RESEARCH NURSES’ ATTITUDES AND PRACTICES REGARDING COMMUNICATION OF RISKS AND BENEFITS DURING THE RESEARCH INFORMED CONSENT PROCESS

A Dissertation Presented

by

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Acknowledgement and Dedication

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I dedicate this dissertation to my family: to my husband Dave and to my dear children Idan and Tom for supporting me spiritually throughout working on my dissertation research. Without their love, support, patience, and help I would not be where I am today.
Abstract

Many studies show that research participants frequently do not fully comprehend information regarding risks and benefits (R&B) associated with clinical trials even though this is a fundamental component of the research informed consent (IC) process, required by ethical and regulatory guidelines. Research nurses often take an active role in obtaining IC while explaining study details and verifying potential participants' understanding. Although there are published recommended strategies to enhance the IC communication process, particularly for R&B communication, there is a paucity of research focused on research nurses’ perspectives about the process. This study addresses this gap in the literature and provides comprehensive empirical data on research nurses’ attitudes and practices related to R&B communication in the informed consent process. Using a two-phase exploratory mixed methodology design, an online survey tool was developed and administered to a national sample of 107 research nurses having experience in obtaining IC for clinical trials. Variations in the research nurses’ attitudes, preparedness, and practices related to R&B communication were identified. Recommendations directed at strengthening the IC process are suggested.
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CHAPTER ONE

Introduction

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Clinical research is conducted around the world to enrich and advance healthcare and requires obtaining information from human participants. In accordance with international ethical and legal principles for research with human subjects, there is an obligation to obtain informed consent (IC) from every participant prior to her/his enrollment into a study (82 FR 7149, 2017; National Commission, 1979; WMA, 2013). The central idea of the IC is that individuals will make an informed choice about, “what shall or shall not happen to them” when considering the possibility of entering a research study (National Commission, 1979, p. 6).

According to the “Model of the Informed Consent Encounter” (Cohn, Jia, Smith, Erwin, & Larson, 2011), a meaningful IC process requires effective communication of information for each of the essential IC elements. Anticipated research associated risks and expected benefits for the participant, or others, are considered to be key elements of the IC process that have significant influence on decisions regarding participation (82 FR 7149, 2017). Therefore, this crucial information must be communicated to potential participants in a clear and understandable form which allows them to make a truly informed choice. Consent administrators such as nurses, when assuming the role of independent investigator, or when employed in the position of research nurses, are responsible for ensuring that research participants know their rights and understand the IC document well.

Over the years, many practical recommendations have been made to promote the quality of the IC process and risks and benefits (R&B) communication in particular (AHRQ, 2009; Fagerlin, Zikmund-Fisher, & Ubel, 2011; Kass, Taylor, Ali, Hallez, & Chaisson, 2015; NCI, 2013; Paasche-Orlow, Taylor, & Brancati, 2003). Yet many research participants do not understand the R&B even after they have agreed to participate in a research study (Koh, Goh, Yu, Cho, & Yang, 2012; Montalvo & Larson, 2014; Smith & Fogarty, 2016). Inadequate
Understanding of R&B may cause some to refuse to participate in a clinical trial (Guedj et al., 2013) or cause future regret concerning having participated in the trial (Stryker, Wray, Emmons, Winer, & Demetri, 2006) that may lead to participants leaving the trial prematurely. This may negatively affect study findings, undermine the validity of the results (Meneguin & Cesar, 2012; Stryker et al., 2006), and may also cause severe physical and psychological harm to the participants (Buchanan, 2013; Shalala, 2000), raising significant ethical concerns. Studies that explored IC communication strategies (Flory & Emanuel, 2004; Isles, 2013; Nishimura et al., 2013; Tait, Voepel-Lewis, Brennan-Martinez, McGonegal, & Levine, 2012), were restricted in the types of communication strategies used (Kao, Aranda, Krishnasamy, & Hamilton, 2016) and few studies obtained research nurses’ feedback on the effectiveness of the strategies (Sabik et al., 2005).

Because nurses are frequently involved in research, recruiting potential participants, and obtaining IC in clinical trials (Best, 2005; Bowrey & Thompson, 2014; Bristol & Hicks, 2014) special attention is required from nursing as a discipline to overcome inadequacies in the existing IC process. In view of the pivotal role of research nurses in the IC process for clinical trials, its complexity, along with the associated deficiencies of the R&B information delivery, and the lack of empirical literature that describes how research nurses perform in this area (Cantini & Ells, 2007; Cresswell & Gilmour, 2014), this study aims to address this gap. This study investigates research nurses consent practices, while also developing a better understanding of how to improve and ensure an ethical IC process. The purpose of this study was to examine communication of the R&B information during the research IC process from the perspective of the research nurses obtaining the IC.
Research Methodology

Nursing research is committed to facilitating and contributing to all areas of nursing practice particularly to those that most need improvement. Therefore, initially, a systematic review of literature that synthesized qualitative and quantitative findings from original nursing research reports about R&B communication in the IC process was completed. To further examine the studied phenomena, an exploratory mixed methods design (Creswell & Plano Clark, 2011), was conducted in two sequential phases. Phase 1 was a qualitative exploration of opinions and attitudes related to conveying R&B messages collected via interviews with experts in the IC process. Findings from the interviews were used to develop a survey questionnaire that was distributed in Phase 2 to a sample of research nurses directly involved in the IC process for clinical trials. The research design of each phase is explained in detail in Chapters 3 and 4 of this dissertation manuscript.

The Aims and Manuscripts

The outcomes of this research project are reported in three manuscripts. The first manuscript reports results of the systematic literature review that aimed to explore and document nurse researchers’ contribution to the R&B communication in the IC process research and related practices of research nurses. The literature review manuscript, Nurse Researchers’ Views Regarding Communication of Risks and Benefits in the Research Informed Consent Process: A Systematic Review, was submitted to the Journal of Applied Nursing Research on September 6, 2016.

The second manuscript reports results from personal qualitative interviews with experts in the research IC process that explores opinions & attitudes about current R&B communication practices. Among others, several authors from the initial literature review who are experts in the
IC process were contacted and agreed to be interviewed. Findings from the interviews were used as the foundation for the development of the survey to examine research nurses’ practices. The qualitative interviews’ manuscript, Communicating Risks and Benefits in Informed Consent for Research: Experts’ Interviews Findings, was submitted on November 6, 2016 to the *Journal of Global Qualitative Nursing Research*.

The third manuscript presents findings from the survey aimed to explore and document attitudes, practices, and preparedness of research nurses in order to enhance potential research participant’s knowledge and understanding of R&B in studies in which they are considering participation. The target journal for the third manuscript, Research Nurses’ Attitudes and Practices Regarding Communication of Risks and Benefits During the Research Informed Consent Process, is the *Journal of Nursing Ethics*.

**Study Significance**

It is important to understand the process of R&B communication in more detail from the perspective of nurses involved in the IC process. This study generated valuable data on research nurses’ attitudes and practices using different communication strategies in order to disclose R&B to potential research participants. Attitudes toward specific strategies may influence how each consenter performs the IC process as well as the specific ways they convey information and ensure research participant comprehension. Knowledge of strategies nurses felt inadequately prepared for, strategies known to be effective that were little used, and strategies that should be used minimally will promote better understanding of factors that impact the IC process. The study further identified deficiencies prevalent in training programs that prepare research nurses and others who are responsible for obtaining IC. Once identified, these shortcomings can guide the planning and development of interventions to adequately prepare research nurses as IC
administrators. Effective supervisory mechanisms should be employed to evaluate the success of these educational efforts, demonstrating the use of clear communication practices to assist potential research participants to make informed decisions, and ultimately improving IC process outcomes.
References


CHAPTER TWO

Nurse Researchers’ Views Regarding Communication of Risks and Benefits in the Research

Informed Consent Process: A Systematic Review

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Abstract

**Background.** Communication of risks and benefits while obtaining informed consent for research is often inadequate. Despite the key role that many nurses have in this process, the nurse researchers’ perspective has not been systematically examined.

**Purpose.** To assess communication of risks and benefits in the research consent process in nurse-led research that addressed this topic.

**Methods.** A systematic review was conducted of topic-relevant studies published in CINAHL (since 1982) and MEDLINE (since 1966), through October 2015.

