

PRINCIPAL INVESTIGATOR: Kalie Nolen

TITLE OF PROJECT: Meeting the Needs of Family Members of ICU Patients

This informed consent is for men and women with family members in the Intensive Care Unit who wish to participate in a voluntary research study. The title of the research project is Meeting the Needs of Family Members of ICU Patients. It is important that you read this material carefully and then decide if you wish to be a volunteer. You must be eighteen years or older to participate.

PURPOSE:

The purpose of this research study is to identify ways to meet the needs of family members in the intensive care unit. Research has been done to identify what the needs are of families with loved ones in the intensive care unit. This study will focus on how well those needs are being met by the current facility and how to better meet these needs.

DURATION:

The study will take place in the intensive care waiting room at the participating hospital. Volunteers will be given a 45 item questionnaire which should take close to fifteen minutes to complete. Following the questionnaire the volunteer will be given an opportunity to participate in a short interview consisting of 10 open formatted questions. Participants are free to complete the questionnaire and decline the interview without any penalties.

PROCEDURES:

This is a non-invasive study in which volunteers will be asked to answer questions regarding their experience as a family member of an intensive care patient. As previously mentioned, participants will be given a 45 item questionnaire in which they will rate each item on a scale of 1-4 depending on how well they feel that need is being met by the hospital and staff. After completion of the questionnaire, participants will be given the opportunity to volunteer for a ten question interview which will be recorded for accuracy of interpretation. Volunteers are free to decline either part of the study if desired.

ALTERNATIVE PROCEDURES/TREATMENTS:

This study is strictly to observe how well the families of intensive care patients feel taken care of during their stay. Results will have no immediate effect on the participants' or the patients' standard of care. Results will be used to improve future care.

POSSIBLE RISKS:

The possible risks of this study are emotional or psychological stress as talking about a family member in an intensive care setting may be hard for participants. No physical risks are involved in this study.

POSSIBLE BENEFITS:

February 1 2013

_____ Subject Initials

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The possible benefits of your participation are helping to identify areas of weakness when caring for families of intensive care patients. If you choose to participate in the interview you will also be given the opportunity to share your opinions on changes that could be made to improve care of family members of intensive care patients. Answers from both parts of the study will be used to improve care in the future.

VOLUNTARY PARTICIPATION:

Participation in this research study is voluntary. You may refuse to participate and you may quit at any time. If you quit or refuse to participate, you and your family member's care will not be affected.

CONTACT FOR QUESTIONS:

If you have any questions or problems at any time you may call Kalie Nolen at (865) 659-8506 or Lisa Davenport at (423) 439-4505. You may call the Chairman of the Institutional Review Board at (423) 439-6054 for any questions you may have about your rights as a research subject. If you have any questions or concerns about the research and want to talk to someone independent of the research team or you can't reach the study staff, you may call an IRB Coordinator at (423) 439-6055 or (423) 439-6002.

CONFIDENTIALITY:

Every attempt will be made to see that your study results are kept confidential. Names will not be recorded for this study. The personal information gathered will be age, sex, relation to the ICU patient, and current length of their stay. Although your rights and privacy will be maintained, ETSU IRB and personnel particular to this research in the ETSU honors college will have access to the study records.

By signing below, you confirm that you are eighteen years of age or older and you have read or had this document read to you. You will be given a signed copy of this informed consent document. You have been given the chance to ask questions and to discuss your participation with the investigator. You freely and voluntarily choose to be in this research project.

SIGNATURE OF PARTICIPANT _____ DATE _____

PRINTED NAME OF PARTICIPANT _____ DATE _____

SIGNATURE OF INVESTIGATOR _____ DATE _____