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## Effect of the Interactive Computerized Information for Surrogates ICU Program in Increasing the Understanding of Informed Consent and the Knowledge of Genetic and Genomics Research

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Effect of the  
Interactive Computerized Information for Surrogates ICU Program  
In Increasing Surrogate's Understanding of Informed Consent and Knowledge of  
Genetic and Genomic Research

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A DISSERTATION

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In

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Advisory Committee

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## Abstract

Background: A significant and growing number of clinical research studies conducted in Intensive Care Units (ICUs) today have some genetic and genomics component. Surrogates approached to authorize participation in clinical research for a loved-one in the ICU may not be prepared to make informed decisions. An author-developed model of stewardship of genetic and genomics research was used as a framework for this study. In addition, the literature review, prepared for publication, identified surrogate education as an important factor in surrogate understanding of the process of informed consent and knowledge of genetic and genomics research. Purpose: The purpose of this investigation was to examine the effect of an author-developed educational program, the Interactive Computerized Information for Surrogates (ICIS) ICU Education Program in assisting surrogates to (1) increase their understanding of the process of informed consent and (2) increase their knowledge of genetic and genomics research. Methods: Visitors in two ICU waiting rooms (potential surrogates) in a large metropolitan medical center were randomly assigned to an experimental group (n = 64) who received the ICIS ICU Education Program plus the Sample Consent Form and the control group (n = 69) who received the Sample Consent Form alone. Both groups completed the author-developed Posttest Instrument ( $\alpha = .730$ ). Results: Overall, understanding the process of informed consent was significantly higher ( $p = .05$ ) in the experimental versus the control group (Wilcoxon  $W = 3346$ ;  $p = 0.000$ ). In addition, knowledge of genetics and genomics research was significantly higher ( $p = .05$ ) in the experimental

versus the control group (Wilcoxon W 3853.5,  $p = 0.000$ ). The ICIS ICU Education Program plus the Sample Consent Form was superior to the Sample Consent Form alone in 9 of the 14 items on the Posttest Instrument in increasing the understanding of the process of informed consent and in increasing the knowledge of genetic and genomics research in surrogates. Based on study findings, the ICIS ICU Education Program was a feasible, useful, and effective program when used to educate surrogates about informed consent and genetic and genomics research in the ICU. A recommendation was made to administer the ICIS ICU Education Program to surrogates prior to asking them to sign the Sample Consent Form. This research has the potential to contribute to the literature regarding the preparation of surrogate consenters for research in the ICU, increase participation in clinical research through education, augment the NIH goal of informing the public about genomics, and provide an interactive educational program that is adaptable to many ICU environments.

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## CHAPTER I

### Introduction

In this chapter the problem, the problem statement, the purpose, and the significance surrounding the issues of surrogate informed consent for genetic and genomics research conducted in the intensive care unit (ICU) are discussed. In addition, associated assumptions and hypotheses are presented.

### Problem

The U.S. Centers for Disease Control and Prevention state that there is some genetic component influencing most disease processes (Beery & Hern, 2004). Understanding the etiology of illness, predicting therapeutic effects or adverse medication reactions, and developing testing and treatment innovations constitutes the promise of genomics research and will transform the provision of health care (Beery & Hern, 2004; Collins, Green, Guttmacher, & Guyer, 2003). This understanding of genetics and genomics is critical to the clinical application of new knowledge of health and disease gleaned from research such as the Human Genome Project. Since the inception of the Human Genome Project, there has been an ongoing debate about the ethical, legal, and social implications (ELSI) of genetic and genomics research. Fundamental ELSI considerations such as privacy, confidentiality, insurability, and discrimination impact stakeholders involved in genetic and genomics research. In fact, project developers anticipated the enormity of ELSI to the Human Genome Project and designated approximately 3% – 5% of the total NIH Human Genome Project

funding package to study its impact on individuals, families, community organizations, and institutions (Ojha & Thertulien, 2005).

#### Specific Clinical Problem

Critically ill ICU patients often are unable to consent to participate in genetic and genomics research due to cognitive impairment associated with trauma, fever, sedation, pain, or shock (Davis, Pohlman, Gehlbach, Kress, McTee, Herlitz, et al. 2003; Freeman, Kennedy, Coopersmith, Zehnbauer, & Buchman, 2006; Jamerson, Scheibmeir, Bott, Crighton, Hinton, & Cobb, 1996). Therefore, surrogate, or proxy, consent may be desired in an emergent situation for which study enrollment cannot be delayed. Surrogate informed consent is a critical component of genomics research in the ICU. Yet, surrogates are asked to make complex research participation decisions for their loved-ones in the ICU; many of whom have an insufficient understanding of the process of informed consent and insufficient knowledge of genetics and genomics research (Davis et al. 2003; Jamerson et al. 1996).

#### Problem Statement

There is a paucity of research about surrogate consenters' understanding of the process of informed consent and knowledge of genetic and genomics research in the ICU. Yet, surrogate decision makers are called upon to give their consent for loved-ones to participate in genomics research with its ELSI considerations. Little is known about the surrogate decision maker experience as it relates to understanding the information disclosed in the process of informed consent or knowledge of genomics research. Thus, surrogates approached to

authorize participation for a loved-one in genomics research in the ICU may be ill-prepared to make these decisions. In fact, there are no published papers focusing specifically on an intervention to facilitate surrogate informed consent for genetic or genomics research in the ICU. An education intervention may have the potential to enhance the understanding of the process of informed consent and knowledge of genetic and genomics research in surrogates in the ICU.

#### Purpose

The purpose of this investigation is to examine the effectiveness of an educational program, the Interactive Computerized Information for Surrogates ICU Education Program (ICIS), in assisting surrogates to (1) increase understanding of the process of informed consent and (2) increase knowledge of genetic and genomics research.

#### Significance of the ICIS ICU Education Program

The ICIS ICU Education Program was developed by the author to facilitate the process of informed consent using technology to complement the information provided on a sample consent form. The ICIS ICU Education Program is an interactive computerized program designed to inform and instruct surrogates in the ICU about the process of informed consent and genetic and genomics research using a straightforward, individually paced, and comprehensive approach. The ICIS ICU Education Program also provides a framework with which to measure understanding of the process of informed consent and knowledge of genetic and genomics research.

This project has the potential to (a) contribute to the literature regarding the educational preparation of surrogate consenters for research in the ICU, (b) support institutional mandates to ensure informed consent, (c) increase participation in clinical research through education, (d) augment the National Institutes of Health (NIH) goal of informing the public about genetic and genomics, and (e) provide an expandable, interactive educational program that is adaptable to many ICU environments.

#### Significance of the Literature Review Regarding Informed Consent and Genetic and Genomics Research in the ICU

A literature review was conducted by the author for publication to add to nursing's knowledge base and facilitate evidence based practice for attaining surrogate informed consent in genetic and genomics research in the ICU. The purpose of this paper was to provide a systematic review of the literature examining the challenges and strategies surrounding the solicitation of surrogate consent for genetic and genomics research in the ICU. Overall, there are few well-controlled studies and still fewer studies specifically focused on genomics research in the ICU. Yet a major theme in this literature is the role of the health care professional in guiding the surrogate through the process of informed consent rather than simply witnessing a signature. The process of informed consent requires explicit strategies to effectively approach the surrogate, educate the surrogate, and assure that informed consent has been attained.

## Significance of the Stewardship Model of Genetic and Genomics Research

A stewardship model of genetic and genomics research was developed by the author to facilitate theory generation and evidence based practice regarding the ethical conduct of the process of informed consent regarding genetic and genomics research. Stewardship of genetic and genomics research is depicted as balancing on a scale between the mandate to conduct essential genetic and genomics research and the preservation and protection of human rights.

### Associated Assumptions

The first assumption in the current study is that genetic and genomics information is intensely personal (Knoppers & Chadwick, 1994). Clearly, sensitive genetic data involving individuals have the potential to be generated, stored, and distributed swiftly and efficiently once obtained. Thus, preserving the privacy and confidentiality of genetic information is central to the concept of stewardship as it relates to genetic information. The second assumption in the current study is that it is in the public interest to produce and disseminate health research (Pang, 2004). The third assumption is that the surrogate consentor has the same right to information as does the participant. The fourth assumption is that genetic and genomics information is different from other research information and requires special consideration.

### Hypotheses

#### *Hypothesis I*

Understanding of the process of informed consent will be greater in the experimental group as compared to the control group.

*Hypothesis II*

Knowledge of genetic and genomics research will be greater in the experimental group as compared to the control group.



## CHAPTER II

### Introduction

Chapter II includes theoretical definitions and a review of literature. Two conceptual models of stewardship of genetic and genomics research are also presented.

#### Theoretical Definitions

##### *Genetics and Genomics*

Genetics is the branch of biology that studies heredity. Genomics refers to the study of all the genes in the human genome together, including their interaction with each other, the environment, and the influence of other psychosocial and cultural factors (Beery & Hern, 2004).

##### *Informed Consent*

Informed consent is the agreement to participate in experimental treatment or another form of clinical research, with the following stipulations: (a) all information relevant to the participant's decision must be disclosed and the participant must understand the information presented, (b) the authorization of informed consent is only valid if the participant/surrogate is mentally competent and consent is given freely and without coercion, and (c) the consent should be given in writing (Maslin-Prothero, 2003; Declaration of Helsinki, 1983). However, informed consent is not complete when a signature is obtained. It is a process that continues throughout the research.

### *Stewardship*

Stewardship, related to genetic and genomics research reflects the commitment by all stakeholders, including the researcher and the institution, to the qualities of ethical research and to responsibility, evidenced by accountability and trust.

### *Surrogate*

A surrogate may be defined as a stand-in for health care decision making when the patient is unable to consent for testing, treatment, or research (Silverman, Luce, Lanken, Morris, Harabin, & Oldmixon et al. 2005).

### *Understanding the Process of Informed Consent*

Understanding the process of informed consent is a cognitive grasp of facts about participating in clinical research.

### *Knowledge of Genetics and Genomics Research*

Knowledge of genetics and genomics research indicates the ability to intellectually process critical facts and information about a highly complex research process.