**Results.** Only twelve research reports met the inclusion criteria. Although these studies investigated important aspects of obtaining informed consent, the number of nurse-led studies and the breadth of perspectives related to this fundamental, essential component of human research participants’ protection are limited.

**Conclusion.** Nursing led research is needed to further define the barriers and improve the process for risks and benefits communication in the informed consent process.

**Keywords:** risks and benefits; informed consent; nursing research; systematic review.
Introduction

In recent years nurses have assumed more active roles in the informed consent process for clinical research, educating potential participants about the specifics of studies and supporting them in making informed choices about participation (Banner & Zimmer, 2012; Bevans et al., 2011; Cresswell & Gilmour, 2014; Elemraid et al., 2013; Johnson & Stevenson, 2010; Spilsbury et al., 2008). The informed consent process is fundamental for the protection of individual rights to self-determination in decision-making and lies at the heart of ethical clinical research. According to United States’ federal regulations (45 C.F.R. §46, 2009), the researcher is required to ensure, as part of the informed consent process, that the study is described and explained to potential participants. A key part of the process is for the consent administrator to provide clear and accurate disclosure of anticipated risks or discomforts as well as benefits inherent in the proposed research study (Tait, Voepel-Lewis, Robinson, & Malviya, 2002). It is also important for the disclosed information to be useful for the person contemplating participation (Cantini & Ells, 2007). Appropriate methodological choices are needed when planning the discussion and elaborating on this information with a potential research participant. Important considerations include: what information to convey, what communication procedure to employ, and how to assess comprehension of the information about risks and benefits (R&B) (Baer, Good, & Schapira, 2011).

Ethical principles in the conduct of research require that potential participants carefully consider R&B and freely decide if they wish to participate. Unfortunately, the process of communication about potential R&B is often flawed. Studies demonstrate that the information disclosed is sometimes incomplete (Buchanan, 2013; Guarino, Elbourne, Carpenter, & Peduzzi, 2006) or misunderstood by participants (Bergenmar, Johansson, & Wilking, 2011; Jefford et al.,
Shortcomings such as these can derail thoughtful consideration of the R&B, lead to misjudgments in the consent process, and impact decisions concerning participation.

Although there is extensive literature by health scientists and ethicists dedicated to improving communication about research related R&B (Macklin, 2015; McCaffery et al., 2012; Peters, Hart, & Fraenkel, 2011), the specific contribution of nurse researchers to this knowledge has not been previously studied. The purpose of this systematic literature review is to examine nurse researchers’ views about the communication of the R&B during the informed consent process and to describe their contribution to this area of research. Findings from this review will help to inform areas for further nurse-led research.

**Methods**

A structured approach was used to review, select, and analyze the literature relating to the aims of this study. Inclusion criteria and study terms were defined and the review was conducted with consultation from an experienced reference librarian and several nurse researchers.

**Inclusion Criteria**

Studies in English that met the following criteria were considered for inclusion in the review: (a) original research reports; (b) published in a peer-reviewed journal; (c) a research focus or findings related to communicating the R&B of participation in clinical research, (d) the first author is a registered nurse, and (e) published between January 1966 and October 2015.

**Literature Search Strategy**

The following three-step search process from the Joanna Briggs Institute (2014) was used to find articles for inclusion:

*Step 1:* Select keywords and terms central to the review purpose.
Step 2: Conduct a specific search of the Cumulative Index to Nursing and Allied Health Literature (CINAHL) and the Medical Literature Analysis and Retrieval System Online (MEDLINE) databases to find full text publications followed by a thorough review of their titles and abstracts to select specific studies for potential inclusion.

Step 3: Examine the reference list in each article to identify additional literature for review.

The key terms identified and defined in Step 1 and used throughout the review process are described in Table 1. The basic terms and keyword combinations as entered into the search engines are: “informed consent”, (risks or harms or benefits), and nurse.

Table 1
Terms and Definitions

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition / Explanation</th>
</tr>
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<tbody>
<tr>
<td>Informed Consent</td>
<td>An individual’s autonomous intentional authorization of the participation in a study, given after understanding what is going to happen to the individual because of involvement in a research study (Beauchamp, 2011).</td>
</tr>
<tr>
<td>Risks</td>
<td>Event representing harm or adverse outcomes and their likelihood of occurring as the result of participation in a clinical research (Ahl et al., 1993; Federal Registrar, 2011; OHRP IRB Guidebook, 1993).</td>
</tr>
<tr>
<td>Harms</td>
<td>The negative impact of research activity on the participant. The nature of possible harm might be physical, psychological, social, economic, or informational (Ahl et al., 1993; Federal Registrar, 2011; OHRP IRB Guidebook, 1993).</td>
</tr>
<tr>
<td>Benefits</td>
<td>The expected valued or desired outcomes; an advantage anticipated due to participating in a trial (OHRP IRB Guidebook, 1993).</td>
</tr>
<tr>
<td>Nurse</td>
<td>The term used to identify a registered nurse.</td>
</tr>
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</table>

In Step 2, CINAHL and MEDLINE electronic databases were searched for specific time periods and with search restrictions as presented in Table 2.

Table 2
Electronic Databases Searched

<table>
<thead>
<tr>
<th>Sources</th>
<th>Time period for Search</th>
<th>Restrictions to Search</th>
</tr>
</thead>
<tbody>
<tr>
<td>CINAHL (Ovid version)</td>
<td>1982–October 2015</td>
<td>English Language, Research Article, Peer Reviewed, First Author is Nurse or “Nursing” as Author Affiliation (AF)</td>
</tr>
<tr>
<td>Medline (Ovid version)</td>
<td>1966–October 2015</td>
<td>English Language</td>
</tr>
</tbody>
</table>
Due to the inconsistencies between search options among electronic databases, different search strategies were used to locate relevant published studies. In the CINAHL database, publication selection was limited to research articles published in English peer-reviewed journals. “Informed consent” as a straightforward phrase, or in the form of a Major Heading - (MM "Consent (Research)"), was used to find articles in this topic area. The research context of the informed consent, as opposed to treatment context, was verified by reading the abstracts of the selected citations.

Several strategies were used to locate reports written by a nurse. CINAHL’s Advanced Search limit “First Author is a Nurse” was applied to narrow the search results to articles authored by nurses. Since this search limiter in CINAHL retrieves records only from November 2009 and later (EBSCO support, 2014), earlier reports were manually assessed for the first author’s credentials. An additional strategy to uncover nurse-authored research was to select a field “AF Author Affiliation” along with entering the term “nursing” in the search box. This search mode aided in retrieving articles written by authors affiliated with Schools or Colleges of Nursing. Finally, to maximize search effectiveness and lessen the chances of missing any relevant work, an additional keyword search was performed, using nurs* as the search term. An asterisk (*) is used to broaden a search, helping to retrieve variations on the ‘nurs’ word stem, leading to records that include “nursing,” “nurse,” or “nurses.” This search resulted in articles with the key word appearing anywhere in the record. The implementation of the latter two strategies required additional examination of the relevant citations to verify the nursing credentials of the first author.

Unlike CINAHL, the MEDLINE database does not have search limits for research reports nor for author’s credentials, eliminating the option of a filtered search. Therefore, a
search of MEDLINE records, abstracts, and/or full texts articles conducted for potentially
relevant citations were screened to confirm the author's credentials and that the article described
a research study. Although a “peer-review” limiter does not exist in MEDLINE, it did not detract
from the overall quality of the search as nearly all citations are peer-reviewed (EBSCOsupport,
2011). Nevertheless, as a part of the review process, all articles selected from the MEDLINE
search were confirmed to meet the inclusion criteria.

In Step 3, a reference-based search strategy was applied to select additional potentially
relevant studies. The reference management software RefWorks v2.0 (ProQuest, 2010) was used
to ensure accuracy in managing and organizing the search findings in a logical and systematic
manner.

Data Abstraction and Synthesis

The thematic analysis process began with a review of each study to identify
predetermined elements, such as the research focus, methods, sample characteristics, and
outcomes of significance for the review. Detailed basic information about each study was	abulated to enable and enhance comparison and assessment. Qualitative and quantitative studies
were analyzed separately since they required different evaluative approaches. Data from all
scientific reports were entered into author-developed abstraction forms to fit each research
design. Review findings were then synthesized into meaningful categories.

