FORM D – INFORMED CONSENT DOCUMENT

Volunteer Name:	

99th Medical Group

INFORMED CONSENT DOCUMENT

Title of Protocol:	Do Script Concordance Tests correlate with Family Medicine standardized tests and failing rotation grades?
FWH #:	FWH20190010H

INFORMATION ABOUT THIS CONSENT FORM: You may be eligible to take part in a research study. This form gives you important information about the study. You may be asked to sign your name in more than one place in this document, as needed. Please take time to review this information carefully. You should talk to the researchers about the study and ask them any questions you may have for them. You may also wish to talk to others (for example, your friends, family, or a doctor) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand the procedures of the study and what the study is about, including the risks and possible benefits to you. If you are taking part in another research study, please tell the researchers or study staff.

VOLUNTARY PARTICIPATION: Your participation in this study is completely voluntary. If you choose not to participate in this research study or leave before it is finished, your decision will not affect your eligibility for care or any other benefits to which you are entitled. If significant new findings develop during the course of this study that may relate to your decision to continue to participate in the study, you will be informed.

PRINCIPAL INVESTIGATOR: The Principal Investigator (PI) is the researcher directing this study and is responsible for protecting your rights, safety and welfare as a participant in the research. The PI for this study is:

PI Name and Degrees:	**Rank:**	**Branch:**	**Department and Base:**
Pamela Hughes, MD	Maj	USAF	Family Medicine Residency/99MDG

PURPOSE OF THIS STUDY (Why is this study being done?)**:** You are being asked to consider participation in a research study because you are a Family Medicine Resident at the 99MDG. The purpose of this study is to determine if a Script Concordance Test (SCT) correlates with Family Medicine In Training Exam (ITE) scores, American Board of Family Medicine (ABFM) certification exam scores, Accreditation Council for Graduate Medical Education (ACGME) medical knowledge and patient care milestones, and family medicine inpatient clinical rotation grades.

Script Concordance Tests (SCTs) are vignettes based upon the theory of clinical reasoning that are used for evaluating reasoning in a context of uncertainty. They confront candidates with a problematic situation, probes their reasoning and gives them a score by comparing their answers to that of a reference panel of Family Medicine experts.

The SCT will be made up of 25-30 vignettes, each with 3-4 question items; topics will cover inpatient, obstetrics, outpatient, sports medicine, and pediatrics.

This study will enroll approximately 130 subjects overall.

PROCEDURES: If you decide to take part in this research study, you will be asked to sign this consent form. During your

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participation in this study, you will be asked to make approximately 3 research visits with the study staff over the course of your 3 year Family Medicine Residency. As a research participant, you will undergo the following research-related procedures:

SCREENING PROCESS TO QUALIFY FOR PARTICIPATION IN THIS STUDY:

- Obtain your Informed Consent Document and HIPAA Authorization.
- We will record your name, current email address, phone number, and Post Graduate Year (PGY) in training.

This screening visit will take approximately 20 minutes.

Study Procedures – as a participant, you will undergo the following study-related procedures:

You will be asked to complete the SCTs once a year during your 3 year residency. The research coordinators will place your unique subject ID on the SCT and hand out to all the PGY 1, PGY 2, and PGY 3 residents enrolled in this study during a didactic session in either June or July. You can choose to complete it at that time and return it to the Research Coordinator directly or complete it and return it at a later date. Once the research coordinator has collected all the SCTs, they will then provide the completed and coded SCTs to a panel of experts to score. The panel will be comprised of Family Medicine physicians with more than 3 years of clinical experience. The research coordinators will be responsible for obtaining all the ITE and ABFM scores, family medicine rotation grades, and ACGME milestones from the Residency Coordinator.

The investigators in this study will not receive any identifiable information regarding the participating Residents. The results of the SCT will not be used to inform any evaluations or academic milestone determinations. The SCT results will be blinded by the research staff prior to scoring and being given to the statistician for analysis.

