# PRA Burden Statement

---

**OMB CONTROL NUMBER: 21XX-XXXX**
**EXPIRATION DATE: mm/dd/yyyy**

**Paperwork Reduction Act Burden Statement**

Collection of this information is authorized by The FAA Reauthorization Act of 2018 (Pub. L. 115-254, Sec. 341, 345). Rights of study participants are protected by The Privacy Act of 1974. Participation is voluntary, and there are no penalties for not participating or withdrawing from the study at any time. Refusal to participate will not affect your benefits in any way. The information collected in this study will be kept private to the extent provided by law. Names and other identifiers will not appear in any report of the study. Information provided will be combined for all study participants and reported as summaries.

Public reporting burden for this collection of information is estimated to take no more than 4 hours per response, including review of instructions and providing the information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Information Collection Clearance Officer, Federal Aviation Administration, 10101 Hillwood Parkway, Fort Worth, TX 76177-1524.

# Informed Consent

**Informed Consent to Participate in Research Study**
**Title: Computerized Cognitive Tests for Aeromedical Safety**

**Principal Investigators (PIs): Kelene Fercho, Ph. D.**, FAA Office of Aerospace Medicine, Human Factors Flight Deck Laboratory and **Susan Jay, Ph. D.**, FAA Office of Aerospace Medicine, Protection and Survival Research Branch
**Sponsors:** FAA Medical Specialties Division and Aerospace Medical Certification Division

**Statement of Research**
It is a basic ethical principle that an individual who voluntarily participates in a research study must give his or her informed consent prior to participation. This consent must be based on the understanding of the purpose and risks of the research. This informed consent document provides important information for understanding the purpose and risks of this research study. Research projects include only participants who voluntarily choose to participate. Please take your time to make your decision. If at any time you have questions, please ask the principal investigators or a member of their research staff.

**Invitation to Participate in Research Study**
Dr. Susan Jay and Dr. Kelene Fercho, researchers at the FAA's Civil Aerospace Medical Institute (CAMI), invite you to participate in a research study about the use of computerized cognitive tests as a non-invasive way to measure cognitive function in pilot populations. The purposes of this research are to: 1) evaluate computerized cognitive tests to determine if they are acceptable for use as a cognitive screening tool; and 2) obtain pilot normative datasets for each cognitive test. The FAA uses computerized cognitive tests only for those pilots who may have a medical condition associated with aeromedically significant cognitive impairment (e.g., stroke, head injury, certain medications) and who wish to return to flight or duty status. Normative datasets are a collection of test scores that represent what is usual or expected in a representative sample of pilots. The outcome of this research will ensure that FAA processes for aeromedical decision-making are consistent with best clinical practices for aerospace medicine and current scientific knowledge.

This study involves completing up to two (2) cognitive tests (approximately 45 minutes for each test) and a series of short questionnaires using a computer provided by the FAA research team. The results from this research may be used to revise the FAA's Aviation Medical Examiners (AME) Guide, update clinical practices, and assure aeromedical safety in the U.S. National Airspace System. There will be an estimated 960 research participant pilots. To be eligible to participate in this study you must:

- Be at least 18 years of age on the day of the study. There is no upper age limit.
- Hold an FAA pilot certificate. This includes any of the following: student pilot certificate, sport pilot certificate, recreational pilot certificate, private pilot certificate, commercial

pilot certificate, flight instructor certificate, or airline transport pilot certificate. At this time, we are not including participants who only hold a remote pilot certificate.
- Have logged flight time in the previous 6 months. Simulator currency time is acceptable.
- Hold a current FAA medical certificate (Class 1, Class 2, or Class 3). It is ok if your medical certificate is issued through a Special Issuance (SI) or Statement of Demonstrated Ability (SODA). At this time, we are not including participants who are flying under BasicMed.

If you do not meet the above criteria you may not participate in this study. Screening procedures throughout the remainder of this study are designed to ensure that all participants meet these criteria. Further, voluntary participation in this study implies that you have read, understand, and provide consent to participate in the current research study.

This study is sponsored by the FAA Medical Specialties Division (AAM-200) and the Aerospace Medical Certification Division (AAM-300), which have no financial interest in the outcome of this study. This study is being conducted by Dr. Kelene Fercho of the Human Factors Flight Deck Laboratory (AAM-510) and Dr. Susan Jay of the Protection and Survival Research Branch (AAM-630) at the FAA's CAMI in Oklahoma City, Oklahoma. The Human Factors Flight Deck Laboratory (AAM-510), the Protection and Survival Research Branch (AAM-630), and the investigators have no financial interest in the outcome of the study.