Findings

Literature Search Results

Following the literature search process, 857 references were retrieved. A total of 33
potentially relevant full text articles were identified by the means of screening the title and
abstract (n = 28), during personal communication with experts on the subject of informed
consent (n = 2) and by searching reference lists of these 30 publications, which resulted in identification of additional publications (n=3). Following the evaluation of the 33 articles, 12 were included in this review (Figure 1).

**Figure 1.** Flow chart of the systematic review.

The 12 articles reviewed, listed in Table 3, provided varied levels of examination of the R&B of the informed consent communication process. Although two of the articles (Cox, 1999; Moore, 2001) referred to communication of the R&B during the consent process as part of a broader discourse of clinical research involvement and participation, ten articles directly dealt with these issues in the context of protection of human research participants and the informed consent process. Each of these studies underwent an in-depth evaluation.
Table 3
Publications Included in the Review

<table>
<thead>
<tr>
<th></th>
<th>Authors</th>
<th>Publication Title</th>
<th>Journal</th>
<th>Volume</th>
<th>Issue</th>
<th>Pages</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Ahern, K.</td>
<td>Informed consent: Are researchers accurately representing risks and benefits?</td>
<td>Scandinavian Journal of Caring Sciences</td>
<td>26(4)</td>
<td></td>
<td>671-678</td>
</tr>
<tr>
<td>2</td>
<td>Barrett, R.</td>
<td>Quality of informed consent: Measuring understanding among participants in oncology clinical trials.</td>
<td>Oncology Nursing Forum</td>
<td>32(4)</td>
<td></td>
<td>751-755</td>
</tr>
<tr>
<td>3</td>
<td>Butler, L.</td>
<td>Consenting to participate in research for the treatment of cancer: The patient's perspective.</td>
<td>Canadian Oncology Nursing Journal</td>
<td>6(3)</td>
<td></td>
<td>124-129</td>
</tr>
<tr>
<td>4</td>
<td>Chang, A.</td>
<td>An exploratory survey of nurses' perceptions of phase I clinical trials in pediatric oncology.</td>
<td>Journal of Pediatric Oncology Nursing</td>
<td>25(1)</td>
<td></td>
<td>14-23</td>
</tr>
<tr>
<td>5</td>
<td>Cohn, E. G., Jia, H., Smith, W. C., Erwin, K., &amp; Larson, E. L.</td>
<td>Measuring the process and quality of informed consent for clinical research: Development and testing.</td>
<td>Oncology Nursing Forum</td>
<td>38(4)</td>
<td></td>
<td>417-422</td>
</tr>
<tr>
<td>6</td>
<td>Cox, K.</td>
<td>Researching research: Patients' experiences of participation in phase I and II anti-cancer drug trials.</td>
<td>European Journal of Oncology Nursing</td>
<td>3(3)</td>
<td></td>
<td>143-152</td>
</tr>
<tr>
<td>9</td>
<td>Pletsch, P. K., &amp; Stevens, P. E.</td>
<td>Inclusion of children in clinical research: Lessons learned from mothers of diabetic children.</td>
<td>Clinical Nursing Research</td>
<td>10(2)</td>
<td></td>
<td>140-162</td>
</tr>
<tr>
<td>11</td>
<td>Thomas, M., &amp; Menon, K.</td>
<td>Consenting to pediatric critical care research: Understanding the perspective of parents.</td>
<td>Dynamics</td>
<td>24(3)</td>
<td></td>
<td>18-24</td>
</tr>
</tbody>
</table>

Methodological Attributes of the Studies

The general characteristics of each study are provided in Tables 4 and 5. Since the study by Cohn and colleagues (2011) was the only one focused on developing a measurement tool, its methodological components are presented separately in Table 5. Tables 6 and 7 provide a description of the reports and evaluation overview in a format adapted from the work of Long and Godfrey (2004).
**Table 4**  
*Methodologic Matrix*

<table>
<thead>
<tr>
<th>Authors</th>
<th>YOP</th>
<th>Purpose</th>
<th>Design</th>
<th>Method of Data Collection</th>
<th>Sampling Method</th>
<th>Gender</th>
<th>Age</th>
<th>Sample Size and Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Ahern, 2012; Australia</td>
<td>2012</td>
<td>To investigate the actual harms and benefits individuals experienced while participating in a qualitative study.</td>
<td>Qualitative, Descriptive, Cross-Sectional</td>
<td>Semi-structured interviews, by phone</td>
<td>Purposive</td>
<td>F=9</td>
<td>Adults, age not specified</td>
<td>n=9, 11 transcripts for analysis obstetrics health professionals</td>
</tr>
<tr>
<td>2. Barrett, 2005; US</td>
<td>2012</td>
<td>To assess IC understanding.</td>
<td>Quantitative, Descriptive, Cross-Sectional</td>
<td>QuIC questionnaire Mailed or hand-delivered</td>
<td>Convenience</td>
<td>M=6</td>
<td>Mean=64.3 y SD=11.9 Range=[39-76]</td>
<td>n=8 oncology patients</td>
</tr>
<tr>
<td>3. Butler, 1996; Canada</td>
<td>1996</td>
<td>To explore patients' experiences with the process of consenting to participate in experimental studies.</td>
<td>Qualitative, Descriptive, Cross-Sectional</td>
<td>Purposive focus groups interviews. Pre-discussion questionnaire hand-delivered</td>
<td>Purposive</td>
<td>M=4</td>
<td>Mean=64 y Range=[52-73]</td>
<td>n=9 in four focus groups oncology patients</td>
</tr>
<tr>
<td>4. Chang, 2008; Canada</td>
<td>2008</td>
<td>To assess perceptions goal &amp; outcomes, IC, role, &amp; factors that influence those perceptions.</td>
<td>Survey, Way for delivery not reported</td>
<td>Qualitative, Exploratory, Cross-Sectional</td>
<td>Survey, Hand delivered</td>
<td>M=22</td>
<td>&lt;30 y=42% &gt;30 y=58%</td>
<td>n=43 pediatric oncology nurses</td>
</tr>
<tr>
<td>5. Cox, 1999; UK</td>
<td>1999</td>
<td>To examine experiences by cancer trial participants.</td>
<td>Quantitative, Longitudinal</td>
<td>Semi-structured in-depth interviews</td>
<td>Purposive</td>
<td>F=33</td>
<td>&lt;59 y=51% &gt;60 y=49%</td>
<td>n=55 oncology patients</td>
</tr>
<tr>
<td>6. Larson et al., 1990; US</td>
<td>1990</td>
<td>To determine patients' attitudes about desired knowledge of, and involvement in clinical research.</td>
<td>Quantitative, Descriptive, Cross-Sectional</td>
<td>Survey, Hand delivered</td>
<td>Population based study, Consecutive sampling</td>
<td>M=103</td>
<td>Mean=46.5 y Range=[17-84]</td>
<td>n=227 patients from various clinical areas</td>
</tr>
<tr>
<td>7. Moore, 2001; UK</td>
<td>2001</td>
<td>To explore patients' perceptions of any benefits from participating in phase I trials.</td>
<td>Quantitative, Descriptive, Cross-Sectional</td>
<td>Semi-structured interviews &amp; Questionnaire, Face-to-face</td>
<td>Purposive</td>
<td>F=12</td>
<td>Age of each participant provided. Range=[33-74] assessed by a reviewer</td>
<td>n=15 oncology patients</td>
</tr>
<tr>
<td>8. Pletsch &amp; Stevens, 2001b; US</td>
<td>2001</td>
<td>To explore factors that influenced mothers to consent to have their children involved in clinical research.</td>
<td>Qualitative, Descriptive, Cross-Sectional</td>
<td>Semi-structured interviews, Face-to-face</td>
<td>Purposive</td>
<td>F=9</td>
<td>Mean=42 y SD = 5.8</td>
<td>n=9 *legal guardians - mothers of children with diabetes proposed to join research trial</td>
</tr>
<tr>
<td>9. Shelton et al., 2015; US</td>
<td>2015</td>
<td>To examine the effectiveness of a new, computer-based education module on surrogates understanding of the process of IC for genomics research.</td>
<td>Quantitative, Experimental Pilot, Posttest-only design</td>
<td>Questionnaire, 13 Likert-type items to measure consent understanding</td>
<td>Experimental</td>
<td>M=20</td>
<td>Experimental M=49.9 SD=15.35 Control: M=45 SD=15.53 Range=[19-82]</td>
<td>n=65 legal guardians - adult visitors to the ICU waiting rooms</td>
</tr>
<tr>
<td>10. Thomas &amp; Menon, 2013; Canada</td>
<td>2013</td>
<td>To describe the experience of parents / legal guardians who consented or declined consent for their child to be enrolled in critical care research study.</td>
<td>Qualitative, Descriptive</td>
<td>Semi-structured interviews, Face-to-face</td>
<td>Purposive</td>
<td>F=5</td>
<td>Adults, age not specified</td>
<td>n=7 *legal guardians - parents of children proposed to join a critical care research trial</td>
</tr>
<tr>
<td>11. Ulrich et al., 2012; US</td>
<td>2012</td>
<td>To describe benefits &amp; burdens of research participation with the development of a preliminary model.</td>
<td>Qualitative, Descriptive</td>
<td>Semi-structured interviews, Face-to-face or via phone</td>
<td>Purposive</td>
<td>M=8</td>
<td>Mean=53.9 y SD=13.8 Range=[29-74]</td>
<td>n=32 oncology patients</td>
</tr>
</tbody>
</table>

