**Informed Consent Notice**

Before agreeing to participate in this research study, it is important that you understand the following explanation of the purpose, benefits and risks of the study and how it will be conducted. If you agree to participate, both you and the interviewer will sign this form together.

**Title of This Study:** *Organizational and cultural barriers to implementing systematic training to reduce human error in healthcare institutions: Case studies.*

**Principal Investigator/Interviewer:** James “Lance” Acree, Lt Col USAF (ret) and PhD candidate at Omega Graduate School (OGS), an accredited research institution in Dayton, TN.

**Committee Chair:** Dr. Curtis McClane.

**Purpose of the Study:** The purpose of this study is to help clarify what may be hindering the adoption of *systematic training* (such as is employed in aviation and nuclear power professions) to reduce preventable human error in healthcare. You are being asked to participate in this research study by sharing your professional perspectives on what barriers in healthcare institutions may be hindering the implementation of systematic training.

More specifically, the interviewer is seeking your professional perspectives on: (1) what organizational policies and processes (e.g., financial, career management, risk management, risk reduction investment, public affairs…); (2) what cultural issues and characteristics (e.g., professional fears, inter-profession attitudes, social stratification of clinicians…); (3) which of these offer the most institutional resistance to implementing systematic training to reduce preventable error?

**Study Procedures:** Based on personal referrals, we invite you to participate in a series of individual interviews. These interviews can take place face-to-face (preferred) or via distance communication (e.g., phone or internet).

The interviews will be audio recorded only if you agree. After a personal introduction and fielding your questions, the interviewer will ask for your permission to record the interview. If you elect not to have the interview recorded, the interviewer will take notes.

After the initial interviews, the interviewer may contact you with follow-up questions. Finally, the interviewer may ask you to participate in a final interview to assess the accuracy of the interviewer’s interpretations and conclusions.

**Foreseeable Risks:** Your participation in this study poses a risk for breach of confidentiality. To minimize this risk, neither the interviewer nor OGS will use your name, your job title, your institution’s name, your geographic location, or any other identifying information in any study records, presentations, or publications without your written permission. We discuss in detail how we will keep your identity information private below. You will be in control of the interview and can decide how much insight to share. Otherwise, the research team considers this study to have no foreseeable risks.

**Benefits to Research Participants or Others:** You may enjoy reflecting on your perspective with the help of an interlocutor (the interviewer), but you may not experience direct benefit from participating in this study. Results of the study may help health care policy makers better understand how to mitigate preventable human error. This understanding may be used to develop better policy, best practices in training and formulate additional research.

**Compensation for Participants:** None

**Procedures for Maintaining Confidentiality of Research Records:** Data identifying your participation in this research—your name, institution and geographic location—will be kept confidential until it is destroyed three years after completion of the study. Once we select interview participants, the interviewer will secure both their personal identity information and the identities of their respective institutions, including any signed copies of this form.

You will control whether any audio recording will be made during your interviews. The interviewer will de-identify recordings and assign an encryption label before they are transcribed and analyzed. The label-to-participant encryption will be hand recorded only and stored in a locked container for the duration of the study until final destruction. Only the PI and his committee chair will have access to the original audio recordings. The PI will keep your de-identified transcriptions on a password protected computer in a location completely separate from your demographic information. We will destroy any audio recordings, the encryption and all traces of participant identity once we complete data analysis. The confidentiality of your individual information will be protected from exposure in any publications or presentations regarding this study.

**Questions about the Study:**

If you have any questions about the study, you may contact James “Lance” Acree at jlacree@ogs.edu or Dr. Curtis McClane at curtismcclane@gmail.com.

**Review for the Protection of Participants:**

This research study has been reviewed and approved by the OGS Institutional Review Board (IRB). You may contact the OGS IRB at 423-775-6596 with any questions regarding the rights of research subjects.

**Research Participants’ Rights:**

Your signature below confirms that you have read all of the above and that you confirm all of the

following:

* The interviewer has explained the study to you and you have had an opportunity to contact him, his committee chair and/or the IRB with any questions about the study. You have been informed of the possible benefits and the potential risks of the study.
* You understand that you do not have to take part in this study, and your decision to withdraw will involve no penalty or loss of rights or benefits. Both you and the principal investigator may choose to stop your participation at any time.
* You understand why the study is being conducted and how it will be performed.
* You understand interviews will be audio recorded only if you grant written permission.
* You understand your rights as a research participant and you voluntarily consent to
* participate in this study.
* You understand you may print a copy of this form for your records.
* You understand you will receive a copy of this form once it is signed.

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Printed Name of Participant

Participant’s Authorization of Audio Recording Interviews: □ Decline □ Approve

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Signature of Participant

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Signature of Interviewer