VA Consent Cover Letter

"Hand-offs" between different clinical specialties are a well-known problem area in clinical care. Different clinics are likely to have different care goals and workflows, respond to different quality or performance criteria, and may have different organizational cultures and communication styles.

This exploratory study seeks to characterize existing workflows and communication processes involved in handing-off patients from the emergency department (ED) to intensive care unit (ICU) in the University of Utah and VA Salt Lake City HCS hospitals. The study is a first step toward future work identifying areas of common communication breakdown and workflow inefficiencies. You have been contacted because you are a provider familiar with clinical workflows in the ED or ICU at the

Your participation is entirely voluntary. If you choose to participate, you may choose not to answer specific interview questions, or to stop your interview or observation session at any time. If you refuse to participate or discontinue participation, you will not be penalized or lose any benefits. *If you express interest in participating, you will receive an email from the investigator to coordinate a convenient time for your interview and/or observation.*

The study has two components. You may participate in one, both or neither of these components:

i) A thirty-minute interview. Questions will focus on your professional background, the overall workflow in your clinic, and the process of handing off patients from ED to ICU.

ii) Observations of your workflow. An observation will optimally last the length of your shift in the clinic. During the observation, the investigator will take notes on your workflow and communication processes.

Loss of confidentiality is a risk in all human subjects research. This study takes appropriate steps to minimize that risk. Audio recordings of interviews will be encrypted and transported on a VA-approved device. Audio recordings will be transcribed using the VA's Centralized Transcription Services Program, and analyzed to identify themes related to barriers and facilitators of patient hand-offs from the ED to the ICU. All audio recordings, transcripts and notes from observations will be stored on a secure server in the VA. De-identified transcripts of these interviews will be used to understand the clinical workflow and communication processes in ED-ICU hand-offs. Data will not be shared with other institutions or investigators. Results of this study may be published, but your identity will not appear in any such publication. The information collected in this research will not be used for future research studies.

There are not any direct benefits to you for participating in this research.

If you have any questions, complaints or if you feel you have been harmed by this research please contact <<researcher name>> at <<phone number>>.

Contact the Institutional Review Board (IRB) if you have questions regarding your rights as a research participant. Also, contact the IRB if you have questions, complaints or concerns which you do not feel you can discuss with the investigator. The University of Utah IRB may be reached by phone at (801) 581-3655 or by e-mail at irb@hsc.utah.edu.

Commented [AS1]: Does the consent process begin with a concise and focused presentation of key information? Yes. A Consent Cover Letter generally provides all the key information in a concise form.

Commented [AS2]: Is there a statement that the study involves research and an explanation of the purposes of the research? Yes

Commented [AS3]: Is there a statement that participation is voluntary? Yes.

Commented [AS4]: Is there a statement that individuals may refuse to participate or discontinue participation without penalty or loss of benefits? Yes.

Commented [AS5]: Is there a description of the procedures to be followed including the identification of any procedures that are experimental? Yes, there is a description of the procedures. There are no experimental procedures.

Commented [AS6]: Is the expected duration of participation stated? Yes.

Commented [AS7]: Is there a description of any foreseeable risks or discomforts to the participant? Yes.

Commented [AS8]: Is there a description of the use of photographs, video, and/or audio recordings to be taken for research purposes? Yes.

Commented [AS9]: Is there a statement about the collection of identifiable private information or identifiable biospecimens? Yes.

Commented [AS10]: Is there a description of any benefits to the participants or others? Yes.

Commented [AS11]: Is the necessary contact information provided? Yes.

Commented [AS12]: This statement is required. The language should be included verbatim.

SAMPLE

MEDICAL TREATMENT OR COMPENSATION FOR INJURY

The VA has the authority to provide medical treatment to participants injured by participation in a VA study. If you are injured as a result of being in this study, the VA will provide the necessary medical treatment in accordance with federal law. If you want to make a legal claim against the VA or anyone who works for the VA, special laws may apply. The Federal Tort Claims Act (28 U.S.C. 1346(b), 2671-2680) is a federal law that controls when and how a person can bring a claim against the U.S. Government. If you sign this document you are not giving up your right to make a legal claim against the United States.

Commented [AS13]: For studies conducted at the VA, the statement that the VA will provide treatment for the research related injury is required.

COSTS TO PARTICIPANTS AND COMPENSATION

There is no compensation for participating in this study. Participation in the study will not cost participants anything.

By participating in the interview and/or observation you are giving your consent to participate.

Commented [AS14]: A Waiver of Documentation of Consent is approvable because the research presents no more than minimal risks of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. Therefore, this cover letter does not require a signature from the participant or participant's legally authorized representative. The participant should receive a copy of the consent cover letter.

SAMPLE