YOP = Year of Publication; Y = Years; QuIC tool = the Quality of Informed Consent tool; IC = Informed Consent; NP = Nurse Practitioners; F = Female; M = Male; ICU = Intensive Care Unit
Table 5
Methodological appraisal of the reviewed P-QIC measure

<table>
<thead>
<tr>
<th>Author Year</th>
<th>Measure Description</th>
<th>Original Population</th>
<th>Outcome measure</th>
<th>Psychometric Properties</th>
<th>Strengths</th>
<th>Weaknesses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cohn et al., 2011; US</td>
<td>Total 20 items: 14 measure facts, 6 measure skills of communication. Likert scale 1-4: done well, done, done poorly, not done. Total score: 40-100 (highest informed consent process quality).</td>
<td>n = 63 of health-sciences students for reliability and validity testing of the final version of the tool.</td>
<td>Consent administrator functioning during consent procedure - conveying of factual consent information &amp; communication skills through observation.</td>
<td>Reliability (r.): Internal consistency: Cronbach α=0.98; Inter-rater r.: Cohen’s k = 0.98; Test-retest r.: Pearson’s r ranges from 0.639 to 0.998 for the scripts. Validity (v.): Face &amp; Content v. (experts &amp; non-experts panels); Convergent v.: ICC = 0.97; Discriminant v.: p &lt; 0.001 [F3, F248 = 528]</td>
<td>Reliable; Valid; Generic scale – fit for use in any clinical trial.</td>
<td>Validated mostly in a simulation environment. Cannot address specific trial related aspects of informed consent. Item #9 is not applicable to all trials.</td>
</tr>
</tbody>
</table>

P-QIC = Process & Quality of Informed Consent; YOP = Year of Publication.

Descriptive analysis of the 12 eligible studies revealed that half were conducted in the United States and the others were done in Canada (n = 3), England (n = 2) and Australia (n = 1). Most of the articles were published between 2005 and 2015 (n = 8), probably reflecting an increased awareness of ethical challenges and nursing research efforts to expand the evidence base related to the ethics of protection of human research participants.

In eight reports, all authors listed were nurses. In the remaining four reports, nurse researchers were a leading part of an inter-professional team, collaborating with a physician (Thomas & Menon, 2013), an education expert (Shelton, Freeman, Fish, Bachman, & Richardson, 2015), a statistician (Ulrich et al., 2012), and a clinical researcher (Cohn et al., 2011).

Seven studies were focused on research participants’ views on the informed consent process. These studies employed quantitative (n = 2) (Barrett, 2005; Larson & McGuire, 1990) and qualitative (n = 5) research designs (Ahern, 2012; Butler, 1996; Cox, 1999; Moore, 2001; Ulrich et al., 2012). Three other reports presented perspectives of the research participants’ legal guardians, using experimental (Shelton et al., 2015) and qualitative approaches for their inquiries (Pletsch & Stevens, 2001b; Thomas & Menon, 2013). Chang (2008) surveyed perceptions of the
healthcare professionals involved in the conduct of clinical research. Only one study (Cohn et al., 2011) used a comprehensive sampling approach, while examining the opinions of various parties involved in the research process. This study dealt with the development of an instrument, the P-QIC, aimed at measuring the quality of the informed consent process.

Half of the studies were cancer trials. The other studies focused on obstetrics (n = 1), diabetes (n = 1), pediatric and adult critical care (n = 2); and two had no specific clinical area. Sample sizes ranged from seven (Thomas & Menon, 2013) to 227 (Larson & McGuire, 1990); eight studies involved fewer than 50 participants. Six studies reported sample ages which ranged from 17 to 84 years old. Some provided age categories and/or the mean age as a measure of central tendency (Chang, 2008; Cox, 1999; Pletsch & Stevens, 2001b), whereas three others (Ahern, 2012; Cohn et al., 2011; Thomas & Menon, 2013) involved adults without specifying age. Nine studies included a mixed gender sample of adults, two interviewed only women (Ahern, 2012; Pletsch & Stevens, 2001b) and two (Chang, 2008; Cohn et al., 2011) reported no gender information.

**Characteristics of the qualitative studies.** As suggested by the Cochrane Collaboration Qualitative Methods Group (Hannes, 2011), a generic evaluative framework proposed by the *Critical Appraisal Skills Programme* (CASP, 2014) was adapted to assess the seven studies that used a qualitative design. As recommended by Noyes and Lewin (2011), appraisals were performed simultaneously with the data extraction process. CASP’s critiquing questions systematically address the clearness of the study aims, appropriateness of the qualitative methodology, research design, recruitment strategy and data collection methods, adequacy of the relationship between the investigator and participants, consideration of ethical issues, rigor of the data analysis, credibility of the research findings, and the study value.
All reports met basic evaluation requirements. First, the research aims were clearly stated by the authors. Second, a qualitative design was appropriate as the investigators intended to illuminate the subjective experience of study participants. Only one of the reports specified a conceptual framework: the Butler study (1996) used the Guidelines on Research Involving Human Subjects by the Medical Research Council of Canada as the framework to guide their data collection process.

In two studies (Butler, 1996; Thomas & Menon, 2013) the authors explicitly stated that they used a qualitative descriptive research design. The approaches undertaken by the other investigators also matched the qualitative descriptive approach by presenting “data-near interpretations,” as expected in this type of research methodology (Sandelowski, 2010, p.78). Accordingly, these authors explored and categorized descriptions of the subjective experiences of being a part of a potentially distressing qualitative study (Ahern, 2012), as well as taking part in a cancer (Cox, 1999; Moore, 2001; Ulrich et al., 2012) or other type of clinical research (Pletsch & Stevens, 2001b).

Most of the qualitative reports did not provide a comprehensive ethical discussion, suggested elsewhere (NICE, 2015), which was possibly precluded by space restrictions in the peer-reviewed journals. Nonetheless, all the articles included a clear statement of approval by research ethics committees and informed consent was obtained from the participants. Several authors briefly discussed how they dealt with various ethical concerns such as taking measures to ensure study participants’ confidentiality by conducting interviews in a private office or a convenient location (Cox, 1999; Pletsch & Stevens, 2001b; Ulrich et al., 2012) or consideration of participants’ health status (Moore, 2001).
It is noteworthy that in one study (Ahern, 2012), the primary investigator did not publish data related to the sample. Detailed description of such research characteristics enables effective transferability of the study findings. However, this omission reflects Ahern’s concern of a potential breach of confidentiality of the research participants’ identity. Therefore, the investigator’s decision exemplifies an ethically appropriate one when a researcher wants to be transparent yet perceives a conflict with ethical obligations to protect participants’ confidentiality. Additional information about the qualitative studies systematic evaluation of outcomes appears in Table 6, describing key study outcomes in their methodological context (Sandelowski, Leeman, Knafl, & Crandell, 2013).