RISKS OR DISCOMFORTS: There are no known risks associated with this study other than those related to an inadvertent breach of confidentiality.

WITHDRAWAL FROM THE STUDY: If you first agree to participate and then you change your mind, you are free to withdraw your consent and discontinue your participation at any time. Your decision will not affect your ability to receive medical care and you will not be penalized or lose any benefits to which you would otherwise be entitled.

BENEFITS: There is no direct benefit to you for participating in this study. We hope the information learned from this study may help future residents by learning about potential clinical reasoning deficiencies earlier in residency.

COSTS: Will taking part in this study cost anything? The investigators have designed this study so that there is no cost to you to participate in this study.

PAYMENT (COMPENSATION): You will not receive any compensation (payment) for participating in this study.

POTENTIALLY BENEFICIAL ALTERNATIVES TO STUDY PROCEDURES: Choosing not to participate in this study is the only alternative.

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CONFIDENTIALITY OF RECORDS OF STUDY PARTICIPATION: Records of your participation in this study may only be disclosed in accordance with federal law, including the Federal Privacy Act, 5 U.S.C. § 552a, the Health Insurance Portability & Accountability Act of 1996, Public Law 104-109 (also known as HIPAA), and their implementing regulations. DD Form 2005, Privacy Act Statement- Military Health Records, contains the Privacy Act Statement for the records. By signing this consent document, you give your permission for information gained from your participation in this study to be published in medical literature, discussed for educational purposes, and used generally to further the generalizable knowledge of medical science community. You will not be personally identified; all information will be presented as anonymous data. Your records may be reviewed by the Air Force, the DoD, other government agencies that oversee human research, and the 59 MDW Institutional Review Board.

A copy of this consent will be stored by the investigator in a locked cabinet in a locked room, as part of your research record. All research data will be kept in an electronic database, which will be double password protected, firewall-protected, encrypted, and access-restricted to people involved in this study. The research data will be coded. As soon as possible, any link between your identity and the research information will be destroyed which means research information about you will be permanently de-identified. Personal identifying information will be destroyed no later than at the closure of the study. The research information collected about you for this study will not be used for any additional research activity beyond what you have approved by signing this consent.

The study staff advises that you protect your copy of the informed consent document. A breach of confidentiality could occur if you inadvertently lose this document or allow others to view the document. In the unlikely event that you experience a loss of confidentiality, the study staff will take appropriate action to assist you.

Complete confidentiality cannot be promised, particularly for military personnel, because information regarding potential UCMJ violations or concerns regarding fitness for duty may be reported to appropriate medical, law enforcement, or command authorities.

ENTITLEMENT TO CARE: In the event of injury resulting from this study, the extent of medical care provided is limited and will be within the scope authorized for Department of Defense (DoD) health care beneficiaries. Your entitlement to medical and dental care and/or compensation in the event of injury is governed by federal laws and regulations, and if you have questions about your rights as a research subject or if you believe you have received a research-related injury, you may contact the Director, 59 MDW Clinical Research Division, (210) 292-7069 or Mike O'Callaghan Federal Medical Center Human Subject Research Protections Officer, (702) 653-3298.

If you sign this form, you do not give up your right to seek additional compensation if you are harmed as a result of being in this study.

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PROTECTED HEALTH INFORMATION (PHI) AND PERSONAL IDENTIFYING INFORMATION (PII) DATA:

All de-identified research data that will be used in the database repository will be kept at the Mike O'Callaghan Military Medical Center, Department of Family Medicine Residency and will be handled and disposed of in accordance with federal regulations. No unauthorized individual or agency outside of 99MDG will have access to this database without permission of the "Mike O'Callaghan Military Medical Center General Research Data Repository (FWH20180064H)", Manager, Col Paul Crawford, and the Wilford Hall Ambulatory Surgery Center (WHASC) 59th MDW Institutional Review Board (IRB).