### *Review of Literature: Surrogate Consent for Genomics Research in ICU*

Genomics refers to the interactive relationship of genes within the genome and with the environment (Beery & Hern, 2004; Feetham, Thomson, & Hinshaw, 2005; Guttmacher & Collins, 2002; Guttmacher & Collins, 2003). In the ICU setting, circumstances arise where the patient is not able to give informed consent for genomics research (Chen, Miller, & Rosenstein, 2002; Davis et al. 2003). These patients often experience cognitive impairment resulting from illness, trauma,

pain, sedation, or anesthesia (Davis, et al. 2003; Freeman et al. 2006; Jamerson et al. 1996). In such circumstances, surrogates are asked to serve as proxies and provide informed consent to genomics research on behalf of a loved one in ICU (American Thoracic Society, 2004; Chen et al. 2002, Davis et al. 2003; Silverman et al. 2005). Yet, without a basic understanding of genomics, surrogates are ill-prepared to make the informed decision necessary to consent to genomics research (Davis et al. 2003; Jamerson et al. 1996). Beery & Hern (2004) and others describe many ELSI considerations of genomics for patient care, education, and research including psychological effects, privacy, stigmatization, insurability, and conflicts of interest (American Thoracic Society, 2003; Arnold & Kellum, 2003; Beery & Hern, 2004; Bigatello, George, & Hurford, 2003; Feetham et al. 2005; Freeman et al. 2006; Hoedemaekers, Gordijn, & Pijnenburg, 2006; Hook, DiMagno, & Tefferi, 2004). These implications have been considered such important issues that the Human Genome Project dedicated 3-5% of its total budget to the study of ELSI (Collins, et al. 2003; Feetham et al. 2005; Hook et al. 2004; Ojha & Thertulien, 2005).

Despite its growing complexity and significance, little is known about the surrogate decision-maker's experience when asked to consent to genomics research in the ICU or about the surrogate's ability to understand the information disclosed in the consent process (American Thoracic Society, 2004; Chen et al. 2002). In addition, surrogates may not know their loved one's health care wishes. Further, written policies regarding surrogate consent do not provide step-by-step guidelines for clinicians and policies vary from state to state (Chen et al. 2002).

The purpose of this paper is to provide a systematic review of the literature examining the challenges and strategies surrounding the solicitation of surrogate consent for genomics research in the ICU. This paper integrates studies and expert opinion from the areas of medicine, nursing, environmental psychology, critical care, ethics, genomics, and education.

From the literature review, a three-step process of informed consent emerged which is used as the framework of this paper: (a) approaching the surrogate, (b) educating the surrogate, and (c) concluding the process of informed consent. The literature about approaching the surrogate has five main themes: surrogate challenges, environment, timing, legal aspects, and misinformation surrounding genomics research and the process of informed consent. The literature on educating the surrogate focuses on language and literacy challenges, teaching the elements of consent, choosing a teaching strategy, and using technology. The literature on concluding the process of informed consent emphasizes readability of consent forms, evaluating surrogate understanding, and ensuring post-consent follow-up. Although the challenges and strategies surrounding solicitation of surrogate consent apply to all kinds of research, this paper specifically focuses on genomics research because of the exceptional nature of genetic information (DNA sequence) and our interest locally in addressing this important issue (American Thoracic Society, 2004; Cobb, Mindrinos, Miller-Graziano, Calvano, Baker & Xiao et al. 2005; Feetham et al. 2005; Green & Botkin, 2003; Hook et al. 2004). Also, this paper specifically focuses on the ICU as a particularly challenging setting because (a) critically ill

patients are frequently unable to communicate their decisions to a loved one and (b) a degree of decisional immediacy is required in the ICU that is not usually necessary in other patient care settings (American Thoracic Society, 2004; Bigatello et al. 2003).

### *Approaching the Surrogate*

#### *Surrogate Challenges*

The nature of critical illness and its treatment frequently prevents direct verbal interactions between staff and patients. Consequently, surrogates in the ICU are approached to supply medical histories, therapy decisions and direction, and a link to the patient's life before illness (Azoulay & Sprung, 2004; Zaforteza, Gastaldo, dePedro, Sanchez-Cuenca, & Lastra, 2005). Also surrogates are called on to make a host of crucial decisions such as choosing among medical treatments, considering advanced directives, meeting other family members' needs, attending to financial obligations, and arranging for transportation and temporary living arrangements (Jamerson et al. 1996). The impact on the surrogate of the unfamiliar and emotionally charged environment of an ICU is considerable (Arnold & Kellum, 2003; Azoulay & Sprung, 2004; Jamerson et al. 1996; Pochard, Azoulay, Chevret, Lemaire, Hubert, and Canoui et al. 2001). For example, Pattison found that the incidence of post-traumatic stress disorder is high in relatives of patients in the ICU (Pattison, 2005). The initial surprise and subsequent shock of the loved one's sudden trauma or illness are compounded by an unplanned addition of responsibility that requires clear thinking and the assimilation of rapidly delivered critical and often complex information (Azoulay &

Sprung, 2004; Jamerson et al.1996; Zaforetza et al. 2005). Within this context, the surrogate decision maker may be psychologically unprepared to accept the additional responsibility attendant to enrolling a loved one in a research study (Azoulay & Sprung, 2004; Davis et al. 2003).

In the context of this highly charged and challenging situation, information and support may be used as strategies to facilitate surrogates' decision making (Arnold & Kellum, 2003; Azoulay & Sprung, 2004; Jamerson et al.1996). The opportunity to talk to a health care professional, share cultural values, and voice concerns can promote understanding and reduce stress (Azoulay & Sprung, 2004; Felgen, 2004; Jamerson et al. 1996; Johnson, Wilson, Cavanaugh, Bryden, Gudmundson, & Moodley, 1998). Another strategy to empower surrogates is to give them access to professionals in the ICU including physicians, primary nurses, nurse specialists, ethicists, spiritual advisors, independent patient advocates, social workers, and translators (Geller, Botkin, Green, Pres, Biesecker & Wilfond et al. 1997; Jamerson et al. 1996; Nelson, Kiyoshi, Meier, Ahmand, & Morrison, 2005). A study by Arnold and Kellum (2003) found that an ethics consultation with families of ICU patients was associated with a shortened ICU stay for their loved ones. When assisted in exploring and clarifying health care issues, surrogates were empowered to make health care decisions (Arnold & Kellum, 2003).

### *Environment*

Understanding how the surrogate subjectively perceives the ICU environment can help health care professionals interpret individual needs and

behaviors (Felgen, 2004; Jamerson et al. 1996; McLaren & Hawe, 2005).

Recognizing the surrogate's sense of contrasting environmental dichotomies is one example. There is a convolution of perceived isolation within a crowded ICU waiting room that often confronts the surrogate (Jamerson et al. 1996; Johnson et al. 1998). Even in an atmosphere of hundreds of people in a hospital community, the surrogate may not be able to identify a support system (Jamerson et al. 1996). Further, despite the fundamental right to autonomy, the surrogate may feel compelled to surrender personal and family control to institutional dictates (American Thoracic Society, 2003; Coppolino & Ackerson, 2001; Geller et al. 1997).

Environmental psychology theory can help guide practice when working with surrogates in the ICU to improve their decision-making abilities (Bilchick, 2002). The health care professional can assist the surrogate to interpret or create alternative perceptions of common ICU stimuli in order to diminish their stressful impact (Pouchard et al. 2001; Zaforteza et al. 2005). Demystifying the environment through orientation is an integral component of ethical practice (Jamerson, 1996). Familiarity with surroundings (sights, sounds, and the "hospital smell") can defuse surrogate fear and anxiety. A physical environment and professional culture that facilitates continuity of care by medical and nursing staff, information access, flexible visiting hours, and spontaneous interactions are essential in facilitating surrogate decision making (Jamerson et al. 1996; Johnson, 1998; Nelson et al. 2005). Providing a private environment when needed is often useful (Felgen, 2004; Jamerson et al. 1996; Tait, Vopel-Lewis, &

Malviya, 2003). Some institutions are achieving therapeutic environments through systems design, practice innovations, and process improvement (Felgen, 2004). As an example, the Pebble Project, a consortium of health care organizations, uses evidence-based models to create fundamental changes in hospital design to enhance healing, engage families, and improve public areas, including the ICU (Bilchick, 2002).

### *Timing*

Deciding when to approach surrogates who may be distressed or distraught, especially early after an ICU admission, is a significant challenge to the process of informed consent and ultimately to research participation (Chen et al. 2002; Shalowitz & Garrett-Mayer, 2006). If surrogates feel rushed to make a decision, there may be a perception of coercion and a hesitance to trust or relate to the researcher or the project (Geller et al. 1997; Tait et al. 2003). Surrogates need time to gather information regarding the condition of the loved one before being asked to consider any proposed research (Jamerson et al. 1996). Consequently, giving surrogates a place to collect the information they need in order to process the emotional devastation that accompanies a serious diagnosis, the time to rebuild and renew relationships, and the opportunity to gather support systems before approaching them about participation in a research study will facilitate the process of informed consent and may increase research participation (Hayes, 2003; Jamerson et al. 1996). On balance, regular family meetings with the research team, presentation of the study information in a professional and relaxed manner, answers to questions, and the opportunity for the surrogate to



consider the information in a private place for 20-30 minutes before being asked to give informed consent are fundamental to the ethical conduct of research (Arnold & Kellum, 2003; Azoulaly & Sprung, 2004).

### *Legal Aspects*

Current regulations about surrogate consent come under the auspices of Health and Human Services and emanate from the Food and Drug Administration, NIH, and Offices of Human Research Protection (American Thoracic Society, 2004; Luce, 2003b). Federal law defines surrogate as one's legal representative. Federal law generally defers to the states to define specifically who a surrogate may be (Bein, 1991; Hook et al. 2004; Fischer, 2006). A few states including California, Arizona, Virginia, and New York delineate the hierarchy of surrogates from legally appointed representative, to spouse, children, parent, and sibling. Some states do not recognize surrogate authority to consent for research (Amdur, Bachir, & Stanton, 2000; American Thoracic Society, 2004; Benner, 2003; Chen et al. 2002). Because of the lack of clear guidelines in most states regarding surrogate consent, researchers in ICU settings rely largely on local Institutional Review Board guidelines and state human research protections program guidelines for direction (Azoulay & Sprung, 2004; Brody, McCullough, & Sharp, 2005; Luce, 2003b).

Many families and potential surrogates do not discuss advanced directives or treatment options before an illness or trauma occurs, much less their thoughts on research participation in the ICU (Bigatello et al. 2003). In fact, Azoulay and Sprung (2004) found that surrogate judgment was not necessarily in agreement

with the participant's own judgment when the loved one's capacity returned after critical illness. Coppolino and Ackerson (2001) studied 100 patient-surrogate dyads to determine how accurately the surrogate would represent the patient's wishes in two non-genomic hypothetical research trials in critical care, one involving minimal risk and the other designated as greater-than-minimal risk. The results suggest that surrogate's decisions regarding research participation differed from those of the patient 16-20% of the time.