Table 6

<table>
<thead>
<tr>
<th>Study</th>
<th>1. Study purpose</th>
<th>2. Key outcomes related to the review aim</th>
<th>Evaluative Summary</th>
</tr>
</thead>
</table>
| Ahern, 2012      | 1. To investigate the actual harms and benefits individuals experienced while participating in a distressing qualitative study. | 2. Sources of harms and benefits of qualitative research participation, as well as factors mitigating harms.                                                                 | • Sampling approach type not stated; purposive sampling used, per description; insufficient description of sample characteristics  
• Potential of memory bias - time interval from the end of the original study until the interview not reported  
• Saturation of data not discussed  
• Iterative thematic analysis used; appropriate quotes provided in support  
• Member confirmation of the study findings used as validation strategy  
• Investigator’s relationship with participants not clear  
• Lack of the in-depth (thick) description of the setting, informants, researcher’s characteristics and relationship to the data; impairs somewhat the transferability of the results  
• Sample consisted of women only; need a more comprehensive account of the studied phenomenon with men required  
• Study findings support nurse researcher practice in qualitative studies                                                                 |
| Butler, 1996     | 1. To explore patients’ experiences with the process of consenting to participate in experimental studies. | 2. Sources of harms and benefits of participation in oncology trials and perception of their communication during the consent process. | • Sampling approach type not stated; purposive sampling used  
• Final sample, 9 out of 32 patients agreed to participate; no report of reasons for not attending focus groups  
• Small size of the groups (from 1-3) weakens study design  
• Detailed description of recruitment process and the group's formation  
• Lack of information about the skills of group facilitators  
• Saturation of data not discussed  
• No report of length of time spent in focus group discussions nor on the amount of data collected  
• Use of content analysis with high inter-rater reliability  
• Member checking used as a validation strategy  
• Study contributions related to understanding the decision-making process by oncology patients who consider taking part in clinical trials; identifying deficiencies in the process of communication of risks of the research; and underscoring the role of nurses on the research team as patient educators                                                                 |
<table>
<thead>
<tr>
<th>Study</th>
<th>1. Study purpose</th>
<th>2. Key outcomes related to the review aim</th>
<th>Evaluative Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cox, 1999</td>
<td>To examine experiences of Phases I &amp; II cancer trials participants.</td>
<td>R&amp;B sources of Phase I and II oncology trials.</td>
<td>Longitudinal research design with four data collection points during a one-year period</td>
</tr>
<tr>
<td></td>
<td></td>
<td>R&amp;B sources of Phase I and II oncology trials.</td>
<td>Insufficient information concerning the recruitment process, interviewees characteristics and data collection procedure</td>
</tr>
<tr>
<td></td>
<td></td>
<td>R&amp;B sources of Phase I and II oncology trials.</td>
<td>Saturation of data not discussed</td>
</tr>
<tr>
<td>Moore, 2001</td>
<td>To explore patients' perceptions of any benefits from participating in Phase I trials.</td>
<td>Sources of R&amp;B in Phase I trials.</td>
<td>Use of the constant comparative method of analysis; assisted by the NUD*IST software</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sources of R&amp;B in Phase I trials.</td>
<td>Trustworthiness and credibility of the data findings not discussed</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sources of R&amp;B in Phase I trials.</td>
<td>Explicit and clear findings; discussed in relation to research aims</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sources of R&amp;B in Phase I trials.</td>
<td>Study contribution - better understanding of the experiences of terminally ill patients participating in clinical research over time</td>
</tr>
<tr>
<td>Pletsch &amp; Stevens, 2001b</td>
<td>To explore factors that influenced mothers to consent to have their children with diabetes involved in clinical research.</td>
<td>Sources of risks and benefits in pediatric diabetes trials.</td>
<td>Detailed description of recruitment process and causes for withdrawal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sources of risks and benefits in pediatric diabetes trials.</td>
<td>Real time accounts of patients before and after their participation in a trial, describing their expectations and actual experiences as trial subjects.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sources of risks and benefits in pediatric diabetes trials.</td>
<td>Discussion of researcher choices for data collection methods, reflects on assumptions and describes how they proved to be incorrect</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sources of risks and benefits in pediatric diabetes trials.</td>
<td>Saturation of data not discussed</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sources of risks and benefits in pediatric diabetes trials.</td>
<td>Use of pilot tested data collection protocols</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sources of risks and benefits in pediatric diabetes trials.</td>
<td>Audiotaped interviews; transcribed verbatim</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sources of risks and benefits in pediatric diabetes trials.</td>
<td>Use of thematic analysis using data reduction techniques</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sources of risks and benefits in pediatric diabetes trials.</td>
<td>Study contribution identifying ethical dilemmas in connection with phase I cancer treatment trials</td>
</tr>
<tr>
<td>Thomas &amp; Menon, 2013</td>
<td>To describe the experience of parents / legal guardians who consented or declined consent for their child to be enrolled in critical care research study.</td>
<td>Risks, burdens and benefits that influenced consent for research participation.</td>
<td>Presentation of details about recruitment and data collection processes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Risks, burdens and benefits that influenced consent for research participation.</td>
<td>Two independent coders categorized the data</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Risks, burdens and benefits that influenced consent for research participation.</td>
<td>Report of rich retrospective accounts of the participants</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Risks, burdens and benefits that influenced consent for research participation.</td>
<td>Saturation of data not discussed</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Risks, burdens and benefits that influenced consent for research participation.</td>
<td>Use of narrative analysis with themes generation; appropriate quotes supported data interpretation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Risks, burdens and benefits that influenced consent for research participation.</td>
<td>Appropriate discussion of transferability of the findings</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Risks, burdens and benefits that influenced consent for research participation.</td>
<td>Study contribution – better understanding of the experiences of well-educated and knowledgeable mothers of European descent considering whether or not their children with stable diabetes should take part in a trial</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Risks, burdens and benefits that influenced consent for research participation.</td>
<td>Recommended use of a sampling approach that includes parents with other cultural and ethnic backgrounds of sicker children would provide a more comprehensive and potentially different perspective on studying experiences</td>
</tr>
<tr>
<td>Ulrich et al., 2012</td>
<td>To describe the benefits and burdens of research participation with the development of a preliminary model.</td>
<td>Benefits and burdens of oncology research participation.</td>
<td>Detailed presentation of recruitment and data collection processes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Benefits and burdens of oncology research participation.</td>
<td>Research assistant collected the data; no discussion on his/her training in data collection Short (20 minutes) audio-recorded interviews; transcribed verbatim</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Benefits and burdens of oncology research participation.</td>
<td>Saturation of data not discussed</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Benefits and burdens of oncology research participation.</td>
<td>An independent reviewer confirmed an inductively developed coding system; enhancing the interpretive rigor of the findings</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Benefits and burdens of oncology research participation.</td>
<td>Use of interpretive content analysis strategy used; appropriate quotes supported data interpretation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Benefits and burdens of oncology research participation.</td>
<td>Study contribution - improving the consent process for research through accounting for parental experiences of children involved in clinical research</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Benefits and burdens of oncology research participation.</td>
<td>Detailed description of sample characteristics, recruitment, data collection processes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Benefits and burdens of oncology research participation.</td>
<td>Clear statement about reaching data saturation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Benefits and burdens of oncology research participation.</td>
<td>Audiotaped interviews; transcribed verbatim</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Benefits and burdens of oncology research participation.</td>
<td>Use of two independent coders and expert reviewer debriefing along with the post-interpretation member checking to ensure credibility and completeness of the interpreted data</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Benefits and burdens of oncology research participation.</td>
<td>Use of multiple quotations support data interpretation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Benefits and burdens of oncology research participation.</td>
<td>Although the maximum variation purposive sampling strategy was used, the results offer uniformity of perceptions on different factors</td>
</tr>
</tbody>
</table>
Study contribution – promoting understanding of the consenting process through appreciation of the benefit-burden balance of human research participants who consider taking part in clinical research.

Characteristics of the quantitative studies. Polit and Beck’s (2012) *Guide to Critique of a Quantitative Research Report* was used to review the five quantitative studies. It provides a structured guide with a template of key questions organized into five subsections for systematic assessment of all major aspects of a scientific report. The five subsections are: 1) introduction (problem statement, research purpose and questions, literature review); 2) methods (ethics; study design, setting and sample; data collection and measurement; 3) procedures/ interventions; 4) results (data analysis, findings), 5) discussion (implications, recommendations); and other comments. Each of the reports reviewed clearly stated the research purpose, and justification for the proposed study by illustrating the scientific background and the gap in the literature. Only two reports (Cohn et al., 2011; Shelton et al., 2015) explicitly described their conceptual frameworks that guided the study design in terms of the development of the tool/intervention and data collection procedures. All but one report (Chang, 2008) included a statement that the relevant ethical committee approved the research study. Two out of five reports (Barrett, 2005; Larson & McGuire, 1990) presented the consent procedure. In these studies, a completed questionnaire represented consent to participate in the study. The evaluative study overview for the quantitative research reports is presented in Table 7.

