyses or made public. The results of the research or any resulting statistics will not be made available in a form that could indirectly identify individuals (e.g., age will be used, not birth dates).
- Your privacy and the confidentiality of all the data collected as a part of this research study will be protected from unauthorized disclosure according to applicable federal law.
- All stated precautions will be taken to protect confidentiality, but there remains a small risk that your confidentiality could be breached.

The following de-identified data will be collected as part of this study:

- Video recordings without visible faces;
- Simulation data recordings (e.g. control inputs and aircraft states);
- Questionnaire responses.

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.

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.
- Safety monitors, medical personnel, or safety committees may review your research data, 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.

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

J. Remuneration:

You will not receive any compensation for participating in the experiment. When participating while on duty, there will be no additional compensation beyond your normal work pay.

K. Participant Rights:

Participation in this study is voluntary. You may withdraw from the study at any time. If you decide to leave before the study is finished, please tell the investigators or study staff. Your refusal will be honored, except 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.

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.

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

Researchers may need to stop your participation in the study even if you want to continue participation. Some examples of this scenario include:

- 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;
- Your 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.

L. Answers to Questions:

If you have any questions pertaining to the research study and your involvement in it, you can contact the Principal Investigator, Dr. Peter Zaal, by phone at (650) 604-5805 or by email at peter.m.t.zaal@nasa.gov. In the event of a research-related injury you should contact the study Medical Monitor, Dr. Ralph Pelligra, by phone at (415) 272-1314 (cell) or by email at ralph.pelligra-1@nasa.gov. Questions about research subjects' rights should be directed to the NASA Institutional Review Board by email at NASA-IRB@nasa.gov.

M. Remedy in the Event of Injury:

In the event of injury or illness resulting from this study and calling for immediate action or attention, NASA will provide, or cause to be provided, the necessary emergency treatment. If you are eligible for and receive workers compensation benefits while participating in this study, you cannot sue your employer because the law makes workers compensation your only remedy against your employer. You may have other remedies against other persons or organizations, depending upon the circumstances of the injury. NASA will pay for any claims of injury or loss of life to the extent required by the Federal Employees Compensation Act or the Federal Tort Claims Act.

Signature

TO THE SUBJECT: Please read this form CAREFULLY. Make sure all of your questions have been answered to your satisfaction. Do not sign this form until you have read and understand the informed consent. You will receive a signed copy of the Consent Form.

A. I, _____(Print Name of Test Subject HERE) agree to participate as a subject in this study and experiments described in this form.

B. I am aware of possible foreseeable consequences that may result from participation, and that such participation may otherwise cause me inconvenience or discomfort as described.

C. My consent has been freely given. I understand that study participation is voluntary and I may withdraw my consent, and thereby withdraw from the study, at any time. I understand (1) that the Principal Investigator may request my withdrawal from the study if I am not conforming to the requirements of the study; (2) that the NASA Medical monitor may request my withdrawal from the study if they feel that my health and well-being are threatened; and (3) that the NASA Facility Safety Manager may terminate the study in the event that unsafe conditions develop that cannot be immediately corrected.

D. I am not releasing NASA or any other person or organization from liability for any injury arising as a result of this study. I understand that I will receive emergency care if I am injured during the study, but payment for any follow-on care will depend on whether I have some form of applicable insurance, or whether I have made some other arrangements for such follow-on care. I may have other remedies against other persons or organizations, depending upon the circumstances of my injury.

E. I hereby agree that all records collected by NASA in the course of this experiment are available to the NASA Medical Officer, Principal Investigator and Co-Investigators and duly authorized research review committee. I grant NASA permission to reproduce and publish all records, notes or data collected from my participation provided that there will be no association by name with the collected data and that confidentiality is maintained unless specifically waived by me. All stated precautions will be taken to protect your anonymity, but there is a small risk that your confidentiality could be breached.

F. I understand that I have the right to contact the NASA Institutional Review Board (contact information available at NASA-IRB@nasa.gov) if I have questions or I feel that my rights as a human research subject have been abused or violated.

G. I have had an opportunity to ask questions and I have received satisfactory answers to each question I have asked. I understand that the P.I. for the study is the person responsible for this activity and that any pertinent questions will be addressed to her during the course of this study. I have read the above agreement, the attached protocol and/or instructions prior to my signature and understand the contents.

Signature of Test Subject Date	Signature of Principal Investigator Date
Printed/Typed Name of Test Subject	Printed/Typed Name of Principal Investigator
Test Subject Phone Number	
	Principal Investigator Address (Street / City, State, Zip Code)
	Principal Investigator Phone Number

Test Subject Signature: Authorization for Video Recording

Test Subject Signature: Authorization for Release of Information to Non-NASA Source(s)