In 2004, the American Thoracic Society hosted a multidisciplinary conference regarding ethical research in the ICU. It concluded that a surrogate with decision-making capacity should be identified and that specific laws should be enacted to establish surrogate rights and responsibilities. Currently, surrogates are directed to use "substituted judgment" to make research participation decisions (Arnold & Kellum, 2004; Bigatello et al. 2003; Chen et al. 2002; Shalowitz & Garrett-Mayer, 2006). Substituted judgment is a proxy decision based on what the surrogate knows about the loved one's specific wishes in a given situation or the decision the loved one would make, if competent (Bigatello et al. 2003; Luce, 2003a, 2003b). When the wishes of the loved one are not known, the surrogate must make a decision about research or treatment based on the loved one's best interest (Arnold & Kellum, 2004; Shalowitz & Garrett-Mayer, 2006) While this approach is not optimal, Arnold and Kellum (2004) reported that over 90% of ICU patients in the studies they reviewed would rather have had a family member make their health care decisions along with their doctor rather than the doctor making these decisions alone. A strategy to assist the surrogate in using

substituted judgment is for the health care professional to encourage the surrogate, through targeted dialogue, to recall specific conversations with the loved one in which the patient's desires and values were shared (Azoulay, Chevret, LeLeu, Pochard, Baboteu, & Adrie, 2000; Hayes, 2003)

### *Misinformation*

In addition to not always knowing the patient's wishes, surrogates often do not understand the nature of genomics research and may hesitate to enroll loved ones in research studies because of long-held misconceptions (Bigatello et al. 2003, Chenaud, Merlani, Luyasu, & Ricou, 2006). Sex, class, race, and cultural characteristics also affect how genomics information is perceived and may perpetuate misconceptions that could have a profound influence on surrogate participation (Benner, 2003; Geller et al. 1997; Ho, 2006; Jenkins, 2001). One common misconception is the notion of *determinism* (Chenaud et al. 2006; Feetham et al. 2005). Determinism, in this instance, refers to the idea that an individual's genetic makeup will cause one to behave in a certain way or the body to perform in a certain manner, leading to the misconception that genetic predispositions are absolute. For example, the sequence of the human genome, touted as the "Book of Life", may cause consumers of health care to believe that their characteristics and their health are predestined, when, in fact, it has been estimated that only 50% of phenotype is determined by genetics (Anderson & Nickerson, 2005; Brody et al. 2005; Guttmacher & Collins, 2003; Miller & Brody, 2003; Ojha & Thertulien, 2005; A second major mistaken notion is the *therapeutic misconception* (American Thoracic Society, 2004; Brody et al., 2005;

Chen et al. 2002; Joffe, Cook, Cleary, Clark & Weeks, 2001a; Joffe, et al. 2001b; Silverman et al. 2005; Stead, Eadie, Gordon, & Angus, 2005). This occurs when, despite receiving detailed information to the contrary, many surrogates enroll their loved ones in studies believing that the participants will receive an immediate and direct therapeutic benefit (Joffe et al. 2001a). In the case of randomized controlled trials, for example, surrogates often do not believe that the research will not benefit the patient directly, that the researcher does not know which treatment the participant is receiving, or that the researcher really does not know which protocol is the better one (Flory & Emmanuel, 2004).

Because of the misconceptions surrogates may have, it is important to approach them in a way that encourages open discussion of preconceived ideas about genomics research in the ICU. Geller et al. suggest that surrogates examine their fears and motives when agreeing to genomics research (Geller et al. 1997). They also advise health care professionals to tactfully elicit personal and cultural perceptions surrounding genomics, correct misconceptions, and develop educational strategies to increase understanding of genomics research. These strategies may help the surrogate to adopt a more realistic view of research benefits and limitations. Lastly, it is important that the health care professional emphasize that clinical research is rarely designed to benefit the participant directly (Miller & Brody, 2003; Silverman et al. 2005; Stead et al. 2005). With careful attention to the surrogate's need to understand how the loved one fits into the research process, it is more likely that surrogates will visualize

themselves and their loved ones as an integral part of the research process (Stead et al. 2005).

### *Educating the Surrogate*

#### *Language and Literacy Challenges*

Surrogate education to facilitate informed decision making becomes even more challenging when language or literacy challenges are added to an already complex decision making process (Geller et al. 1997). For example, the interpreting skills of family translators may be inadequate resulting in the communication of misinformation, especially regarding health information. Family translators also are not desirable because they may violate patient privacy and may present conflicts of interest. Clearly, professional interpreters should be used when critical or complex information must be conveyed (Azoulay et al. 2000). Other strategies to address language and literacy issues include becoming familiar with societal and governmental mandates related to literacy, patient education, linguistic resources, and multicultural resources (Azoulay & Sprung, 2004; Joffe et al. 2001a; Joffe et al. 2001b). Offering an audio recording of educational sessions would allow the surrogate to review information independently (Arnold & Kellum, 2003). The use of specially equipped computer communication devices such as translating programs, pictorial supplements to text, and speech recognition also may be useful (Dreger & Tremback, 2002; Jimison, Sher, Appleyard, & LeVernois, 1998). Actively assessing surrogates for language and literacy barriers will help the health care professional choose appropriate techniques to facilitate surrogate education.

*Teaching the Elements of Consent*

Greater attention is needed toward educating surrogates about essential elements of the process of informed consent (Table 1). Items 1,3,4,5,6, elements in Table 1 are derived directly from the Code of Federal Regulations (Flory & Emanuel, 2004; Schats, Brilstra, Rinkel, Algra, & VanGijn, 2003; U.S. Department of Health and Human Services; 1991). The next essential element is the ELSI considerations (U.S. Department of Energy, 2005). Another essential element is ownership and security of stored specimens (Azoulay et al. 2000; Jeffers, 2001; Prows, Glass, Nicol, Skirton, & Williams, 2005; Topol, Murray, & Frazer, 2007). Regarding ownership, even when consent is withdrawn, surrogates should know that recent legal decisions may prevent previously collected specimens from being destroyed (Harris, 2006). The last essential element of the process concerns the role of the surrogate and substituted judgment (Coppolino et al. 1997). The surrogate must be taught and be able to demonstrate an understanding of all of the elements of consent before the consent form is signed.

*Choosing a Teaching Strategy*

Given the challenges associated with surrogate learning, using multiple educational strategies based on surrogates' preferred learning styles may be useful (Dreger & Tremback, 2002; Geller et al.1997) Decisional aids and written information that support the educational needs of surrogates may increase their satisfaction in the decision-making process and reduce conflicts between surrogates and staff (Arnold & Kellum, 2003; Azoulay & Sprung, 2004; Geller et

al.1997). Surrogates benefit from repetition of information delivered in small increments over time and from repeating concepts back to the educator (Dreger & Tremback, 2002; Geller et al.1997). Ryan and Lauver (2002) analyzed 20 research studies that used tailored informational interventions in home care to improve health outcomes in elders. All outcomes related to the tailored interventions were equal to or better than the standard informational intervention. Another study, conducted in a community hospital among elderly patients, used a multimedia strategy and found increased knowledge about non-drug pain control strategies among those given a tailored educational program (Tracy, Dufault, Kogut, Martin, Rossi, & Willey-Temkin, 2006). Additional strategies to enhance the use of multimedia educational tools include the use of printed materials with Braille, large type, serif fonts, and contrasting color (Davis et al, 2003).

### *Using Technology*

Interactive computer-based and Internet-based educational tools are attractive options for educating surrogate decision makers in the ICU (Arnold & Kellum, 2003; Geller et al.1997). However, most research on the use of these approaches has been conducted in patients with chronic illness (Bond, 2006). Ideally, interactive computer-based and web-based educational tools would assist the surrogate to increase knowledge, facilitate skill development, enact behavioral change, and enhance decision making (Arnold & Kellum, 2003; Bond, 2006; Jimison et al.1998). There are many advantages to using interactive computer programs as teaching tools: (a) they can be accessed any time of the day or night and Web-based programs can be accessed anywhere an Internet

connection is available; (b) learning can be reinforced immediately; (c) the material presented does not vary; (d) basic information can be provided with links and explanations to more sophisticated and detailed information; and (e) multimedia presentations that provide clear examples can be used (Bond, 2006; Lewis, 2003).

Although the effectiveness of interactive and Web-based education has not been definitively established, there have been some encouraging results. For example, a web-based information program for families of nursing home residents used the Technological Readiness Index to explore their likelihood of using the technology for education (Rosen, Mittal, Mulsant, Degenholtz, Castle, & Fox, 2003). According to the Technology Acceptance Model, people use technology if it is user-friendly and provides satisfaction. Participants, the majority being elderly with limited computer experience, were able to complete the program and were very satisfied with the intervention (Rosen et al. 2003). Similarly, the Personal Education Program (PEP) using computer-based information was designed to supplement face-to-face interactions between nurses and older clients. An evaluation of PEP indicated that elderly clients were successful in utilizing computerized technology for acquiring information (Neafsey, 2003). Also a randomized controlled trial indicated that a computerized Interactive Multimedia Program for Asthma Control and Tracking was a good adjunct to traditional asthma educational interventions in children and caregivers (Krishna, Francisco, Balas, & Konig, Graff, & Madson, 2003). Another out-patient study, investigating the effect of providing computerized, anonymous, non-



judgmental, information to breast cancer patients, found that it fostered self-efficacy to a greater degree than a pamphlet only (Reis, Trackel, King, & Remmert, 2004). It is not surprising, then, that the Society of Critical Care Medicine as well as the American Thoracic Society support the development of interactive Web-based education that can empower individual learners to satisfy personal educational needs (Flory & Emanuel, 2004; Bond, 2006).

Challenges to the use of these strategies with surrogates in the ICU setting include the substantial cost for computer hardware, software, support, and web accessibility. Further, factors which interfere with surrogates' readiness to learn include anxiety, fear, and discomfort (Azoulay & Sprung; 2004; Pochard et al. 2001). Also economic, cultural, and demographic factors may stratify surrogates in their ability to use technology (Lewis, 1999; Lewis, 2003).

Face-to-face follow-up has been shown to increase the effectiveness of interactive computerized educational programs for surrogates (Davis et al. 2003; Geller et al. 1997; Silverman et al. 2005). Although there is little information available in the literature regarding surrogate computerized education in the ICU, the surrogates described in these studies are likely to be similar in age and education to surrogates in the ICU setting. Because of the potential usefulness of computer-based programs for surrogate education in the ICU, it follows then that developing computer-based learning tools for surrogate education in the ICU would be a worthy deliverable.