**Table 7**

*Evaluative study overview for quantitative research reports*

<table>
<thead>
<tr>
<th>Study</th>
<th>1. Study purpose</th>
<th>2. Key outcomes related to the review aim</th>
<th>Evaluative Summary</th>
</tr>
</thead>
</table>
| Barrett, 2005  | 1. To assess informed consent understanding. | 2. The level of understanding of information R&B of the | • Measurement of the knowledge of the informed consent elements by assessing the recall of this information within two weeks from the consent encounter  
• No discussion on the target sample size and its calculation |
<table>
<thead>
<tr>
<th>Study</th>
<th>1. Study purpose</th>
<th>2. Key outcomes related to the review aim</th>
<th>Evaluative Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Use of a valid QuIC measure to assess objective and subjective comprehension of the informed consent selected elements</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Data collection from one medical center using a self-administered questionnaire</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>No discussion of the target sample size and its calculation</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Clear definition of census sampling strategy</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Sample of patients who had a prior experience in clinical research responded to the questions related to the informed consent process</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Survey response rate: 50%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Authors’ recommendation for more personalized approach of information delivery during informed consent is needed, specifically emphasizing the need to provide additional information about R&amp;B of the research study</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Clear presentation of the recruitment procedure, reasons for non-enrollment and withdrawal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Random assignment from one medical center to the intervention (education module in addition to sample consent form) and comparison (sample consent form) groups of the post-test only experiment</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>No discussion of confounding factors e.g., participants’ general knowledge and prior participation in research that might influence how they performed on the test</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Post-test questionnaire items that examine R&amp;B are limited to a proxy consent process and to checking on general understanding only of the consent requirements</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Tool designed to collect observational data of the actual informed consent encounter rather than participant recall of the encounter</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Tool with a high degree of both internal consistency and test-retest reliability (Table 5); mostly examined in a simulated environment</td>
</tr>
</tbody>
</table>

**Synthesis of the Qualitative and Quantitative Review Findings**

The studies evaluated were diverse regarding the research methodology, settings, and types of outcomes. The heterogeneity of the review findings resulted in the selection of a data-
driven thematic analysis approach to combine and summarize review outcomes as suggested elsewhere (Dixon-Woods, Agarwal, Jones, Young, & Sutton, 2005). From the reviewed 12 studies, the research focus areas can be classified into three risk/benefit communication categories: 1) examining sources of harm and benefits of research participation, 2) assessing and assuring the quality of the messages, and 3) exploring attitudes towards consent process for clinical research. Figure 2 provides a schematic model of the findings.

**Figure 2.** Schematic model of the systematic literature review findings.

**Examining sources of benefits and harms of research participation.** The majority of studies reviewed (n=8) emphasized the importance of understanding of the personal risk-benefit
balance made by people considering study participation. The researchers emphasized that this information is critical to make an informed decision. They also conclude that this information be addressed when designing and planning a consent discussion with potential human subjects.

All the studies found that the anticipation of good for the individual, and for society, were important benefits of research participation. Some studies (Butler, 1996; Pletsch & Stevens, 2001b) found that personal benefit was favored over social benefit. Some references supported this category by identifying benefits including maintaining a hope for patients (Cox, 1999; Moore, 2001), exposing to a new (Cox, 1999; Pletsch & Stevens, 2001b; Ulrich et al., 2012) or high quality treatment (Moore, 2001) and free medications (Ulrich et al., 2012), receiving treatment by experts (Cox, 1999), and having follow up and close monitoring of a health condition (Pletsch & Stevens, 2001b; Thomas & Menon, 2013; Ulrich et al., 2012). Other findings show that research participation makes people feel better about themselves and their lives. Research participation has been described as something that brings order to everyday activities (Moore, 2001), provides a life purpose and place of acceptance (Cox, 1999), contributes to a sense of self-accomplishment (Ulrich et al., 2012) and improves quality of life (Chang, 2008). Interestingly, Ahern’s (2012) study showed that potentially distressful interview questions were described by some as a beneficial experience.

Research related risks and burdens were found to heavily influence the consent process in some cases (Thomas & Menon, 2013), while in others, risks played a minor role in decisions about research participation (Butler, 1996; Pletsch & Stevens, 2001b). In the latter studies, the decision was mainly based on the bond of trust between the research-physician and patient, which led patients to avoid a thorough review of the risk information. Experimental treatment toxicities, side effects, and additional pain (Chang, 2008; Cox, 1999; Thomas & Menon, 2013;
Ulrich et al., 2012) were perceived as harmful experiences by many. An overall sense of additional burden was felt by research participants in terms of their daily routine (Cox, 1999; Pletsch & Stevens, 2001b) and quality of life (Chang, 2008) as well as in economic, familial, and educational spheres of life (Ulrich et al., 2012). Moreover, psychological harms accompanying research participation included a fear of loss of control, a sense of uncertainty (Ulrich et al., 2012), and increased stress and anxiety (Thomas & Menon, 2013). Some people also feared that trial demands would become unbearable over time (Cox, 1999), while others were concerned about feeling isolated or abandoned after trial completion (Cox, 1999; Moore, 2001).

Unrealistic expectations from research participation and false hopes for a cure were reported as negative outcomes by a sample of research nurses in Chang’s (2008) study. In addition, Chang (2008) displayed a unique account concerning R&B of working with phase I trial participants by nurses. Viewing themselves mostly as patient advocates and educators, half of these nurses felt an ethical conflict related providing false hope for patients. Also, nurses indicated that their workload is more stressful and intensive as opposed to nursing activities in a pure treatment setting. Other nurses reported benefits of their work with research participants, viewing it as a satisfying and prestigious activity that offered an additional treatment option to people. In their qualitative inquiry, Ahern (2012) found that participants were concerned about two potential harms to themselves: first, the potential for a confidentiality breach and second, the perceived threat from the member checking process.

Assessing and assuring the quality of risks and benefits messages. This category describes possible ways to measure and improve the quality of communication with potential research participants. The three studies in this category indicated that assessment of the level of
comprehension of R&B information could identify areas for improving participant knowledge and understanding (Barrett, 2005; Cohn et al., 2011; Shelton et al., 2015).

Barrett’s (2005) study found that while participants understood that the trial provided no prospect for direct medical benefits, half still did not understand that the trial could pose additional risks to them. The tool used in this study, the QuIC tool, evaluates subjective and objective levels of understanding globally, but does not assess understanding of specific trial details. Comparing outcomes of perceived comprehension with the participant’s actual knowledge could help to identify deficiencies in the individual’s consent education.

Cohn and colleagues (2011) presented a new observational tool where the rater measures the quality of sharing the information about risks, discomforts, side effects, and benefits of research participation. The added value of this tool is that it also assessed what the professional did to ensure participant understanding of the information. These items, as they appear in the tool, check if the consent administrator “stops and answers questions during the interaction” and “asks participants to explain the study in their own words.” Although of value, the teach-back method measured general understanding rather than understanding of specific study-requirements and personal implications of participation.

Shelton and colleagues (2015) focused on another approach, the effectiveness of a computer-based education module in enhancing understanding of the informed consent elements by a proxy person. Participants in this study’s experimental group had a greater understanding that the research might not have direct benefits to them, but might benefit others, and the potential risks of the study must be disclosed to them. Similar to Barrett’s study, neither of the questionnaire items were designed to check understanding of specific R&B, nor the quality of the communication process.
Exploring attitudes towards consent for clinical research. This category illustrates that when patients were asked what they want to be informed about before deciding to take part in a research study, the information about R&B was listed as the most important, along with the study purpose and the expected patient’s involvement (Larson & McGuire, 1990).

Discussion

This is the first study to provide a systematic account of nursing research focused on communication of the R&B of participation in clinical research.

