

## Consent to Participate in a Research Study

**STUDY TITLE:** The National Simulation Study: Evaluating Simulated Clinical Experiences in Nursing Education

**PROTOCOL DATE:** 3/21/11

**PRINCIPAL INVESTIGATOR AND COLLABORATORS:**

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Anyone who is asked to participate in a research study must give his or her consent prior to participating. In order to decide if you want to take part in this study, you need to understand the risks and benefits that are involved. The consent form you are about to read gives detailed information about this study. Once you understand the study, you will be asked to sign this consent form if you wish to participate. A signed copy of this consent form will be given to you for your records.

### **INTRODUCTION**

This study is being done to determine if teaching methods that use simulated clinical experiences are similar to the usual method of clinical experiences used in clinical nursing education.

Clinical experiences in nursing education involve hands-on learning experiences where students directly care for patients in various healthcare settings. These experiences may include “shadowing” a nurse, having observation experiences during procedures or surgery, providing patient care in a variety of settings (i.e., hospital, nursing home, home health visits), and participating in health fairs. Students in a clinical group usually meet with the instructor at the beginning of the clinical day for pre-conference, and the group usually meets at the end of the clinical day for a post-conference.

Simulated clinical experiences involve the use of a high-tech, sophisticated computerized manikin to practice skills, such as conducting patient assessments, performing nursing

interventions, communicating with patients, families and other health care team members, and making clinical decisions while in an environment where a mistake will not harm a patient. Patient simulators can be programmed to have different medical conditions with corresponding vital sign changes, varying heart and lung sounds, pulse changes and can respond to simulated medications. Clinical simulations are conducted with trained simulation faculty and clinical instructors present. Simulation scenarios can be conducted with almost any patient condition and are followed with a debriefing session.

Many nursing schools are beginning to substitute some clinical time with simulated clinical experiences. Nursing educators and regulators need research data to understand if simulated clinical experiences are comparable to traditional, hands-on clinical experiences.

### **STATEMENT OF PURPOSE**

The purpose of this study is to determine if there are differences in educational outcomes among graduating nursing students when 50%, 25%, or up to 10% of traditional clinical hours are substituted with simulation experiences. This study will be evaluating clinical competency, nursing knowledge and how well student learning needs were met in each clinical environment.

### **NUMBER OF SUBJECTS INVOLVED**

Ten nursing programs across the US will be participating in this study. It is expected that 1000 nursing students will participate in this study, about 125 students will participate at Lancaster General College of Nursing and Health Sciences.

You are being asked to take part in this study because you are an undergraduate nursing student who will begin your nursing clinical coursework in the fall 2011 semester. If you choose to take part in this study, you will be followed over the four semesters of your nursing program through graduation, and taking the NCLEX-RN examination.

You may not take part in this study if you:

- are under 18 years old; or
- have a nursing license (either LPN/VN or RN).

### **PROCEDURE, DURATION OF PARTICIPATION, AND REQUIRED FOLLOWUP**

There are 3 study groups in this research project:

- Up to 10% of traditional clinical hours will be substituted with simulation (this is the usual teaching method used in this nursing program)
- 25% of traditional clinical hours will be substituted with simulation
- 50% of traditional clinical hours will be substituted with simulation

Once written consent has been obtained, you will be randomly assigned (like the flip of a coin) to one of the three study groups in a 1:1:1 ratio. This means you have an equal chance of being assigned to any one of the 3 study groups. You will remain in the same study group (≤10%, 25% or 50%) throughout your nursing program.

### Simulation Day

Time in simulation will count as an equal substitute for time in clinical; 1 hour of clinical will be replaced with 1 hour of simulation. The simulation day will consist of stations where groups of study participants will rotate through different scenarios. Stations may consist of scenarios with manikins, role play/standardized patients (patient actors), skills stations, or computerized clinical judgment scenarios.

Debriefing (a group discussion to reflect on the completed scenario) will occur immediately after each scenario and will be conducted by a member of the study team. Clinical instructors will attend the simulation day to evaluate study participants assigned to the primary nursing roles of a scenario. These evaluations will be for study purposes only, and will not be used as part of your course grade.

You will rotate throughout the simulation day in the roles you are assigned in each scenario (i.e., primary nurse, nurse orientee, family member, observer). You will be equally assigned the primary nursing role throughout the course.

### Data to be collected

You will be asked to complete questionnaires throughout the study. Below is a list of the questionnaires you will complete for the study:

- A demographic form
- A student information sheet-this will be completed once each semester.
- Clinical Learning Environment Comparison Survey (CLECS)-this survey asks you to rate how well your learning needs were met in both the clinical environment and the simulation environment. This will be done once per clinical course, and at graduation.
- Student Perception of Effective Teaching in Clinical Simulation Scale (SPETCS)-this survey has you rate the study team in how well they ran the simulation and the debriefing for one of your sessions. This will be done once per clinical course.
- Debriefing Assessment for Simulation in Healthcare-Student Version (DASH-SV)-this form has 6 questions for you to rate your debriefing experience, and will be done twice per semester.

### Other data to be collected

During simulation experiences and clinical experiences, your clinical instructor will be completing a form to rate how well you did in simulation or in clinical. These evaluations are for study purposes only and will not be part of your course grade. The study team will also collect information for the study that is a part of your usual nursing program requirements. This includes your grade point average (GPA) at the end of each semester, and ATI Content Mastery Series<sup>®</sup> scores (tests taken at the end of each course).