### *Concluding the Process of Informed Consent*

#### *Readability of Consent Forms*

Concluding the consent process with difficult to read informed consent forms may provoke frustration, confusion, and doubt (Geller et al. 1997; Stead et al. 2005). In fact, the readability of consent documents is too complicated for up to 60% of patients and surrogates (Burkell & Campbell, 2005). Level of education often does not correlate with reading ability and cannot be used to determine the appropriateness of written material. Davis et al. (2003) recommended developing written materials at a sixth grade reading level. Yet, Stead et al. (2005) cautioned that important information may be lost as the document is simplified. One study which examined a variety of consent forms concluded that the forms should be shortened and simplified, use lay language, and include a glossary or video to emphasize important information (Flory & Emanuel, 2004; Silverman et al. 2005). Multimedia consent forms, such as computer-based educational programs, may be helpful in many patient populations (Lewis, 2003).

#### *Evaluating Surrogate Understanding*

Surrogates' understanding of essential information must be evaluated prior to concluding the consent process. Tait et al. (2003) conducted a study involving the parents of 505 pediatric patients in a preoperative environment. Parents were interviewed to determine their level of knowledge and understanding of information presented. Although parents reported that they had a good understanding of the research project that had been described to them, only 59% of the parents understood the purpose of the study and only 33% understood the

confidentiality policy. Similarly, Schats et al. (2003) asked patients and their relatives to recall critical information presented in the process of informed consent several months after signing the form. The authors found that only 14% of participants could spontaneously recall one or more details of the essential elements of consent, whereas none could recall all of the elements. Wendler (2004) has reported that 40% of potential research participants, after signing the consent form, do not understand the essential elements of informed consent and may still fail to understand them even after an educational intervention. Nelson et al. (2005) stated that half of the families of patients in ICU do not have a basic understanding of the information they are given, such as information on treatments, prognosis, or research.

Geller et al. addressed this concern with the use of a two-part consent form. Part one explained the study while part two asked specific questions concerning the content of part one (Geller et al. 1997). Using such an approach, misconceptions can be corrected, remedial teaching can be done, and questions can be answered. Another strategy, the Deaconess Informed Consent Comprehension Test, uses a verbal test designed to quantify a participant's knowledge of the elements of informed consent. A strength of this instrument is the immediate correction of misconceptions (Silverman et al. 2005; Wendler, 2004). Additionally, the Quality of Informed Consent for Cancer Trials instrument was developed to evaluate patients' understanding of essential concepts in the process of informed consent and to establish whether the "therapeutic misconception" persists (Joffe et al. 2001a; Joffe et al 2001b; Silverman, 2005).

Ultimately, whatever methods are used, a signature on an informed consent form should be solicited only after it has been determined that the surrogate understands the materials presented (American Thoracic Society 2004).

#### *Post Consent Follow-Up*

The consent process does not end after the consent form is signed because the researcher must also provide post consent follow-up, which includes periodically apprising the surrogate of the patient's situation (Azoulay & Sprung, 2004; Hook et al. 2004; Pochard et al. 2001; Luce, 2003a). Continuity of care over time, especially with the patient's primary physician, facilitates the provision of consistent and clear information (Azoulay & Sprung, 2004). The surrogate must have current contact information for the researcher throughout the entire process, including follow-up (Geller et al. 1997). Finally, should the patient regain decision-making capacity, obtaining consent directly from the patient should be considered (Chen et al. 2002; Bigatello, et al. 2003).

#### *Conclusion*

Health care professionals have both an ethical responsibility to protect and advocate for their patients during the process of informed consent and the legal accountability that occurs with witnessing a consent document (Azoulay et al. 2000; Urbanski, 1997; Wendler, 2004). The ICU is a particularly challenging environment, in which obtaining surrogate consent may be difficult due to personal, environmental, logistical, educational, and ethical considerations (Beery & Hern, 2004; Fuller, Kahn, Ellis, Barr, Biesecker, & Crowley, 1999; Kim, Appelbaum, Jeste, & Olin, 2004). Jeffers argues that identifying and dealing with

ethical issues, as genetic and genomics research continues to develop, may prevent future conflicts in values, respect, and human dignity (Jeffers, 2001).

The three steps of the process of informed consent (approaching the surrogate, educating the surrogate, and concluding the process of informed consent) can be used as a framework with which to construct, implement, and evaluate human studies policies to effectively and ethically obtain surrogate consent for genomics research in the ICU. Beery and Hern (2004) and Azoulay and Sprung (2004) encourage institutions to mobilize resources to improve the skill sets of health care professionals in evaluating families for potential barriers to surrogate decision making. With knowledge in pharmacogenomics, genetic testing, referrals, education, counseling, treatments, and research, health care professionals can take the lead in educating stakeholders regarding priorities and policies about privacy, the use of information and biological specimens, ethical conduct of research, at-risk individuals and groups, case management priorities, and educational and computer resources as they relate to the ICU setting (Chung, Laramie, Province, & Cobb, 2002; Conley & Tinkle, 2007, Feetham et al. 2005; Hook et al. 2004, Jenkins & Calzone, 2007; Ojha & Thertulien, 2005; Prows et al. 2005).

Currently available data on obtaining informed consent are insufficient to adequately guide patients, surrogates, and health care professionals in the ICU setting reflecting great challenges for the future (Jenkins, Grady, & Collins, 2005). New research on education and informed consent that leverages the power of computers and the internet is especially needed.

### Stewardship Models of Genetics and Genomics Research

Two models of stewardship of genetic and genomics research are presented. The models help explain the stewardship responsibilities implicit in informed consent for genetic and genomics research and particularly for the difficult challenges experienced by surrogates in the ICU.

The Jeffers' Emerging Model of Research Risk focuses on stored information and human biological specimens. It illustrates the need for human rights protections by minimizing research risk. Second, the author-developed model of stewardship of genetic and genomics research expands the ideas in the Jeffers' model to illustrate the concept of stewardship of genetic and genomics research and the balance necessary to conduct needed research with the protection of human rights.

#### *Jeffers' Emerging Model of Research Risk*

Jeffers (2001) utilized the recommendations of the National Bioethics Advisory Commission (2001) and developed a model of stewardship as it relates to genetic and genomics research specifically concerned with human tissue and biological samples (Figure I). Genetic information, according to Jeffers, has both social value and social risk (Jeffers, 2001). The risks include privacy, confidentiality, stigmatization of families and communities, prospective consent issues, and commercialization of donated human biological material (Jeffers, 2001).

*Stewardship Model of Genetic and Genomics Research*

The stewardship model of genetic and genomics research is presented as a balance scale as depicted in Figure 2. The scale is composed of a fulcrum, a lever, and a pivot point on which stewardship is balanced. The fulcrum represents responsibility and its critical attributes: trust and accountability. The lever, situated on the pivot point of the fulcrum, represents the continuum of stewardship. At one end of the lever is the mandate for genetic and genomics research and at the other end of the lever is the preservation and protection of human rights which is comprised of community rights, family rights, and individual rights. The inclusion of family and community in the protections of human rights exemplifies the uniqueness of genetic and genomics research in contrast to the emphasis of autonomy and individual rights essential in other forms of research. If too much emphasis is placed on the research mandate of genetic and genomics research then human rights may be violated. If too much emphasis is placed on human rights, then little genetic and genomics research will be conducted. A balance between these factors is ideal and represents the balance necessary for stewardship to occur.

## Summary

This chapter summarized theoretical and research aspects about informed consent and the stewardship of genetic and genomics research in the ICU. Further research is needed to better understand the implications of genetic and genomics research in the ICU, to promote stewardship of genetic and genomics

research, and to inform and educate stakeholders about genetic and genomics research.

## CHAPTER III

### Introduction

Chapter III includes hypotheses and methods. Within methods, design, sample and setting, instruments, intervention, data collection procedures, and data analysis are presented.

### Hypotheses

#### *Hypothesis I*

Understanding of the process of informed consent will be greater in the experimental group as compared to the control group.

#### *Hypothesis II*

Knowledge of genetic and genomics research will be greater in the experimental group as compared to the control group.

### Methods

The protocol and the flyers were approved by Washington University and the University of Missouri – St. Louis IRB. Data collection began in March, 2008 and was completed in August, 2008.



*Design*

This study has a cross-sectional, prospective, experimental posttest design with a control group and random assignment to group. The experimental group received the ICIS ICU Education Program plus the Sample Consent Form and the control group received the Sample Consent Form alone.

Experimental	X	O
RA		
Control		O

*Sample and Setting*

Subsequently, Internal Review Board approval was obtained from the hospital and from the University of Missouri – St. Louis prior to initiating the study (Appendix B, Figures 5, 6).

Two intensive care waiting rooms in a major metropolitan area health center were used as the setting for the current study. There were 134 participants in the current study. The inclusion criteria for this study included (a) visitors to specific medical center's ICU waiting rooms, (b) age 18 or older, and (c) willingness to participate in the study. The exclusion criteria for the current study included (a) under 18 years of age, and (b) unwilling or unable to participate in the study.

Using Cohen's table, a power analysis was conducted, indicating a need for a total of 64 participants per group to detect a .50 effect with a power of .80, and an alpha value of .05.

*Instruments*

The Posttest Instrument is an author-developed 14-question multiple-choice questionnaire. It was designed to determine the extent to which the ICIS ICU Education Program would increase understanding of the process of informed consent and knowledge of genetic and genomics research among experimental group participants in the ICU. Thirteen questions are directed to the understanding of informed consent and one question concerns knowledge of genetic and genomics research. No reliability of this instrument has been established. Cronbach's alpha will be calculated during data analysis. Face and content validity was established through the use of a content analysis table and examination by the dissertation committee (Table 2). Construct validity was specifically derived from guidelines from the Code of Federal Regulation concerning informed consent (U. S. Department of Health and Human Services, 1991). Both the experimental group and the control group completed the 14-question Posttest Instrument.

*Intervention*

The Interactive Computerized Information for Surrogates (ICIS) ICU Education Program is an author-developed educational program which uses a series of 36 slides to inform and instruct a potential surrogate visiting the ICU about the process of informed consent and the ethical conduct of genetic and genomics research and its ELSI components. The ICIS ICU Education Program Content Analysis Table for the Essential Elements of Informed Consent can be found in Appendix A, Table 2. The content analysis table shows the concepts of

informed consent and genetics and genomics and connects them with the slides in the ICIS ICU Education Program and the 14 questions on the Posttest Instrument. The intervention is available from the author on request. The experimental group received the ICIS ICU Education Program plus the Sample Consent Form and the control group received the Sample Consent Form alone.

#### *Data Collection Procedures*

Using a random numbers table, participants will be randomly assigned to the experimental group or the control group. The experimental group was given up to ten minutes to complete the ICIS ICU Education Program. Then, the participant was given the Sample Consent Form to read. The Sample Consent Form required up to ten minutes to read. The interview script was read to the participant and responses recorded. The participant was asked to complete the Posttest Instrument requiring about five minutes and a demographic form requiring about five minutes.