Strengths and Limitations of Review Methodology

As previously reported (Molassiotis et al., 2006), it is a challenge to identify nursing research in the electronic reference collections. A strength of this review is that it provides a detailed description of the generic search strategy used to locate nursing research published in CINAHL and MEDLINE. This description may be beneficial to other researchers involved in health care or research and interested in finding a published nursing research study. An additional strength of this review is the use of a uniform tabulated format to describe the characteristics of the reviewed studies (see Tables 4, 5, 6, 7), allowing for more effective review and appraisal.

Another strength of this review is that its conclusions are drawn from different types of research, integrating results from both quantitative and qualitative studies into a “mixed research synthesis” (Sandelowski, Voils, & Barroso, 2006, p.29).

A potential limitation of this study is use of strict inclusion criteria that may have limited the robustness of the review process. In addition, some methods and sources of citation searching were not used, such as identification of non-English-language articles and the “gray literature,” (e.g. unpublished research reports, dissertations, and theses). Restricted time and resources
precluded using these methods and sources, which may have introduced a level of bias into the findings by possibly missing relevant publications. In addition, some nurse-led original research could have been overlooked due to variation in listing authors and their roles in the study. Despite these limitations, this report provides a current representation of nursing research evidence.

**Discussion of the Results and their Implications**

This systematic review synthesized data from 12 original nurse-led research studies, identifying and presenting major areas of nursing research regarding communication of R&B in the research consent process. The methodological quality of the studies was found mainly to be adequate despite small sample sizes in some studies.

The reviewed studies concentrated mainly on the exploration of possible sources of the R&B as perceived by the research participants or their proxies. These assessments of the views and opinions exemplify how individuals may balance the R&B for themselves in deciding on research participation. Careful consideration should be given to determine what information to share with the potential research participant. Research ethics standards require that informed consent documents provide clear information about R&B for the research participant (45 C.F.R. §46, 2009). Therefore, revision of the informed consent process for ongoing or future research recruitment in similar studies should consider the revealed participants’ experiences perceived as beneficial or harmful to them, and should also be considered in regulatory agency requirements for clinical research such as Food and Drug Administration and individual IRBs. The proposed approach relates to the ongoing regulatory changes of the Common Rule. The aim is to ensure more meaningful consent process through presenting relevant “and appropriate details about the research” (Federal Register, 2015), such as possibly private experiences of the individuals
involved in the study. Also, the suggested approach is directly applicable to the currently promoted paradigms of patient-centered communication and a shared healthcare decision-making model. The importance of the participant’s views of sources of harms and benefits of research participation requires expanded investigation beyond the specialty areas examined by studies in this review sample, which included predominantly oncology research.

The three reports included in the category of nursing researchers who conducted studies to assess the quality of the delivery of the informed consent focused on two elements: Effectiveness of the informed consent communication process and general understanding of the consent information by the individual. Given the importance of the issue, it is not surprising that numerous studies led by other health professionals have also dealt with the appraisal of the quality of the consent process (Guarino, Lamping, Elbourne, Carpenter, & Peduzzi, 2006; Miller, O’Donnell, Searight, & Barbarash, 1996; Sugarman et al., 2005; Wendler, 2004). One of the reviewed studies used a validated tool, but it only included eight participants in the sample (Barrett, 2005). The other two reports (Cohn et al., 2011; Shelton et al., 2015), developed original measures of the quality of the consent procedure, however, they did not refer to any specific study R&B that participants might consider prior to completion of informed consent. It is worth noting that unlike all other investigators who used post-consenting interviewing to evaluate the quality of the consent process, Cohn and colleagues (2011), assessed the consent discussion by using systematic observation of the actual consent encounter in real time, evaluating the communication skill of consent administrators’ based on a predefined structured measure. The evidence presented in this category of nursing research clearly demonstrates the need for further empirical research to develop and examine ways to measure an understanding of the specific harms, discomforts, and benefits of research and their chances of occurring.
An additional issue that was identified in this review is there has been a very limited effort to present research nurses’ opinions, attitudes, and practices of disclosing the R&B of research or to include their views in the discussions about related issues in the informed consent process. None of the reviewed nursing studies explored the actual communication procedure and strategies used to convey R&B information by nurses. The reviewed studies primarily focused on examining research participants’ views and experiences with little recognition of the opinions of nurses who are active partners in the consent encounters. As a result, the understanding of the views of nurses who provide this information to potential research participants is inadequate.

As an established leader in nursing research, the American Association of Colleges of Nursing emphasizes that nursing research should be ingrained at every level of nursing professional activity (AACN, 2006). Extensive involvement of nurses in clinical research, specifically in research enrollment activities makes this an integral part of today’s professional nursing practice. As the nursing research discipline expands (American Nurses Association, 2015) and nurses are more engaged in leading research studies, there is a need for greater involvement of nurses in researching informed consent.

Nurses are recognized as providers of holistic care and, as such bring a unique perspective and perhaps a better understanding of the research participants and their needs, considering the entirety of the physiological, psychological, and sociological implications of participation in a study. Furthermore, the interaction with patients is considered as a “natural environment” for nurses, as noted by Grady, the director of the National Institute of Nursing Research (Brown, 2010). In this sense, nurse researchers are well positioned to conceptualize and develop studies to further understand personal interaction and communication processes central to the consent discussion. Given this, nursing research about the R&B of research participation
could further define barriers and improve the standard of communication in the informed consent process.

Future nursing research should be conducted on the process of communicating R&B of participation in a research study. Key foci of studies are needed to understand and present nurses’ views on the provision of risk information and to describe nurses’ current performance and practices related to this communication process. Future research can further identify risk communication strategies that facilitate prospective research participants’ understanding of critical information needed to make an informed decision. Studies are also needed to demonstrate the value of the nurse’s role in terms of the impact on the quality and outcomes of the consent encounter. Finally, future interprofessional research is needed to develop and test strategies to facilitate effective R&B communication with quality performance and patient advocacy as the center of the research endeavor. These proposed research directions should be of interest to: academics in designing risk communication models; investigators in choosing how best to deliver risk-related information to help with decision-making; and administrators and regulators in developing guidelines to support the use of effective ethical research standards.

Conclusions

This systematic review contributes to an enhanced understanding of the extent of nursing research related to the communication about the R&B of research participation during informed consent encounters and suggests areas for future nursing research. There is limited nursing research evidence assessing the process of R&B communication. Although the 12 reviewed studies investigated important aspects of research consent, the number of nurse led studies, and the breadth of perspectives examined, are inadequate on this important topic.
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CHAPTER THREE

Communicating Risks and Benefits in Informed Consent for Research:

A Qualitative Study

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Abstract

Multiple studies have documented severe limitations in the informed consent process for the recruitment of research participants. One challenging aspect of this process is successful communication of risks and benefits (R&B). Seventeen personal semistructured in-depth interviews were conducted with experts in informed consent who hold a variety positions in the field of clinical research and protection for human subjects. Experts’ attitudes and perceptions regarding strategies used in conveying the risks and benefits of research to potential research participants were documented. Inconsistencies in opinions, and critique of certain widely used communication practices, necessitate further consideration and research. A set of core themes and subthemes from this study informed the development and design of a survey about the perspectives of research nurses.

Keywords: risks and benefits; research, clinical; informed consent; interviews, semistructured.


**Introduction**

Informed consent (IC) for clinical research requires good communication of study risks and benefits (R&B) so that potential research participants can decide whether or not to participate (21 C.F.R. §50, 2012; 82 FR 7149, 2017; ICH, 1996). Communicating R&B information ineffectively stands in the way of the ethically appropriate consent. Effective communication of R&B is a key feature of quality IC. Research professionals who seek the IC are expected to convey this information in a clear and unambiguous way, adapting “the presentation of the information to the subject's capacities” (National Commission, 1979, Part C, para. 8) and ensuring its comprehension.

In recent years, several approaches have been suggested to facilitate communication of IC information. Guidelines for the simplification of the language of IC forms were proposed (AHRQ, 2009; NCI, 2013; Paasche-Orlow, Taylor, & Brancati, 2003). Methods for conveying numerical probability expressions of risk were developed and tested showing improvement in research participants’ understanding of risk information (Cabeeza, Ramisetty, Thompson, & Khan, 2005; Fagerlin, Zikmund-Fisher, & Ubel, 2011; Ulph, Townsend, & Glazebrook, 2009). The Agency for Healthcare Research and Quality (AHRQ) (2009) published general recommendations on how to enhance the IC process. For example, the AHRQ informed consent toolkit suggests methods for improving the IC process, such as reading the IC form with participants, asking them to repeat study information in their own words, using open-ended questions to assess comprehension of the main consent messages, and encouraging the potential research participant to ask questions.