**Description of Participant Involvement**

If you agree to participate voluntarily in this study, your involvement will last up to four (4) hours. In some situations, when time availability is of concern, it may be possible to reduce the duration to two (2) hours. During this time, you will be asked to complete up to two (2) computerized cognitive tests and a short series of computer-based questionnaires. The computerized cognitive tests will involve performing tasks that assess cognitive skills such as attention, working memory, information processing speed, and reaction time. These questions and tasks will require you to manipulate a computer keyboard and/or mouse. You will provide a response to the questions and tasks by typing your response into a text box or tapping a button on the keyboard or mouse.

The computer-based questionnaires will include questions about your general medical history, demographic information (e.g., age, gender, aviation experience), as well as several short standardized questionnaires that will help the investigators better understand the relationship between cognitive test performance and other related factors. These related factors include current sleepiness, circadian typology (i.e., morning-type vs. evening-type), alcohol use, anxiety, depression, personality type, impulsivity, resilience, and your current mood. At the end of the testing session, the investigators will also ask you questions about your experience during the testing session.

Additionally, you will receive a printout copy of your cognitive test results. Please keep in mind that your results are a "snap shot" of your cognitive performance today during the testing session and are not considered clinically relevant. Additionally, your results will not be reviewed

by a medical professional, such as a neuropsychologist, qualified to perform neuropsychological examinations or analyze the results.

**Potential Benefits**
There are no immediate, direct benefits from voluntary participation in this research study. Although you may not benefit directly from being in this study, others may benefit from your participation. The outcome of this research may help some pilots return to flight or duty status if it is safe for them to do so, and your participation contributes to the overall aeromedical safety in the U.S. National Airspace System.

**Risks and Discomforts**
There may be some risks from participating in this study. You may find some questions to be of a sensitive nature and you may become uncomfortable or upset as a result. You may stop at any point while completing a questionnaire or choose not to answer a question. You may find some of the tasks in the computerized cognitive tests to be difficult or frustrating. A short rest break between each cognitive test will be provided.

**Alternative Procedures or Courses of Treatment**
Your participation is voluntary. You may refuse to participate or you may stop your participation at any time without penalty or loss of benefits unrelated to the research. Your decision on whether or not to participate in this research study will not affect your current or future relationship with the FAA. If at any time you decide to stop participating in this research study, you will need to tell the principal investigator(s), or a member of their research staff, who will stop the testing session immediately.

**Compensation**
Pilot participants will be monetarily compensated based on medical certification class. The compensation amount was determined by the hourly rate based on the median wage for pilots with similar experience per the U.S. Bureau of Labor Statistics (https://www.bls.gov/oes/current/oes_nat.htm), and by compensation used in similar research projects. The monetary compensation listed in this section will be the only form of compensation provided to you. This compensation will be provided in the form of a pre-paid gift card at the end of the study.

- Medical Class 1 pilot: $500
- Medical Class 2 pilot: $400
- Medical Class 3 pilot: $300

If you do not complete two (2) computerized cognitive tests, you will be reimbursed $150 for your time.

To ensure a balanced design, this study aims to recruit an equal number of pilot participants within specific age groups and across medical certificate classes (Class 1/2 and Class 3). In the case where we have met the recruitment limit for pilots with a Class 1 medical certificate for an age group, pilots holding a current Class 1 medical certificate may elect to participate as a pilot holding a Class 2 medical certificate; however, please note that you will be reimbursed as a

Class 2 pilot at the rate of $400.

If you are a federal government employee, you must have permission from your manager to participate in this study during work hours. If you participate in this study during work hours, you will not receive monetary compensation in the form of a pre-paid gift card.

Federal government employees may also choose to participate in this study during their personal time. If you participate in this study during your personal time, you do not need manager approval, and you will be reimbursed with a pre-paid gift card at the same rate as other pilot participants.

**Participant's Rights**
The FAA's CAMI Institutional Review Board, which is responsible for the ethical conduct of human subjects research performed by FAA researchers, has reviewed this research study and found it to be acceptable, according to applicable state and federal regulations designed to protect the rights and welfare of research participants.

**Cost to Participant**
You will be responsible for the cost of your transportation to and from the research study, as well as any other incurred expenses (for example, lodging or meals).

**Confidentiality**
Your research study records (i.e., cognitive test scores and questionnaire responses) will be de-identified so that your personal information is removed. The study records will be reviewed, analyzed, and stored on secure FAA servers/computers at the FAA's CAMI, Aerospace Human Factors Research Division (AAM-510), 6500 South MacArthur, Oklahoma City, Oklahoma 73169. These servers/computers are password-protected and encrypted.