The control group was given the Sample Consent Form only and was given ten minutes to read the material. The interview script was read to the participant and responses recorded. Then control group participants were asked to complete a Posttest Instrument requiring about five minutes and a demographic form requiring about five minutes.

The duration of the study was between 20 and 30 minutes in total. A corrected Posttest Instrument key was given to each participant after the study to minimize reinforcement of misperceptions. There was no remuneration.

*Data Analysis*

Using SAS, descriptive statistics were used to define sample characteristics. A Student t-test was used to compare the means of the Posttest Instrument scores between the experimental group and the control group. The assumption of normality required for the Student t-test was violated as indicated by the Shapiro-Wilk test conducted on each item for both groups. Data transformation attempts were unsuccessful. Since the normality of the data could not be assumed, Fisher's exact test was used. Missing data were imputed using the grand means where required. Missing data was left blank when describing individual items. Multiple regression was used to test the relationships specifically between the groups and the posttest scores. The nonparametric Wilcoxon Test of Two Independent Samples was used for interval and ratio data and the Levine test for equality of variance also was used. Top Box statistics were computed to further illustrate the differences between the experimental group and the control group. Top Box considers the actual number of participants that chose the most correct answer (5) for each posttest question for both the experimental group and the control group to make a determination of effectiveness of the ICIS ICU Education Program.

## CHAPTER IV

### Introduction

In Chapter IV, the hypotheses, results, and a summary of the results are presented.

### Hypotheses

Hypothesis I: Understanding of the process of informed consent will be greater in the experimental group as compared to the control group.

Hypothesis II: Knowledge of genetic and genomics research will be greater in the experimental group as compared to the control group.

### Results

#### *Sample Characteristics*

A total of 137 visitors (potential surrogates) in the surgical/trauma and cardiac ICU waiting rooms participated in this study from May 2008 to August 2008. Three participants were called away during the session and did not complete the study. Therefore, there were a total of 134 participants. There were 65 (48.5%) participants in the experimental group and 69 (51.5%) participants in the control group. Table 3 presents sample characteristics of study participants.

Participant ages ranged from 19-82 ( $M = 47.3$ ;  $SD = 15.19$ ) (see Table 3). There were 45 men (33.6%) and 89 women (66.4%) in the sample. There were 33 African Americans participants (24.6%), 100 Caucasian participants (74.6%), and 1 Hispanic participant (0.75%). Level of education in the sample ranged from less than a high school degree to those with a post-graduate degree. Most typically, the relationship to the patient was parent, child, or other. Participants

had widely ranging occupations. Four participants were health care workers. One health care worker was a chaplain, and three were RN's. One participant was a non-professional recruiter for a medical research firm. Using Fisher's Exact test, groups did not differ significantly by age (decade or other age categories), gender, race, education level, or relationship to the patient (see Table 3). In summary, the sample was predominantly female and Caucasian, at an education level mostly of high school, some college, or college, and whose relationship to the patient was most typically parent, child, or other.

#### *Missing Data*

There were four different missing data points on three posttest measures from participant 24, 45, and 57. Table 4 presents characteristics of participants with missing data points. Item 13 explains that a surrogate has the right to know if there is a plan for compensation for harm that might come to a subject during research. Item 2 defines genomics. Item 4 concerns whether the surrogate may or may not withdraw from research until it is finished. Item 3 states that a loved-one may be too ill to agree to participate in research. When that happens, the surrogate may be asked to give permission for research participation.

#### *Regression*

Using linear regression, no relationship was found between age, gender, race, education, relationship to the patient, and previous participation in medical research and the outcomes: understanding of the process of informed consent and the knowledge of genetic and genomics research.

*Hypothesis Testing**Hypothesis I: Understanding the Process of Informed Consent Will be Greater in the Experimental Group as Compared to the Control Group*

Hypothesis I was accepted. Items 1 and 3-14 were designed to measure the understanding of the process of informed consent among surrogates in the ICU. Overall, understanding the process of informed consent was significantly higher in the experimental versus the control group (Wilcoxon  $W = 3346$ ;  $p = 0.000$ ). Differences in mean scores between groups pertaining to understanding the process of informed consent were greatest in Items 3, 11, and 14. Specifically, 8 of the 13 items tested were significantly ( $p < 0.05$ ) higher in the experimental versus the control group, namely: Items 1, 3, 4, 7, 8, 11, 13, 14 (see Table 5). The Top Box showed the percentage of participants by group that picked the most correct response (5) for each of the 13 questions and its chi-square  $p$ -value (see Table 6). Participants in the experimental group chose the most correct response (5) significantly more often than the control group for Items 1, 3, 4, 7, 8, 11, 13, and 14. Findings about the understanding of the process of informed consent were the same between the analysis of items and the Top Box approach for Hypothesis I.

*Hypothesis II: Knowledge of Genetic and Genomics Research Will be Greater in the Experimental Group Compared to the Control Group*

Hypothesis II was accepted. Item 2 was designed to measure the knowledge of genetic and genomics research among surrogates in the ICU. Table 5 showed that knowledge of genetics and genomics research was significantly higher in the

experimental versus the control group for Item 2 (Wilcoxon W 3853.5,  $p = 0.000$ ). In addition, Top Box showed the percentage of participants by group that picked the most correct response (5) for Item 2 and its chi-square  $p$ -value (Table 6). Findings about the knowledge of genetic and genomics research were found to be the same between the analysis of the items and the Top Box approach for Hypothesis II.

### *Further Analyses*

#### *Items Covered in the ICIS ICU Education Program and Items Covered in the Sample Consent Form*

The ICIS ICU Education Program was designed to educate the surrogate about 14 essential elements of informed consent regarding genetic and genomics research, hence the 14 Items. Table 2 depicts the 14 essential elements as covered in the ICIS ICU Education Program and the Sample Consent Form. All the elements are covered using slides in the ICIS ICU Education Program. The Sample Consent Form gives information only on Items 1, 4, 5, 6, 8, 10, 12, 13, and 14.

#### *Cases Where the ICIS ICU Education Program Plus the Sample Consent Form was Effective Above and Beyond the Sample Consent Form Alone and the Sample Consent Form Provided Information (Items 1, 4, 8, 13, 14)*

Table 5 shows the five cases where the ICIS ICU Education Program plus the Sample Consent Form augmented the information in the Sample Consent Form alone (Items 1, 4, 8, 13, 14). Regarding Item 13, eleven participants erroneously thought that the portion of the Sample Informed Consent Form



instructing the reader about who to contact if they felt they had been harmed during research, believed they had read that there was no compensation for harm available.

*Cases Where the ICIS ICU Education Program Plus the Sample Consent Form was not Effective Above and Beyond the Sample Consent Form Alone and The Sample Consent Form Provided Information (Items 5, 6, 10, 12)*

Table 5 shows 4 cases where the ICIS ICU Education Program plus the Sample Consent Form did not augment the information in the Sample Consent Form (Items 5, 6, 10, 12). In these cases, the information on the Sample Consent Form was very adequate, diminishing any differences between groups.

*Cases Where the ICIS ICU Education Program Plus the Sample Consent Form was Superior to the Sample Consent Form Alone and the Sample Consent Form Provided No Information (Items 2, 3, 7, 11)*

Table 5 shows that the ICIS ICU Education Program plus the Sample Consent Form provided the missing information in Items 2, 3, 7, and 11 when the Sample Consent Form provided no information.

*Cases Where the ICIS ICU Education Program Plus the Sample Consent Form was not Superior to the Sample Consent Form Alone and the Sample Consent Form Provided No Information (Item 9)*

In one case (Item 9) the ICIS ICU Education Program plus the Sample Consent Form did not provide significant information where there was no information given in the Sample Consent Form. It is likely, therefore, that the ICIS ICU Education Program could not provide significant information regarding this

item because the idea that the researcher must give you all the information you need to make an informed decision about research is common knowledge among the public. Overall, these findings provide support for the decision that the ICIS ICU Education Program does not need to be modified, even though at first glance it looked like the ICIS ICU Education Program was not effective for some items.

#### *Instrument Reliability*

Internal consistency reliability of the Posttest Instrument was evaluated using Cronbach's alpha (0.730), indicating moderately-high reliability. Internal consistency reliability for the questions related to Hypothesis I (1 and 3-14) was 0.723. Cronbach's alpha could not be computed for Item 2 alone.

#### *Additional Findings*

##### *Results From the Posttest Instrument as a Whole*

Using the Wilcoxon test, the total score on the Posttest Instrument was significantly ( $p < .05$ ) higher in the experimental versus the control group.

##### *Past Participation in Medical Research*

There were 11 participants who had participated in medical research prior to this study. The majority of those participants ( $n = 9$ ) felt that they received sufficient information to make an informed decision as to whether or not to participate in the research and two felt that they did not.

##### *Responses to the Scripted Question*

Table 7 lists a sample of responses to the scripted question asked of each participant: "Thank you for reading the sample informed consent form. What

questions would you need to ask to understand this research?" There were no questions directly related to the Sample Consent Form. There were several comments and questions about why the study was designed the way it was and the concept of substituted judgment.

#### *Reasons for Not Participating in the Study*

Table 9 is a summary of comments made by participants who declined to participate in the current study, (e.g. "I am just too tired; I've been here since four in the morning." Another reason frequently given was: "I can't think right now." A third reason was: "I have too much on my mind.") Visitors who declined participation cited their intention to see their loved-one soon, to go to get something to eat, or to go home.

#### Summary

The current study was conducted with predominately female participants. The groups did not significantly differ by age, race, education, or relationship to the patient. No significant relationships were found between sample characteristics and either the understanding of the process of informed consent or the knowledge of genetic and genomics research. Overall, participants in the experimental group had significantly greater understanding of the process of informed consent and a significantly greater knowledge of genetic and genomics research. These findings were substantiated by the fact that most items were significantly higher in the experimental versus the control group and by the fact that the most correct top box (5) answer choice was chosen significantly more often by the experimental versus the control group. The Posttest Instrument was

shown to be a reliable measure overall, and regarding the understanding of the process of informed consent. Reliability of the Posttest Instrument in measuring the knowledge of genetic and genomics research could not be determined.

## CHAPTER V

### Introduction

In Chapter V, the summary of the problem, the problem statement and the purpose, as well as the findings are discussed. This chapter also presented study limitations and implications for nursing theory, nursing practice, nursing science and future research. Finally, conclusions are presented.

