Informed Consent to Participate in Research Study

Pilot Medical Disclosure Decision Making Survey

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Co-investigator: Tammy Ho, BS, NAS-SR

Invitation to Participate in Research Study

Key Information

Dr. Julia Beckel invites you to participate in a research study about pilot decision-making regarding medical symptom disclosure. This study is part of an effort by the Office of Aerospace Medicine to better understand how Airline Transport Pilots (ATPs) decide whether to report physical or mental health symptoms.

The findings from this study will help the FAA improve safety risk assessments and develop more effective policies to support pilot health and reduce the likelihood of medical non-disclosure.

This study will be conducted via an anonymous, online survey. The survey will take 10-15 minutes to complete. Approximately 1,950 ATPs holding an FAA medical certificate will be invited to participate. You have been selected as a potential participant because you are a certificate-holding ATP in the FAA's medical certification database.

After completing the survey, you will be compensated in the amount of $25.00. Compensation will be based on full completion of the survey and the provision of appropriate responses to questions embedded to ensure your full attention.

Your participation is entirely voluntary. Please take time to consider your decision, and if needed, discuss it with family, friends, or colleagues. If you choose to participate, you will be asked to confirm your consent before beginning the survey.

This study is sponsored by the Office of Aerospace Medicine which has no financial interest in the outcome of this study. Payments are made to the NAS-SR Research Laboratory at the Civil Aerospace Medical Institute in Oklahoma City, Oklahoma. The NAS-SR Research Laboratory and Dr. Julia Beckel do not have any financial interest in the outcome of the study.

Description of participant involvement

If you agree to participate in this research study, you will be asked to complete a one-time, confidential online survey. The survey will take 10-15

minutes to complete. You will access the survey via the QR code and associated survey link provided to you in your recruitment communications. A unique link has been generated for each participant and may only be used once. Please do not share the link to your survey with anyone else.

The online survey will consist of multiple-choice and Likert-scale questions about:

- Your beliefs and perceptions regarding factors that influence disclosure relating to one of three hypothetical health conditions (i.e., depression, sleep apnea, cardiac disease.
- Your opinion on the usefulness of potential strategies intended to reduce barriers and burdens associated with health-related disclosure
- Basic demographics (e.g., age, gender, occupational background)

You will be compensated $25.00 for your complete participation. Complete participation is defined as 100% completion of the online survey, including appropriate response to embedded attention checks. You may choose to withdraw your participation at any time.

Potential Benefits

Although you may not directly benefit from participating in this study, this research is important to maintaining and improving aviation safety. Your participation in this research survey will inform researchers identify future Stress Management training for ATC field trainees.

Risks and discomforts

There are little to no risks associated with this study. Responses collected in the survey, interview, and focus group are confidential. Names or other identifying information will not be linked to participant responses. Additionally, we expect that participants will respect the privacy and confidentiality of other interview and focus group members by not disclosing any content discussed during the focus group.

Alternative Procedures or courses of treatment

You may choose to not participate at all. Refusal to participate or to continue to participate will not harm or influence your employment or training status.

Compensation

An electronic gift card with a value of $25.00 will be reimbursed to participants upon the completion of the survey *and* upon correct response to survey's attention checks. Complete participation is defined as 100% completion of the online survey, including appropriate response to embedded attention checks.

Participant's Rights

The Institutional Review Board responsible for human subject research at the Civil Aerospace Medical Institute (CAMI) has reviewed this research project and found it to be acceptable, according to applicable state and federal regulations designed to protect the rights and welfare of subjects in research.

Your participation in this study is completely voluntary and you can withdraw from this study at any time and for any reason. You will not be required to disclose the reason. There will be no penalty, loss of benefits, or negative repercussions for terminating your participation.

Cost to Participant

You will not incur any costs for participating in the study.

Confidentiality

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 maybe 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.

Your research records that are reviewed, stored, and analyze at CAMI will be kept electronically on a password protected device accessed only by authorized CAMI personnel. Your name and personal identifiers will be removed from the research records. The research records will be scanned into a portable document format (electronic scanned record) and will be maintained on a computer housed in the Aerospace Medical Research Division.

