RESEARCH CONSENT FORM

You are being asked to participate as a subject in the research project entitled, Constructing the Cornerstones for C.A.T.E.S., under the direction of Leigh Ann Cates, MSN, RN, NNP-BC, RRT-NPS, CHSE Assistant Professor UTMB SON Neonatal Nurse Practitioner (NNP) Program.

PURPOSE OF THE STUDY

The purpose of this Real Time Delphi (RTD) Study is to lay a solid and evidence based foundation for C.A.T.E.S an instrument used to evaluate multidimensional competency of NNPs participating in simulation. You are being asked to participate because you have expertise in one or more of the following areas: 1) neonatal care; 2) instrument development; 3) competency development or assessment 4) healthcare simulation.

PROCEDURES RELATED ONLY TO THE RESEARCH

This study will utilize a Real-Time Delphi (RTD), an extremely innovative process, recently developed by Gordon and Pease (2006). The typical Delphi Method is an iterative process, whereas RTD studies are the dearth of repeated rounds as well as the 24 hour a day simultaneous computation and delivery of the participant’s responses (Gordon & Pease, 2006). Thus, RTD is an uninterrupted round-less process resulting in a condensed time frame required to conduct massive and complex studies. Additionally, experts are not limited to the number of judgments that can be made by the number of rounds. The number and location of experts that can participate in a RTD is limited only by internet access, and can be ended at any time by the administrator once he or she is satisfied with existing responses (Gordon & Pease, 2006). Finally, the anonymity of a RTD allows for individuality, while the degree of interaction between experts is increased, as well as the implied push for increased cognitive examination, thus, maximizing the overall validity of the study. Thus, in a relatively short amount of time, this RTD study will entail the examination of four specific aims including:

Specific Aim 1: Identify which cognitive, technical, and behavioral dimension of NNP competency accurately reflects each of the global items. Specific Aim one is based on The Iceberg Theory of Competency developed by Spencer and Spencer (1993).

Specific Aim 2: Indicate whether each of the global statements is correctly mapped into the following NANNP Core Competency domains. Specific Aim two is based on the NANNP Competency Toolkit (2010) & The National Organization of Nurse Practitioner Faculties (NONPF) Population Focused Competency Domains (2013).

Specific Aim 3:
Determine if the operational definitions are accurate reflections of NNP performance while being observed in simulation.
Specific Aim three is based on Patricia Benner’s Novice to Expert Model (1984).

Specific Aim 4: 
Choose the essential scenarios to evaluate multidimensional NNP competency.
Based on the National Certification Corporation’s Core Testing Domains (National Certification Corporation [NCC], 2012), and NANNP Competency Domains (2010).

The amount of time necessary for completion of each aim will vary for each panelist, but should range from approximately 15-30 minutes. There are no right and wrong answers to the questions. This study is seeking your expert opinion. I think that you will find the information and process interesting, and the results will be made available to you at the conclusion of this study.

It is imperative that you understand that participation in this study is entirely voluntary. If you do not wish to participate in this study it will not affect your employment or service provided. In addition, any information provided will be confidential and will be kept in a locked office on a password protected computer available only to myself (Leigh Ann Cates) the principal investigator (PI). When results are reported, you will not be identifiable in the findings. Your name will NOT be recorded on any rounds; instead you will be allocated a unique identifying code that can only be identifiable by the PI. You will remain anonymous to the other experts throughout this RTD study and only the PI will be able to identify your specific answers. Upon entry to the study through the included study link and code you will be asked to confirm consent and confidentiality through electronic agreement. Your electronic agreement will imply your consent to participate as well as your understanding that confidentiality of the items contained within the study MUST be maintained.

PROCEDURES NOT RELATED TO THIS RESEARCH (i.e., standard of care)
There will be no procedures performed that are not directly related to the research.

RISKS OF PARTICIPATION

There are no potential risks from participation in the study. All data collected will be the responsibility of principle investigator (PI). Additionally, the participants will be assigned a code ID and pseudonym recognized only to the PI and kept in a master codebook. Items with identifying information will be locked on a password protected computer in the PI’s office.

RISKS TO THE FETUS

There are no risks to the fetus.