#### Summary of the Problem

The U.S. Centers for Disease Control and Prevention state that there is some genetic component influencing most disease processes (Beery & Hern, 2004). Understanding the etiology of illness, predicting therapeutic effects or adverse medication reactions, and developing testing and treatment innovations constitutes the promise of genomics research and will transform the provision of health care (Beery & Hern, 2004; Collins et al. 2003). This understanding of genetics and genomics is critical to the clinical application of new knowledge of health and disease gleaned from research such as the Human Genome Project. Since the inception of the Human Genome Project, there has been an ongoing ELSI of genetic research. Fundamental ELSI considerations such as privacy, confidentiality, insurability, and discrimination impact stakeholders involved in genetic and genomics research. In fact, project developers anticipated the enormity of ELSI to the Human Genome Project and designated approximately 3% – 5% of the total NIH Human Genome Project funding package to study its impact on individuals, families, communities, and institutions (Ojha & Thertulien, 2005).

Critically ill ICU patients often are unable to consent to participate in genetic and genomics research due to cognitive impairment associated with trauma, fever, sedation, pain, or shock (Davis, et al., 2003; Freeman, et al. 2006; Jamerson et al. 1996). Therefore, surrogate, or proxy, consent may be desired in an emergent situation for which study enrollment cannot be delayed. Surrogate informed consent is a critical component of genomics research in the ICU. Yet, surrogates are asked to make complex research participation decisions for their loved-ones in the ICU; many of whom have an insufficient understanding of the process of informed consent and insufficient knowledge of genetics and genomics research (Davis et al. 2003; Jamerson et al. 1996).

#### Summary of the Problem Statement

There is a paucity of research about the surrogate consenter's understanding of the process of informed consent and knowledge of genetic and genomics research in the ICU. Yet, surrogate decision makers are called upon to give their consent for loved-ones to participate in genomics research with its ELSI considerations. Little is known about the surrogate decision maker experience as it relates to understanding the information disclosed in the process of informed consent or knowledge of genomics research. Thus, surrogates approached to authorize participation for a loved-one in genomics research in the ICU may be ill-prepared to make these decisions. In fact, there are no published papers focusing specifically on an intervention to facilitate surrogate informed consent for genetic or genomics research in the ICU. An education intervention may have

the potential to enhance the understanding of the process of informed consent and knowledge of genetic and genomics research in surrogates in the ICU.

#### Summary of the Purpose

The purpose of this investigation is to examine the effectiveness of an educational program, the Interactive Computerized Information for Surrogates ICU Education Program (ICIS) in assisting surrogates to (1) increase understanding of the process of informed consent and (2) increase knowledge of genetic and genomics research.

#### Discussion of Results

Of the 134 participants in the study, 66% were women and 34% were men. There were more women visitors to the ICU waiting room than men. The average study participant was middle aged with a mean age of 47 years. There were 33 African American participants, 100 Caucasian participants, and one Hispanic. In summary, the sample was predominantly female and Caucasian, at an education level mostly of high school, some college, or college, and whose relationship to the patient was most typically parent, child, or other. The experimental and the control groups did not differ by age, race, education, or relationship to the patient.

Hypothesis I and Hypothesis II were accepted. Understanding the process of informed consent was significantly higher in the experimental group than the control group. Additionally, knowledge of genetic and genomics research was significantly higher in the experimental group compared to the control group.

The ICIS ICU Education Program provided adequate information. No modifications of the ICIS ICU Education Program are recommended. The

Sample Consent Form lacks information on Items 2, 3, 7, 9, and 11 which are related to surrogate informed consent, the knowledge of genetic and genomics research, and the purpose of the Institutional Review Board. Likewise, surrogates must know that they have a right to all of the information they need to make a research decision and that they have a responsibility to represent the patient in making research decisions. However no recommendation is made regarding modifications of the Sample Consent Form because it is an IRB-approved form, meeting the requirements of IRB, and it already contains five pages of information. Moreover, Items 2, 3, 7, 9, and 11 go beyond the scope of the purpose of the Sample Consent Form. Review of the clarity of information on harm in the Sample Consent Form is suggested.

Because the essential elements reflected in Items 2, 3, 7, 9, and 11 are critical to the conduct of genetic and genomics research in the ICU with surrogate consent, and because the Sample Consent Form is inadequate regarding this information, it is recommended that the ICIS ICU Education Program be administered prior to the Sample Consent Form to augment information given in the Sample Consent Form when genetic and genomics research in the ICU with surrogate consent is conducted.

#### Study Limitations

Only one Hispanic participant was recruited and the rest were African-American and Caucasian. There were no Asian, Bosnian, Native American, Pacific Islanders or Vietnamese known to have visited the ICU waiting room during data collection. This lack of diversity is a limitation of the current study.



Also, study findings might have been different if a different Sample Consent Form was used. Additionally, the current study used an author-developed education program and an author-developed Posttest Instrument that were tested for the first time in the current study. The instrument will require additional reliability and validity testing. In addition, the study was conducted in two ICU waiting rooms from one institution and may not be generalizable to other ICU waiting rooms. Finally, transitory personal factors, such as fatigue, hunger, mood, fear, and anxiety could have possibly caused errors of measurement.

#### Implications for Nursing Theory

Stewardship was not the focus of the current study, but the author-developed stewardship model was used as the overarching framework in the study, specifically in the development of the ICIS ICU Education Program. The stewardship model and the ICIS ICU Education Program adds to nursing's body of knowledge in the development of nursing theory in this area. In addition, each of Carper's four patterns of knowing in nursing, empirical knowledge, aesthetic knowledge, personal knowledge, and ethical knowledge, was used in the development of the stewardship model, ICIS Education Program, and Posttest Instrument (Carper, 1978). Along with aesthetic knowing, environmental theory also was used to comprehend the challenges of the ICU environment to the surrogate (Bilchick, 2002; Felgen, 2004; Malkin, 2002; McLaren & Hawe, 2005). Ethical knowing was used to create the ICIS ICU Education Program slides that were based on the Federal Common Rule (U. S. Department of Health and

Human Services, 1991). Finally, the Posttest Instrument tested the participant about their understanding of informed consent which contains ethical concepts.

#### Implications for Nursing Practice

Recognizing the significance of genetics and genomics to the future of health care and the future of nursing practice, the American Nurses Association published “Essential Nursing Competencies and Curricula Guidelines for Genetics and Genomics” in conjunction with the National Human Genome Research Institute (NHGRI), National Institutes of Health (NIH), and the Office of Rare Diseases (Consensus Panel, 2006). Genetics and genomics will influence nursing practice as the prevention, diagnosis, and treatment of illness and injury and the realization of personalized health care emerge as deliverables of genetic and genomics research. Teaching is a major role in nursing practice and the availability of educational materials such as the ICIS ICU Education Program will give nurses new strategies with which to inform stakeholders about the future of genetic and genomics research in health care.

#### Implications for Nursing Science and Future Research

Genetic and genomic discoveries have increased ELSI concerns and policy debates (NHGRI, 2001). Nurses, are consistently identified as respected and trusted professionals. As such, nurses are ideally suited to address ELSI concerns and facilitate the stewardship of genetic and genomics research by balancing the mandate of genetic and genomics research with the protection of human rights. The ICIS ICU Education Program can be used to increase surrogate’s understanding of the process of informed consent and increase their

knowledge of genetic and genomics research thereby ensuring the balance between needed research and human rights protections. In fact, when practitioners are properly in-serviced, the ICIS ICU Education Program can be a resource with which to teach patients, families, community organizations, and surrogates about the process of informed consent and about genetic and genomics research.

### Conclusions

Genetic and genomics research is essential for the future of health care. Yet this important research cannot be conducted without a balance between the research mandate and the protection of human rights. The current research was supported by an extensive literature review that was written and accepted for publication. The manuscript included the development of a three-step process for obtaining informed consent from surrogates in the ICU for genetic and genomics research. Also, an author-developed stewardship of genetic and genomics research model was used as the framework for the current study. From this foundation, the author-developed ICIS Education Program and the author-developed Posttest Instrument were created.

Significant findings of the current study were:

1. Overall, the understanding of the process of informed consent and the knowledge of genetic and genomics research were statistically significantly higher in the experimental group than in the control group.

2. Understanding the process of informed consent and the knowledge of genetic and genomics research was statistically significantly higher in nine of the 14 Items on the Posttest Instrument.
3. There was moderate internal consistency reliability of the Posttest Instrument.
4. Based on the study findings, the ICIS ICU Education Program was feasible, useful, and effective. No recommendations were made to modify the ICIS ICU Education Program. No recommendations were made to modify the Sample Consent Form. A suggestion was made to review the clarity to wording on the part of the Sample Consent Form addressing compensation for harm.
5. Because the Sample Consent Form does not address Items 2, 3, 7, 9, and 11, the use of the ICIS ICU Education Program along with the Sample Consent Form is recommended because the Sample Consent Form alone does not address information related to surrogate informed consent, the knowledge of genetic and genomics research, and the purpose of the Institutional Review Board. Likewise, surrogates must know that they have a right to all of the information they need to make a research decision and that they have a responsibility to represent the patient in making research decisions.

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## Appendix A, Table 1

## Essential Elements of Surrogate Informed Consent in Genomics Research

	Element	Includes
1	All benefits associated with the study	Are there benefits to the participant? Is surrogate aware that research rarely benefits participant (therapeutic misconception)?
2.	Genetic and Genomics Research and ELSI considerations	Is the surrogate aware of the ethical, legal, and social implications of genetic and genomics research (stigmatization, emotional and psychological trauma, prospective consent issues, employment, adoption, insurability, conflicts of interest, and commercialization of donated human biological material, equipoise)?
3.	Role of the surrogate	Is the surrogate aware that they may be asked to consent for a loved-one to participate in research?
4.	Participation can be withdrawn	Is surrogate aware that consent can be withdrawn any time? Is the surrogate aware recent legal opinions may prevent specimens already collected from being destroyed?
5.	Loved one is being asked to participate in research	Is the study experimental or not? What procedures may be needed? What is the purpose of the study? What is the duration of the study?
6.	Risks associated with the study	What are the anticipated or potential risks? Are the risks minimal or substantial?
7.	Human research protections	Is the surrogate aware of the Federal Common Rule? Is the surrogate aware of the IRB?

