RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title: The National Simulation Study: Evaluating Simulated Clinical Experiences in Nursing Education

Application No.: NA_00050032

Sponsor: National Council of State Boards of Nursing

Principal Investigator: Pamela R. Jeffries

1. What you should know about this study:
   - You are being asked to join a research study.
   - This consent form explains the research study and your part in the study.
   - Please read it carefully and take as much time as you need.
   - Please ask questions at any time about anything you do not understand.
   - You are a volunteer. If you join the study, you can change your mind later. You can decide not to take part or you can quit at any time. There will be no penalty or loss of benefits if you decide to quit the study.
   - During the study, we will tell you if we learn any new information that might affect whether you wish to continue to be in the study.
   - Ask the study team to explain any words or information in this informed consent that you do not understand.

2. Why is this research being done?

   This research is being done to determine if teaching methods that use simulated clinical experiences are similar to the usual method of clinical experiences 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 (for example, hospital, nursing home, or home health visits), and taking part 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 an actual patient. Patient simulators can be programmed to have different medical conditions with corresponding vital sign changes, varying heart and lung sounds and pulses, 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. The purpose of this study is to learn if there are differences in educational outcomes among graduating nursing students when 10%, 25%, or up to 50% of traditional clinical hours are substituted with simulation experiences. This study will evaluate clinical competency, nursing knowledge, and how well student learning needs are met in each clinical environment.

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.

**How many people will be in this study?**
Ten nursing programs will take part in this study across the United States. It is expected that 1,000 students will take part in this study at all sites. About 130 students will take part at Johns Hopkins University School of Nursing.

**3. What will happen if you join this study?**
If you agree to be in this study, we will ask you to do the following things:

There are 3 study groups in this research study:
- 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 you give written consent, you will be randomly assigned by chance (like drawing numbers from a hat) 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 stay in the same study group (up to 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 right 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 (for example, the primary nurse, nurse orientee, family member, or 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
- 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® 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. The simulation experiences will be videotaped.

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.

**How long will you be in the study?**
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.
4. **What are the risks or discomforts of the study?**
There are no physical risks in this study. You may feel uncomfortable about sharing your demographic data, test scores, and cumulative 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 taking part in the study does not hinder your education. If 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 retrained. Faculty will work with you to identify areas that need 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.

You may get tired or bored when we are asking you questions or you are completing questionnaires. You do not have to answer any question you do not want to answer.

5. **Are there benefits to being in the study?**
There may be no direct benefit to you for taking part in this study. Your participation will contribute to the results of this study. Information learned from this study may help guide nursing educators and regulators to make decisions that could impact the future of nursing education.

6. **What are your options if you do not want to be in the study?**
The only alternative to taking part in this study is not to take part. If you choose not to take part, 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 nursing program. You will be evaluated as usual by your clinical instructor, and you will not have to complete the study required surveys. You also will not have to take the ATI tests at the end of each clinical course.

You do not have to join this study. If you do not join, your grade at Johns Hopkins University will not be affected.

7. **Will it cost you anything to be in this study?**
No. 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. You will not pay for any ATI study products or testing fees for exams at the end of each course.

8. **Will you be paid if you join this study?**
No.

9. **Can you leave the study early?**
Taking part in this study is voluntary. You may decide not to take part or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled. If you choose not to take part, it will not affect your grade, your student status, or current or future relations with Johns Hopkins University.
Approved June 21, 2011

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 you clinical instructor will stop completing the evaluation forms required by the study, you will not complete any of the study surveys, and you will not take the ATI examinations. You will be re-assigned to a new clinical group that receives up to 10% of clinical time substituted with simulation (the usual method at this nursing program) for the following semester.

10. **Why might we take you out of the study early?**
Your participation in this study may be stopped at any time by the study team or the sponsor without your consent for any of the following reasons:
   - If it is in your best interest.
   - You do not consent to continue in the study after being told of changes in the research that may affect you.
   - The study is cancelled.
   - There may be other reasons to take you out of the study that we do not know at this time.

11. **How will your privacy be protected?**
Johns Hopkins has rules to protect information about you. Federal and state laws also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

   Generally, only people on the research team will know that you are in the research study and will see your information. However, there are a few exceptions that are listed later in this section of the consent form.

   The people working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may collect other information including your name, age, and other demographic information.

   The research team will need to see your information. Sometimes other people at Johns Hopkins may see or give out your information. These include people who review the research studies, their staff, lawyers, or other Johns Hopkins staff.

   People outside of Johns Hopkins may need to see your information for this study. Examples include government groups (such as the Food and Drug Administration), safety monitors, and companies that sponsor the study, or work with the study sponsor.

   We cannot do this study without your permission to use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

   We will use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside Hopkins who receive your information may not be covered by this promise. We try to make sure that everyone who needs to see your information keeps it confidential - but we cannot guarantee this.
The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by calling the Johns Hopkins Privacy Officer at 410-735-6509 or by sending a letter to:

Johns Hopkins Privacy Officer  
5801 Smith Avenue  
McAuley Hall, Suite 310  
Baltimore, MD 21209  
Fax: 410 735-6521

Please be sure to include the name of the principal investigator, the study number and your contact information.

If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

12. **What other things should you know about this research study?**  
   a. **What is the Institutional Review Board (IRB) and how does it protect you?**  
      The Johns Hopkins Medicine IRB is made up of:  
      - Doctors  
      - Nurses  
      - Ethicists  
      - Non-scientists  
      - and people from the local community.

      The IRB reviews human research studies. It protects the rights and welfare of the people taking part in those studies. You may contact the IRB if you have questions about your rights as a participant or if you think you have not been treated fairly. The IRB office number is 410-955-3008. You may also call this number for other questions, concerns or complaints about the research.

   b. **What do you do if you have questions about the study?**  
      Call the principal investigator, Pamela Jeffries at 410-614-4081. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-955-3008.

   c. **What happens to Data that are collected in the study?**  
      The data collected from you during this study are important to both this study and to future research in nursing education.

      If you join this study:  
      - You will not own the data given by you to the investigators for this research.  
      - Both Johns Hopkins and any sponsor of this research may study your data and the tissue, blood or other specimens collected from you.  
      - If data are in a form that identifies you, Johns Hopkins may use them for future research only with your consent or IRB approval.  
      - You will not own any product or idea created by the researchers working on this study.  
      - You will not receive any financial benefit from the creation, use or sale of such a product or idea.
d. **What are the Organizations that are part of Johns Hopkins?**

Johns Hopkins includes the following:

- The Johns Hopkins University
- The Johns Hopkins Hospital
- Johns Hopkins Bayview Medical Center
- Howard County General Hospital
- Johns Hopkins Community Physicians.
- Suburban Hospital
- Sibley Memorial Hospital
13. **What does your signature on this consent form mean?**

Your signature on this form means that:
- you understand the information given to you in this form
- you accept the provisions in the form
- you agree to join the study

You will not give up any legal rights by signing this consent form.

**WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM**

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**NOTE:** A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; AND, IF APPROPRIATE A COPY OF THE CONSENT FORM MUST BE PLACED IN THE PARTICIPANT’S MEDICAL RECORD.

**ONLY CONSENT FORMS THAT INCLUDE THE JOHNS HOPKINS MEDICINE LOGO SHOULD BE USED TO CONSENT RESEARCH PARTICIPANTS. IF THIS CONSENT FORM DOES NOT HAVE A JOHNS HOPKINS MEDICINE LOGO, DO NOT USE IT TO CONSENT RESEARCH PARTICIPANTS.**