NUMBER OF SUBJECTS PARTICIPATING AND THE DURATION OF YOUR PARTICIPATION
The anticipated number of subjects involved in the study will be 25-30. The length of time for your participation is one year.

**BENEFITS TO THE SUBJECT**

The direct benefits to you may include a better understanding of one's own competency and an opportunity to reflect on one's career as an NNP as well as the opportunity to be a part of the development of C.A.T.E.S. an instrument to be utilized in the evaluation of competency for NNP students and practicing NNP while performing in simulation. However, this/these benefits cannot be guaranteed.

**SAFE WITHDRAWAL FROM THE STUDY**

Each participant will receive a copy of the written consent prior to the start of the study with ample opportunity to ask questions or voice concerns prior to signing the consent and may voluntarily withdrawal at any time at no risk.

**REIMBURSEMENT FOR EXPENSES**

There will be no reimbursement for participation in this study, but can be credited on your CV and future employment evaluations.

**COMPENSATION FOR RESEARCH RELATED INJURY**

There will be no substances administered or procedures performed other than interviews during this study.

**COSTS OF PARTICIPATION**

There is no cost of participation.

**REASONS FOR THE STUDY INVESTIGATOR TO STOP YOUR PARTICIPATION**

The PI may stop your participation if you are unwilling to participate.

**PROCEDURES FOR WITHDRAWAL**

If you choose to withdraw from the study, you may withdraw your consent by notifying Leigh Ann Cates at 281-330-7598 or lacates@utmb.edu. You will be sent an email stating that the PI has opted to withdrawal you from the study.

**USE AND DISCLOSURE OF YOUR HEALTH INFORMATION**

In order to comply with the requirements of the Health Insurance Portability and Accountability Act (HIPAA), this section must be included in the consent form. The following statements must be included:

**Use and Disclosure of Your Medical Information Section for Non-Patients**
Study records that identify you will be kept confidential as required by law. Federal privacy regulations provided under the Health Insurance Portability and Accountability Act (HIPAA) provides safeguards for privacy, security, and authorized access of your records. These regulations require UTMB to obtain an authorization from you for the use and disclosure of your health information. By signing this consent form, you are authorizing the use and disclosure of your health information related to the research study. Except when required by law, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier in study records disclosed outside of the University of Texas Medical Branch (UTMB). For records disclosed outside of UTMB, you will be assigned a unique code number. The key to the code will be kept in a locked file in Leigh Ann Cates’ home office.

No tests will be run or health information will be collected.

ADDITIONAL INFORMATION

1. If you have any questions, concerns or complaints before, during or after the research study, or if you need to report a research related injury or adverse reaction (bad side effect), you should immediately contact Leigh Ann Cates at 281-330-7598.

2. Your participation in this study is completely voluntary and you have been told that you may refuse to participate or stop your participation in this project at any time without penalty or loss of benefits and without jeopardizing your medical care at UTMB. If you decide to stop your participation in this project and revoke your authorization for the use and disclosure of your health information, UTMB may continue to use and disclose your health information in some instances. This would include any health information that was used or disclosed prior to your decision to stop participation and needed in order to maintain the integrity of the research study. If there are significant new findings or we get any information that might change your mind about participating, we will give you the information and allow you to reconsider whether or not to continue.

3. If you have any complaints, concerns, input or questions regarding your rights as a subject participating in this research study or you would like more information, you may contact the Institutional Review Board Office, at (409) 266-9475.

The purpose of this research study, procedures to be followed, risks and benefits have been explained to you. You have been allowed to ask questions and your questions have been answered to your satisfaction. You have been told who to contact if you have additional questions. You have read this consent form and voluntarily agree to participate as a subject in this study. You are free to withdraw your consent, including your authorization for the use and disclosure of your health information, at any time. You may withdraw your consent by notifying Leigh Ann Cates at 281-330-7598 or lacates@utmb.edu. You will be given a copy of the consent form you have signed.
Informed consent is required of all persons in this project. Whether or not you provide a signed informed consent for this research study will have no effect on your current or future relationship with UTMB.

Finally you agree that all information included in this study is kept confidential and will not be shared or discussed with anyone other than the PI.