- |     |   |   |
|-----|---|---|
| 8.  | Contact information   | Is investigator contact information available to the surrogate prior to and during the study?   |
| 9.  | Right to have sufficient information                                    | Is the surrogate aware of the right to have sufficient information to make a research decision?<br><br>Has surrogate understanding of the information given been evaluated prior to obtaining consent?  |
| 10  | Voluntary study   | Is the surrogate aware that participation is voluntary?   |
| 11. | Alternative treatments  | Are there additional or alternative treatment options?<br><br>Is there Equipoise?   |
| 12. | Confidentiality, privacy and ownership and security of stored specimens | What are the study's privacy and confidentiality policies?<br><br>Can health information concerning the participant's family be shared with them without the participant's consent?<br><br>Is ownership of human biological specimens clear?<br><br>Are stored specimens or information identifiable? |
| 13. | Compensation availability if participant harmed                         | Are the policies concerning whether compensation is available, for harm that may come to a participant related to a research study, clearly articulated prior to consent in studies involving more than minimal risk?   |
| 14  | Substituted judgment  | Is the surrogate aware of the obligation to make research decisions based on what the loved-one would want?   |

- Source Elements 1,4,5,6,8,9,10,11,12,and 13: Source Elements 1-8, 11: U.S. Department of Health and Human Services. 45 Code of Federal Regulations 46. 1991. Available at: <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>. Accessed April 8, 2006.
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## Appendix A, Table 2

Content Analysis of Essential Elements of Informed Consent in Genetic and  
Genomics Research in the ICU With Corresponding ICIS ICU Education  
Program Slides

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Item	Essential Element	Slides
1	All benefits of research must be explained.	8, 11, 21, 34, 36
2	Genetic and genomic information	20-29, 31, 32, 36
3	Role of the surrogate	5, 15
4	May withdraw from study at any time	16, 21, 35
5	Research, purpose, and duration.	4, 6, 8, 21, 34
6	All research risks must be explained.	9, 10, 21
7	Human Research Protections	17
8	Contact information for researcher given	13, 21, 36
9	Right to sufficient information.	6, 7, 14, 16, 20, 34, 35
10	Research is voluntary	19, 21, 33, 34
11	Substituted judgment	15
12	Disclose privacy and confidentiality policy	29, 30, 35
13	Compensation for harm	11, 21, 34
14	Treatment alternatives must be described	12, 21, 34

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## Appendix A, Table 3

## Characteristics of the Sample

Category	Characteristic	Experimental		Control		Fisher's Exact <i>p</i>
		Frequency	%	Frequency	%	
Age						0.871
Gender	Male	20	14.9	25	18.7	0.503
	Female	45	33.6	44	32.8	
Race	African American	15	11.2	18	13.4	0.562
	Caucasian	50	37.3	50	37.3	
	Hispanic	0	0	1	8	
Education	Less than high school	2	1.5	1	8	0.608
	High school	15	11.2	19	14.2	
	Some college	23	17.2	24	17.9	
	College	22	16.4	18	13.4	
	Postgraduate	3	2.2	7	5.2	
Relationship to the patient	Spouse	10	7.5	10	7.5	0.265
	Fiancée	0	0	3	2.2	

Significant other	1	0.8	2	1.5
Parent	13	9.7	7	5.2
Sibling	5	3.7	13	9.7
Child	12	9	13	9.7
Friend	2	1.5	2	1.5
Other	22	16.4	19	14.2

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## Appendix A, Table 4

## Characteristics of Participants With Missing Data Points

Characteristics of participants						
Participant	Item	Group	Age	Gender	Race	Education
24	13	Experimental	41	Female	Caucasian	College
45	2, 4	Control	67	Male	African-American	High School
57	3	Control	37	Male	African-American	Some college

## Appendix A, Table 5

Non-parametric Analysis of Differences In Posttest Instrument Scores, Between  
Groups By Item

Item	Experimental			Control			Wilcoxon $p$
	Mean	Median	SD	Mean	Median	SD	
1	4.7	5.0	0.74	4.2	5.0	1.18	0.015
2	4.5	5.0	0.85	3.9	4.0	1.08	0.000
3	4.8	5.0	0.53	3.7	4.0	1.37	0.000
4	4.9	5.0	0.56	4.4	5.0	1.26	0.002
5	4.7	5.0	0.76	4.6	5.0	0.84	0.362
6	4.9	5.0	0.27	4.7	5.0	0.90	0.117
7	4.7	5.0	0.63	4.2	5.0	0.97	0.001
8	4.9	5.0	0.45	4.7	5.0	0.57	0.034
9	4.9	5.0	0.45	4.8	5.0	0.55	0.079
10	5.0	5.0	0.28	4.9	5.0	0.29	0.710
11	4.7	5.0	0.61	4.1	4.0	1.17	0.000
12	4.9	5.0	0.27	4.9	5.0	0.34	0.317
13	4.6	5.0	0.90	4.1	5.0	1.34	0.005
14	4.6	5.0	0.98	4.0	4.0	1.22	0.001

## Appendix A, Table 6

Percent and Chi-Square Results for Participants Selecting the Most Correct

Answer (5) by Group (Top Box)

Item	Experimental	Control	Chi-square $p$
	%	%	
1	74	55	0.024
2	68	35	0.000
3	86	38	0.000
4	95	75	0.001
5	85	78	0.345
6	92	84	0.141
7	80	54	0.001
8	91	77	0.029
9	91	80	0.073
10	97	96	1.000
11	78	48	0.000
12	92	87	0.312
13	80	58	0.006
14	80	49	0.000

Appendix A, Table 7

Responses to the Script Question

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Response
“If I said OK to this, can I pick what I would let you do? Can I say it is OK to take blood, but not do other things?”
“You all should know that you can’t take up this much of my time with this stuff! Just tell me what I need to know and be done with it, and don’t call me up in the middle of the night to give permission for something, cause I won’t give it! I’m here all day and nobody asks me nothing...”
“They should change those cartoons, they insult my intelligence.”
“I think everything is pretty clear...”
“How do I know if my husband is on this study now?”

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## Appendix A, Table 8

## Reasons Expressed by Visitors in the ICU Waiting Room for Non-participation

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Reason

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Visitors stated that they were summoned to the hospital at night and were fatigued and had difficulty thinking.

Visitors stated that they were overwhelmed with fear and grief and could not deal with anything else.

Visitors stated that research was a low priority for them.

Visitors stated that they did not want to leave their space in the ICU waiting room to participate in the study for fear that they would lose "their corner". Other resources that visitors wanted to protect were recliners, tables, blankets, pillows, and proximity (or distance) from the television.

Visitors stated that they could not leave personal belongings unattended if other family members were not present, and were not willing to leave family members to participate in the research if family members were present. Personal belongings included computers, and bags with medications, food, and toiletries.

Visitors stated that their privacy was being invaded. Visitors stated that they thought they were being approached by a staff member to talk about their loved-one and were disappointed to realize that they were being asked to participate in research instead. Some visitors verbalized that being approached in their personal "refuge" was inconsiderate.

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## Appendix A, Table 9

Table of Essential Elements of Informed Consent (1-14) Reflected in Posttest Items (1-14), Where Essential Elements of Informed Consent are Covered, and Outcomes

Essential Element and its Respective Posttest Item (1-14)	Covered in ICIS	Covered in SCF	ICIS plus SCF effective above and beyond SCF alone and SCF provides information on certain items	ICIS plus SCF not effective above and beyond SCF alone and SCF provides information on certain items	ICIS plus SCF superior to SCF alone and SCF provides no information on certain items	ICIS plus SCF superior to SCF alone and SCF provides no information on certain items
1. Research is intended to benefit patients in the future. It may not help your loved-one.	5 slides	x	x			
2. Genomics studies heredity and the environment to answer important health questions.	3 slides				x	
3. A loved-one may be too ill to agree to participate in research. When that happens, you may be asked to	1 slides				x	

give permission for your loved-one.

4. If you agree to participate in research, you may not withdraw from the study until it is finished.

3 slides

x

x

5. You have the right to know the purpose of the study and how long it will last.

5 slides

x

x

6. Research risks your loved-one might face must be explained to you.

3 slides

x

x

7. The Institutional Review Board approves research. Part of their job is to help protect research participants.

1 slide

x

8. The researchers will make sure you know how to contact them if you wish to ask more questions.

3 slides

x

x

9. The researcher must give you all the information you need to make an informed decision about research.

7 slides

x

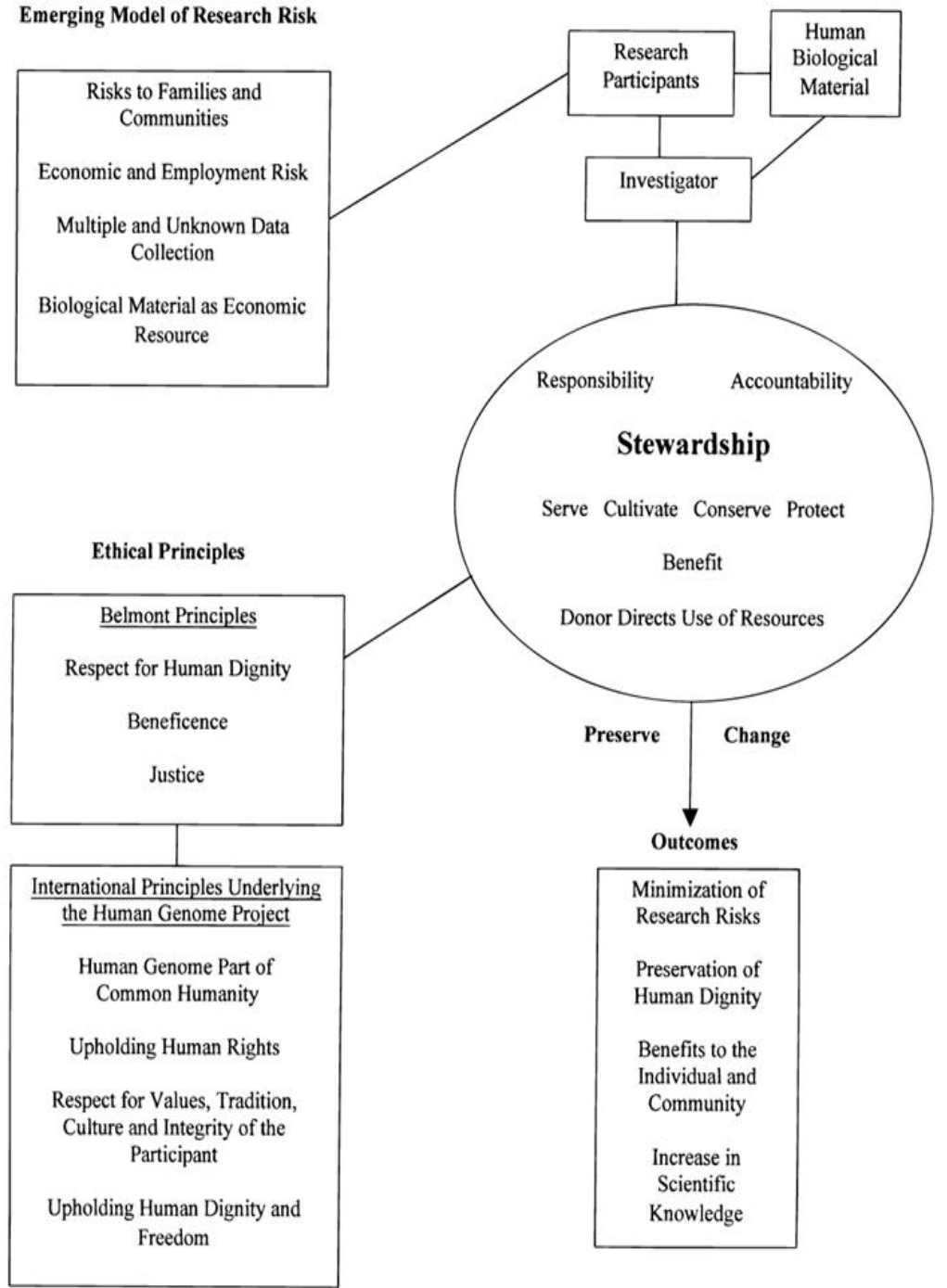
10. Participating in research is voluntary.	4 slides	x		x	
11. You should decide whether to allow a loved-one to participate in research based on what your loved-one would want.	1 slide				x
12. You have the right to know if the researcher plans to keep your loved-one's personal information confidential.	3 slides	x		x	
13. The informed consent process includes providing information about compensation for harm that may come to your loved-one during research.	3 slides	x	x		
14. Some research involves a treatment. You must be told if there are other treatments you may choose instead.	3 slides	x	x		

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Note: ICIS = ICIS ICU Education Program. SCF = Sample Consent Form.