You will also complete two simulation experiences that will be evaluated by a blinded evaluator (a person who does not know you). These simulations will occur at the end of the first year of your nursing program and at the end of your program, before graduation. These simulations will take between 30-60 minutes to complete.

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After you take the NCLEX-RN licensing examination (after graduation), your score will be collected by the study sponsor. If you take the NCLEX-RN exam more than once, all of your scores will be collected by the study sponsor.

### Follow-up study

At the end of the study (graduation), you will be given an additional consent form for the follow-up portion of the study. The follow-up portion of the study will follow you for up to one year as you begin to practice as a new graduate nurse.

### **BENEFITS**

There may be no direct benefit to you for participating in this study. Your participation will contribute to the results of this study. Information learned from this study will help guide nursing educators and regulators to make decisions that could impact the future of nursing education.

### **RISKS, DISCOMFORTS, AND INCONVENIENCES**

There are no physical risks in this study. You may feel uncomfortable about sharing your demographic data, test scores and grade point average (GPA). Some students report feeling anxious the first few times in the simulation environment. You may feel uncomfortable rating how your learning needs were met in both the traditional clinical environment and the simulation environment.

You will be carefully monitored throughout the study so that participation in the study does not hinder your education. Should it be determined that the simulation groups are learning or performing clinically at a lower level than participants in the control group, the study will be put on hold and you will be remediated. Faculty will work with you to identify areas needing improvement. ATI online skills modules and practice tests will be available if you need assistance with nursing content. Additional practice with psychomotor skills will be available in the skills lab and additional simulation sessions can be scheduled if you are struggling with clinical.

### **ALTERNATIVE TO PARTICIPATION**

The only alternative to participating in this study is not to participate. If you choose not to participate, you will be assigned to receive clinical as usual, which is up to 10% of clinical time substituted with simulation experiences. This is the usual teaching method at this program. You will be evaluated as usual by your clinical instructor, and you will not have to complete the study required surveys. You will still take the ATI tests that are required by your nursing program; however, you will be responsible for the fees for these examinations.

### **COSTS**

There are no costs associated with your participation in this study. Any study guides, manuals or licensing fees that may be associated with participation in simulated clinical experiences will be provided at no cost to you. Study participants will not be responsible for any ATI study products or testing fees for exams at the end of each course.

### **PAYMENTS**

You will not be paid for participating in this study.

**QUESTIONS / FURTHER INFORMATION**

If you have any questions about this research or if you believe you have been injured as a result of participating in this research study, you can contact Kay Buchanan, MSN, RN at 717-544-4912 x 77059.

**SUBJECT'S RIGHTS OR QUESTIONS**

If you have any questions about your rights as a participant in this research study, you may contact the Chairman of the Institutional Review Board at Lancaster General Hospital, at 717-544-5091.

**VOLUNTARY PARTICIPATION**

You understand that your participation in this study is voluntary. You may refuse to participate in or withdraw from this study at any time it will not affect your grade, your student status, or current or future relations with LGCNHS. If significant new information is found during the course of this study which may affect your decision to participate, this information will be provided as soon as possible to you and your nursing faculty for review and discussion.

**TERMINATION OF PARTICIPATION / RIGHT TO WITHDRAWAL**

If you choose to withdraw from the study, it will not affect your grade, your student status, or current or future relations with LGCNHS. If you choose to withdraw from the study, you should notify the study team right away. You will need to stay in your assigned clinical group until the end of the semester; however your clinical instructor will stop completing the evaluation forms required by the study, and you will not complete any of the study surveys. You will be re-assigned to a new clinical group that receives up to 10% of clinical time substituted with simulation for the following semester.

If you choose to withdraw, you will still complete ATI exams as required by the nursing program; however, you will have to pay the examination fee.

In the event that you do withdraw from this study, the information you have already provided will be kept in a confidential manner.

Your participation in this study may be stopped at any time by the study team or the sponsor without your consent if it is in your best interest.

**CONFIDENTIALITY**

The data for this study will be kept confidential to the extent allowed by federal and state law. No published results will identify you, and your name will not be associated with the findings. A number will be assigned to each participant at the beginning of the project. This number will be used on project records rather than your name, and no one other than the researchers will be able to link your information with your name. This list will only be shared with the researchers at the coordinating center (NCSBN) upon graduation, for the purposes of obtaining NCLEX-RN scores.

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Study records/data will be stored in locked filing cabinets and protected computer files at Lancaster General College of Nursing and Health Sciences. After the study is completed, the data for this study will be kept for five years.

The results of the study may be published or presented at professional meetings, but the results will be presented as a group so that no individual person could be identified.

While we will make every effort to protect your privacy, it cannot be absolutely guaranteed. The study sponsor will have access to your identifiable information. In rare cases, a research study may be evaluated by an oversight agency, such as the Lancaster General Hospital Institutional Review Board or the U.S. Office for Human Research Protections. If this occurs, records that identify you and the consent form signed by you may be inspected so that they may evaluate whether the study is properly conducted and the rights of participants were adequately protected.

### **STATEMENT OF CONSENT**

I have read the above information, or have had it read to me, and I understand the purpose of the study, as well as the potential benefits and risks of participation in the study. I have had the opportunity to ask questions, and all of my questions have been answered to my satisfaction. I freely give my informed consent to be a participant in this study. I will be given a signed copy of this consent form.

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Subject Name (Printed)

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Name of person obtaining  
consent (printed)

\_\_\_\_\_  
Signature of person obtaining  
consent

\_\_\_\_\_  
Date