Injury

There is little to no risk of injury associated with this study. In the event of injury resulting from this research, medical treatment is available but will be provided at the usual charge. It is the policy of this institution to provide

neither financial compensation nor free medical treatment for research-related injury.

Voluntary nature of the study

Your participation in this study is completely voluntary and you can withdraw from this study at any time and for any reason. You will not be required to disclose the reason. There will be no penalty, loss of benefits, or negative repercussions for terminating your participation.

If you withdraw from this study before completion, you will not receive reimbursement, your information and data provided will be destroyed.

Participation and Withdrawal

Participation in this study is completely voluntary and it is your choice whether to participate or not. You may decline or withdraw participation from the study at any time. The choice to decline or withdraw from the study will not cause any penalty or loss of any benefit to which you are entitled. If you decide to withdraw early, your information and data provided will be destroyed.

Dr. Julia Beckel, Principal Investigator, may decide to stop or withdraw you from the study under certain circumstances without your permission. Some possible reason that you may be removed from the study are such as a risk or harm to your medical or psychological interest; not following the study instructions, or administrative reasons. In the event that your participation in the study ends early, you may request, or you may be requested to speak to the principal investigator.

Contact Information

If you have questions or concerns about the study, please contact the principal investigator, Julia Beckel at julia.l.beckel@faa.gov during normal business hours. You can ask any questions that you have about this study at any time.

If you feel that you have been treated unfairly, or you have questions regarding your rights as a research participant, you may contact the Civil Aerospace Medical Institute Institutional Review Board (a group of people who review the research to protect your rights) at (123) 456-7000.

Signature and Consent to be 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 received a copy of it. I have had the opportunity to ask questions and to discuss the study with an investigator. My questions have been answered to my satisfaction. I have been told that I can ask other questions any time. I voluntarily agree to participate in this study. I am free to withdraw from this 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 and I will not lose any benefits to which I am otherwise entitled. I agree to cooperate with the principal investigator and the research staff and to inform them immediately if I experience any unexpected or unusual symptoms.

____ I understand the risks and benefits of this research and agree to participate.

Below, I have indicated my decision about being re-contacted for related studies in the future by placing an “X” next to my choice:

___ Yes, please contact me about related studies

___ No, please do NOT contact me about related studies

Participant: By signing this consent form, you indicate that you are voluntarily choosing to take part in this research.

_____

Printed Name of Participant

_____

Name of Legal Representative (if applicable)

_____ _____

Signature of Participant or Legal Representative Date

Investigator

Principal Investigator:

I have fully explained this study to the subject or his/her representative to the best of my ability. As a representative of this study, I have explained the

purpose, the procedures, the possible benefits and risks that are involved in this research study. I have answered the subject's questions to his/her satisfaction before requesting the signature(s) above. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily. There are no blanks in this document. A copy of this form has been given to the subject or his/her representative.

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Printed name of Principal Investigator or designee

_____ _____ _____

Signature of Principal Investigator or designee Date Time

REVISION HISTORY

Rev	Description of Change	Effective Date
1	This revision history identifies changes made to this document, to include: minor word clarifications throughout, removed form number AAM-700-003-F2 from this guidance because it is not a form to be filled out, but rather, guidance with examples for creating an informed consent document. Removed reference to “acceptable forms of birth control” and changed verbiage in the example provided for communicating information on injury and compensation. This guidance aligns with requirements in AAM-700-004-WI (Revision 3).	7/30/2015
2	Revised this document from guidance for creating an informed consent document, to a template used for all research informed consent documents. Included reference source for information pertaining to confidentiality and HIPAA.	3/4/2019
3	Added provision to the confidentiality statement regarding FOIA and/or other disclosures required by law. Added participant statement regarding the understanding of personally identifiable information in regard to FOIA and/or other disclosures required by law.	1/5/2023
4	Added required Key Information section at the beginning of the template. Removed last sentence in “you must include this language” portion of the Confidentiality section. Added example of Certificate of Confidentiality Informed Consent example language and corresponding NIH link.	10/5/2023