The Investigators are asking for your permission to store your de-identified research data in the database repository for future use in research studies. The specifics of these research studies are unknown at this time, but these studies will frequently be in the area of clinical reasoning in patient care. Your stored de-identified research data will be information such as SCT scores, ITE and ABFM scores, failing family medicine rotation grades, and ACGME milestones. This data is considered non-identifying information and cannot be traced back to you as a donor when added to a database. The Principal Investigator and Database Repository Manager will take every precaution possible to safeguard your information to eliminate the possibility of any breach of confidentiality. This is explained above in the section, "Confidentiality".

The Database Repository Manager, Col Paul Crawford, is responsible for all de-identified research data stored in the repository. All recipient investigators requesting data from the repository must have approval from the Database Repository Manager and must have a research study approved through a DoD Institutional Review Board (IRB) and the 59th MDW IRB. Only de-identified data (no personal identifiers or information) will be released to recipient investigators, so specific information can't be traced back to you as the donor of the data. Recipient investigators may only receive limited data sets of de-identified information necessary to conduct their research. Generally, you will not be provided with the results of these research studies using your de-identified data from the repository. Any results would be of unclear value and unknown clinical meaning, since your de-identified data will be combined with other de-identified data from numerous residents and/or patients used for the study. You will not be able to request that your de-identified research data be withdrawn from the database repository since we will have no way of identifying whom the data belongs to. If you have any questions, you can contact the Database Repository Manager at Col Paul Crawford or mailing your request to the following address: Col Paul Crawford, MD, c/o Department of Medical Education, 4700 Las Vegas Blvd North, Nellis AFB, NV 89191.

_____NO: I do not authorize the storage of my de-identified research data for future use in research studies.

_____YES: I authorize the storage of my de-identified research data for future use in research studies.

_____
Signature of Study Participant

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CONTACT INFORMATION:

****In the event of an emergency, dial "911" or immediately seek assistance at your nearest emergency room.****

Principal Investigator (PI): The principal investigator and alternate member of research staff will be available to answer any questions concerning procedures throughout this study.

Title	Name	Duty Phone	After-Hours Phone
Principal Investigator	Maj Pamela Hughes	(702) 653-3298	(702) 349-0452
Associate Investigator	Lt Col Carlton Covey	(702) 653-3298	(702) 349-0452

Institutional Review Board (IRB): The 59 MDW Institutional Review Board (IRB), the 59 MDW committee that reviews research on human subjects, will answer any questions about your rights as a research subject, and take any concerns, comments or complaints you may wish to offer at 210-292-4683. You can contact the IRB by calling the Chairperson of the 59 MDW IRB at 210-916-8251, or by mail to IRB at 59 MDW/STC, 1100 Wilford Hall Loop, Bldg 4430, JBSA Lackland, Texas 78236. If you have any questions about your rights as a research subject, research-related injuries or any other concerns that cannot be addressed by the PI, you can also contact the Mike O'Callaghan Military Medical Center Human Subject Research Protections Point of Contact, (702) 653-3298, or the Eglin Air Force Base Human Subject Research Protections Point of Contact, (850) 883-8834.

All oral and written information and discussions about this study have been in English, a language in which you are fluent. If you agree to participate in this research study, please sign this section. You do not waive any of your legal rights by signing this form.

SIGN THIS FORM ONLY IF THE STATEMENTS LISTED BELOW ARE TRUE:

- You have read the above information.
- Your questions have been answered to your satisfaction.
- Your consent to participate in this study is given on a voluntary basis.

A signed copy of this form has been given to you.

_____ _____

VOLUNTEER'S SIGNATURE **DATE**

_____

VOLUNTEER'S PRINTED NAME

_____ _____ (_____)_____-_____

ADVISING INVESTIGATOR'S SIGNATURE **DATE** **PHONE#**

_____

PRINTED NAME OF ADVISING INVESTIGATOR

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