To ensure your confidentiality, the personally identifiable information (i.e., your name) that you provide through the informed consent process will not be linked to your cognitive test scores and questionnaire responses. Your responses will be assigned a unique identifier to maintain your anonymity. Your collected research data (i.e., cognitive tests scores and questionnaire responses) **will not be linked to your FAA medical records data**, nor to your location, organization, operator, or company so there is no risk of retribution should you decide to participate in this research study.

**The results of this study will not be linked to any FAA medical certification records. Your participation in this study will not impact your current or future FAA medical class status.**

The collected research data may be made available to other researchers for related studies or secondary data analysis following completion of this research study without additional informed consent. No personally identifying information will be shared or made available to other researchers.

For professional research publications (e.g., academic conference presentations, FAA technical reports, research journal articles), no personally identifying information will be shared and all results will be reported in aggregate (i.e., group averages).

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that certain people or groups may inspect and copy records pertaining to this study. Examples of other people or groups are the FAA's Office of Aerospace Medicine Institutional Review Board. This is a committee that reviews and approves research studies for the protection of Human Subjects. Some of these records for review could contain personal information that identifies you. Reasonable efforts will be made to keep your personal information contained in the research record private and confidential. But, absolute confidentiality cannot be guaranteed.

The data and information you provide during the course of this research is confidential. No personally identifiable information, data, or statements will be disclosed in any report, briefing, presentation or discussion of the research ***unless such information is required to be disclosed under the Freedom of Information Act (FOIA), 5 U.S.C. § 552, or otherwise required to be disclosed by law. Information, data, or statements subject to FOIA may be protected from release if it falls within one of the nine FOIA exemptions. Such exemptions include the protection of personally identifiable information (PII) under exemption b(6) when such information would constitute a clearly unwarranted invasion of personal privacy of the individuals involved. However, de-identified information, data, or statements may still be disclosed under FOIA. The de-identified data may also be made available to other researchers for research-related purposes only.*** All analyses, reports, briefings, presentations and discussions of the research will rely on group-level, aggregate analyses and descriptions.

**Participation and Withdrawal**

Your participation in this study is voluntary and it is your choice whether or not to participate. You may decline to participate or withdraw from this research study at any time. The choice to decline or withdraw from this research study will not cause any penalty or loss of any benefit to which you are entitled. If you start and then withdraw from this study, you will be compensated $150 for your time.

The principal investigators, or their research staff, may decide to stop or withdraw you from the study under certain conditions without your permission. Some possible conditions for which you may be removed from the research study include risk or harm to your medical or psychological well-being, not following instructions, or administrative reasons. In the event that your participation ends early, you may request to speak with the principal investigators, or the principal investigators may request to speak with you.

**Principal Investigator Contact Information**

We encourage you to ask any questions you may have about this study before agreeing to

participate; however, you may ask questions at any time. For questions, concerns, or complaints about this research study, please contact the principal investigators: Dr. Kelene Fercho at 405-954-0127 / Kelene.A.Fercho@faa.gov or Dr. Susan Jay at 405-954-5500 / Susan.M.Jay@faa.gov.

If you need to change your appointment or have administrative questions, please call 405-954-2647 or e-mail the research team at cogstudy@faa.gov.

If you feel that you have been treated unfairly, or you have questions regarding your rights as a research participant, you may contact Dr. Thomas Chidester, Chair of CAMI's Institutional Review Board. Dr. Chidester may be reached at 405-954-1003.

**Signature and Consent to Voluntarily Participate in the Research Study**
I have been informed about the purpose, procedures, possible benefits, and risks of this research study. I have read (or someone has read to me) this form and I have been offered a copy. I have had the opportunity to ask questions and to discuss the study with a principal investigator. My questions have been answered to my satisfaction. I have been told that I may ask other questions at any time. I voluntarily agree to participate in this research study. I am free to withdraw from this research study at any time without the need to justify my decision. The withdrawal will not in any way affect my future treatment or medical management in any way, and I will not lose any benefits to which I am otherwise entitled. I agree to cooperate with the principal investigator and their research staff and to inform them immediately if I experience any unexpected or unusual symptoms.

Do you consent to participate in this research study?

- ○ Yes
- ○ No

**Participant:** By typing your full name on this consent form, you indicate that you are voluntarily choosing to take part in this research study.

_____

_____

_____

_____

_____

Please raise your hand so a researcher can double check your consent form.

Please enter the admin password (researcher use only).

_____