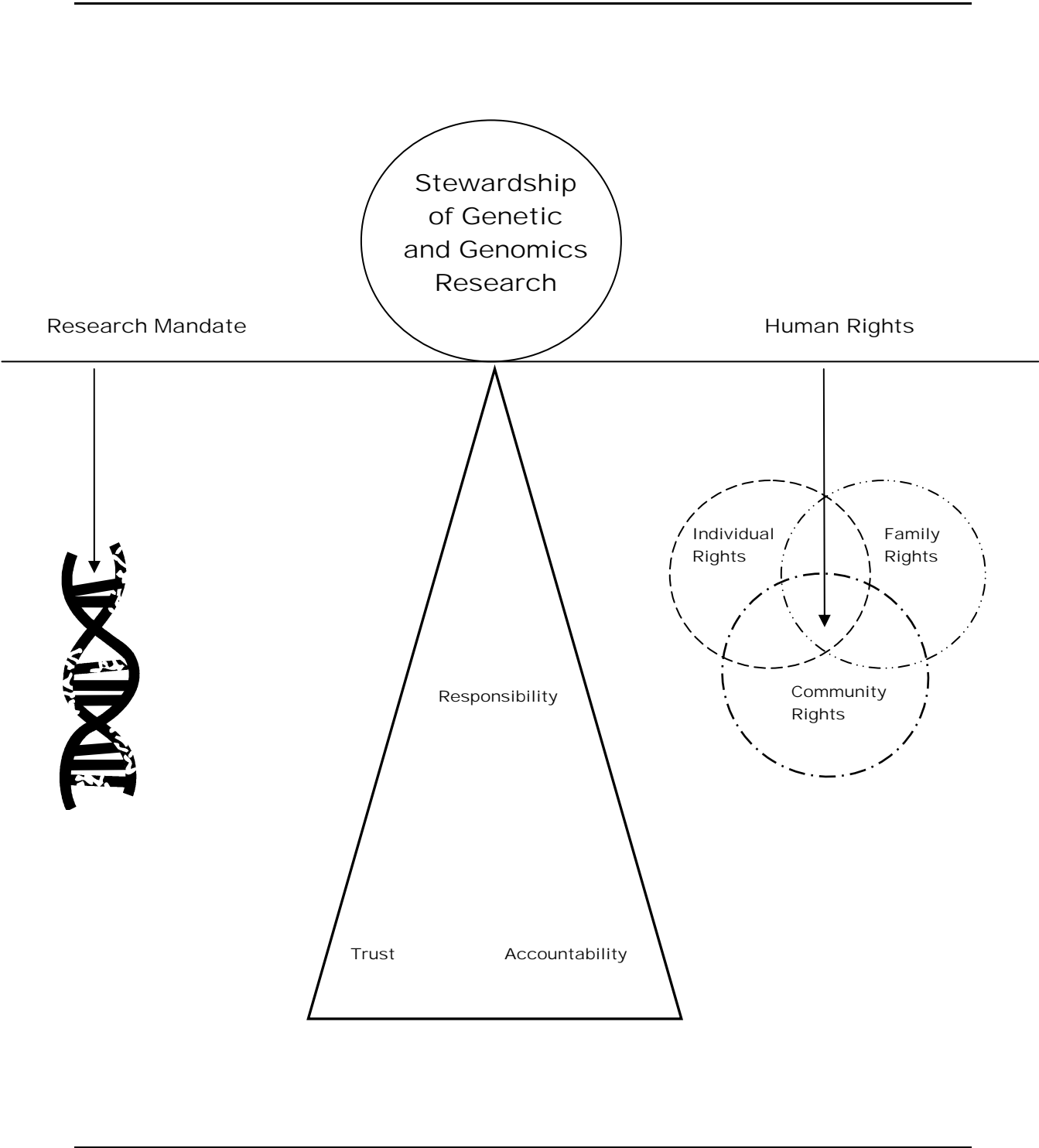
Appendix B, Figure 1

Jeffer's Emerging Model of Research Risk



Appendix B, Figure 2

Stewardship Model of Genetic and Genomics Research



## Appendix B, Figure 3

## Instrument: ICIS ICU Education Program Posttest

For each statement, please place an "X" in the correct column.

	<b>Statement</b>	<b>Definitely True</b>	<b>Probably True</b>	<b>Unsure</b>	<b>Probably False</b>	<b>Definitely False</b>
1.	Research is intended to benefit patients in the future. It may not help your loved-one.					
2.	Genomics studies heredity and the environment to answer important health questions.					
3.	A loved-one may be too ill to agree to participate in research. When that happens, you may be asked to give permission for your loved-one.					
4.	If you agree to participate in research, you may <u>not withdraw</u> from the study until it is finished.					
5.	You have the right to know the purpose of the study and how long it will last.					
6.	Research risks your loved-one might face must be explained to you.					
7.	The Institutional Review Board approves research. Part of their job is to help protect research participants.					
8.	The researchers will make sure you know how to contact them if you wish to ask more questions.					
9.	The researcher must give you all the information you need to make an informed decision about research.					
10.	Participating in research is voluntary.					
11.	You should decide whether to allow a loved-one to participate in research based on what your loved-one would want.					
12.	You have the right to know if the researcher plans to keep your loved-one's personal information confidential.					
13.	The informed consent process includes providing information about compensation for harm that may come to your loved-one during research.					
14.	Some research involves a treatment. You must be told if there are other treatments you may choose instead.					

Appendix B, Figure 4

Demographic Data Form

Thank you for taking the time to complete this survey. Please select the answer that most pertains to you.

1.	What is your gender?	Male	Female
2.	What is your age (in years)?	_____	
3.	What is your race?	African-American	Asian      Caucasian Hispanic      Other_____
4.	What is your occupation?	_____	
5.	What is your relationship to the patient? (check one)	Spouse	Fiancé      Significant Other Parent      Child      Brother/Sister Friend      Other_____
6.	What is the highest grade you completed in school?	Less than High School High School or GED Some College or Associates Degree College Graduate Post Graduate	
7.	Have <u>you</u> ever participated in medical research?	Yes	No
	7a. If you answered "yes" to number 7, did you feel that you had enough information to make a decision?	Yes	No

Appendix B, Figure 5

IRB Approval from Washington University

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Barnes Jewish Hospital  
St. Louis Children's Hospital  
Washington University

January 9, 2008

Dr. J. Perren Cobb  
Surgery/Acute and Critical Care  
Campus Box 8109

RE: Project Title: "Effectiveness of the Interactive Computerized information for Surrogates (ICIS)"  
HRPO Number: X07-49  
Approval Date: January 8, 2008  
Approval Type: New, Exempt  
Funding Source: None Stated

Dear Dr. Cobb:

In accordance with 45 CFR 46.101(b), the above-referenced project has been granted an exemption by the Washington University Human Research Protection Office (HRPO) under category (2). Please note that because your project meets the criteria for research that is exempt from federal regulations protecting human subjects in research, your project is not subject to the requirement for continuing review or documentation of informed consent. No further action is required as long as research procedures described in this application remain the same.


You are, however, required to obtain IRB approval for any revisions or modifications to your original project description **prior** to implementation of those changes. You are also responsible for reporting any unanticipated events involving risk to research participants or others, and all other requirements as outlined in the Project Director's Statement of Responsibilities found at: <http://hrpo.wustl.edu/> (click on "Policies" tab).

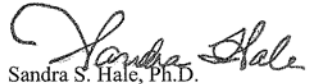
All documents approved at the time of this review are enclosed and are affixed with the HRPO stamp of approval. These documents should be retained with your research record.

HRPO complies with regulations outlined in 45 CFR 46 and all its sub-parts. Our Federal Wide Assurance number is FWA00002284.

If you have any questions, please contact the HRPO at (314) 633-7479 or [turnera@wustl.edu](mailto:turnera@wustl.edu).

Sincerely,

  
Philip A. Ludbrook, M.D.  
Associate Dean & Executive Chair, HRPO

  
Sandra S. Hale, Ph.D.  
Chair, Behavioral Minimal Risk Subcommittee

cc: Sharon A. Reise



## Appendix B, Table 6

University of Missouri – St. Louis IRB Approval Letter

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**OFFICE OF RESEARCH ADMINISTRATION****Interdepartmental Correspondence**

Name: Ann Shelton

Title: Effectiveness of Interactive Computerized Information For Surrogates (ICIS)

The chairperson of the Human Subjects Committee for UM-St. Louis has reviewed the above mentioned protocol for research involving human subjects and determined that the project qualifies for exemption from full committee review under Title 45 Code of Federal Regulations Part 46.101b. The time period for this approval expires one year from the date listed below. You must notify the Human Subjects Committee in advance of any proposed major changes in your approved protocol, e.g., addition of research sites or research instruments.

You must file an annual report with the committee. This report must indicate the starting date of the project and the number of subjects to date from start of project, or since last annual report, whichever is more recent.

Any consent or assent forms must be signed in duplicate and a copy provided to the subject. The principal investigator must retain the other copy of the signed consent form for at least three years following the completion of the research activity and they must be available for inspection if there is an official review of the UM-St. Louis human subjects research proceedings by the U.S. Department of Health and Human Services Office for Protection from Research Risks.

This action is officially recorded in the minutes of the committee.

Protocol Number	Date	Signature - Chair
080211S	2-21-08	<i>Carl J. Davis</i>

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