Despite of these requirements and recommendations, studies show that many research participants still feel under-informed about study risks, discomforts, and/or benefits (Koh, Goh,
Yu, Cho, & Yang, 2012; Montalvo & Larson, 2014) nor has there been routine evaluation of participant comprehension (Brown, Butow, Butt, Moore, & Tattersall, 2004).

The aim of this qualitative study is to explore the attitudes, opinions and perceptions of experts in IC and clinical research about current R&B communication in the consent process. We believe that this first systematic analysis of experts’ views of the consent process will shed additional light on the current challenges in this process and possibly provide greater understanding and better solutions. The opinions and attitudes provide important insights about the quality of the IC process and can be used to generate items for future surveys to assess research nurses’ attitudes and practice regarding R&B communication while seeking consent to a clinical trial.

**Methods**

**Study Design and Sample**

A qualitative descriptive study design based on semistructured, open-ended individual in-depth interviews was used to complement literature review findings for the development of a future survey. Then a semistructured format provided a common framework for all interview encounters. The descriptive end product included near-data detailed interpretations of the explored conditions (Sandelowski, 2010).

To capture a diversity of perspectives, a nonprobabilistic, purposeful maximum variation sampling technique was used to select individuals for the study sample (Creswell, 2007). The inclusion criteria were demonstrated IC expertise and the consent to be audio-recorded during the interview. Expertise was defined as any combination of the following: (a) publications in peer-reviewed literature, current research activity in clinical area, presentations in national and international scientific conferences and (b) currently serving on an Institutional Review Board
(IRB) committee. The inclusion criteria provided the highest potential to identify individuals who encounter the subject matter from different angles and positions, therefore augmenting the possibility to capture maximum variation in opinions and attitudes. There were no exclusion criteria for participation in the study.

The lead investigator (LN) identified potential interviewees, recruited, and verified their eligibility. These key informants were identified through the review of the literature and from meeting individuals presenting at conferences on the topic of human subjects’ protection. The lead investigator also conducted and analyzed all the interviews. Of the 17 individuals invited to participate in the study, all agreed to be interviewed. Recruitment of individual informants stopped once data saturation was achieved. Saturation was achieved when interviewing additional informants did not add new information, which was determined when the ideas provided by the informants were repeated in a number of cases (Richards & Morse, 2007).

The study sample (n=17) was mostly female (n=14, 82%) with a mean age of 54 years (range 28-70 years). The majority (59%) were nurses (n=6, 35%) or physicians (n=4, 24%); others were clinical psychologists (n=2), research assistants (n=2), a lawyer-ethicist, a health educator and an IRB administrator. All informants were based in the USA. The mean length of primary professional experience was 26 years, with 18 years of experience, on average, related to conducting clinical research. Seventy-five percent of all informants had prior experience in research IC; all but one had trained others to obtain consent. Most informants were currently employed by academic institutions (n=15, 88%), one worked for the federal government and one for a non-profit organization. The informants represented a number of overlapping clinical research related roles, such as principal investigator, data collector, regulation or IRB member, and research nurse.
Data Collection and Analysis

Interview procedure and ethical considerations. The interviews were carried out in English from October to December 2013. They were held at a pre-arranged day and time in a private place at the convenience of the informant. Thirteen individuals were interviewed in-person and the rest four interviews were conducted over the telephone. The interviews took on average 65-minutes (range 40 to 150 minutes). All interviews were audio-recorded and transcribed verbatim with informants’ written permission. In addition, memos were completed immediately after each interview. These records supplemented interview data by noting the date, time, and location, along with notes of the ideas and new insights related to the responses and interview procedure. Informants were not paid for their time; however, each informant was offered a copy of the final report of the study.

Written consent was obtained by the investigator before each interview. After the potential informant read the IC document, the investigator reviewed it with them, and asked if they had any questions. Once satisfied that all concerns had been discussed, the potential informants were asked to sign the consent form, with each informant receiving a copy of the signed consent form. Phone interviewees signed the consent form electronically.

The study protocol and the IC form were reviewed and approved by the Northeastern University IRB.

Interview protocol. The interview protocol included several predefined open-ended questions, see Table 1. The literature review and three pilot interviews, conducted by the lead investigator, were used to develop the study’s interview questions qualitative codebook. New in vivo codes and categories were added as they emerged through the process of close analysis (Saldaña, 2016).
Table 1
Exemplars of Interview Questions

Example Questions

- From your experience and/or knowledge, how is information about R&B of research communicated to potential research participants?
- What do you think is the best way for members of the research team who seek IC to convey information about R&B?
- How would you define / describe effective communication about R&B of research participation to potential participant?
- What don’t you like about the current process of communication of R&B?
- How can confirmation of the understanding of R&B be done effectively?
- How do you think a practitioner should be prepared to adequately discuss R&B of research with potential participant?

The interview protocol was used more as a conceptual guide across the topic domains generated for this study. During the interview, LN personalized the question order, adding various questions and probes depending on the responses and from insights gained from previous informant interviews. The questions were designed to assist informants to consider the issues in a critical manner. For example, they were encouraged to share their visions for communication practices that work better than others and also to reflect on whether current required training in IC adequately addresses the R&B communication process. At the conclusion of the interview, informants were invited to complete a short form, answering several background questions, such as basic demographics (age, gender), primary profession, length of clinical research experience, practice setting, and perceived proficiency pertaining to clinical research conduct and protection of human subjects. An overall scheme of the data collection and analysis processes is presented in Figure 1.

![Data Collection and Analysis Flow Chart](image-url)
**Qualitative analysis.** All verbatim transcriptions from structured interviews underwent thematic analysis using Qualitative Data Analysis Miner v.4 software (Provalis Research, 2011). The software application assisted with efficient data storage and coding procedures (Creswell, 2009).

The interviews were coded and analyzed prospectively. This iterative approach helped to further develop and modify the coding system and determine when saturation was reached. Notes reflecting on the process and documenting ideas about the evolving themes were made during the process and these records were later integrated into the final report of the study (Creswell, 2009; Miles, Huberman, & Saldaña, 2014).

The transcripts were coded both deductively and inductively, using a “hybrid coding” analytic approach (Saldaña, 2016, p.75). Several pre-determined categories, informed by the study aim, guided the initial coding process and facilitated the organization of the materials by increasing its efficiency (Guest, MacQueen, & Namey, 2012; Miller & Crabtree, 1994). Some of the predefined categories in this study were: actual communication strategies of R&B information, and preparation and training of consent administrators. Additional codes were added to the analysis as the interviews proceeded.

The coding was done in several iterative steps as described in Figure 2. Initially the entire transcript was read for an overall sense of the data. In an attempt to describe and interpret the data, the text was summarized with codes, providing a codes report. After the initial coding of long texts of verbatim data, expressions with similar meaning along with an immediate part of the context and reference (informant’s identifying code), were compiled together into categories through classifying and integrating coded units of the data (Saldaña, 2016). Doing constant inter-
and intra-categorical comparison increased sensitivity to new categories that emerged from the data.  

![Diagram showing qualitative data analysis procedures](image)

**Figure 2. Qualitative Data Analysis Procedures**

The final results are classified as a thematic survey, similar to Sandelowski and Barroso’s (2007) typology of qualitative findings. This typology addresses the “degree of researcher transformation of data” (2007, p.140). The transformation of the data represents the actual intellectual work that is done to impart a “latent pattern” in the data. The qualitative categories were further analyzed to identify repetitions and possible relations or patterns in the data, which were compiled into the overarching themes. The results of the qualitative analysis were also used to formulate statements and response alternatives for a future survey on perceptions and experiences of research nurses regarding the communication of R&B. Conclusions from this analysis were documented in the final descriptive summary, presenting themes and main points from the code report with verbatim quotations from the informants to exemplify the discussed point.

**Data Rigor and Credibility**

Rigor was achieved through several features in the study design. The verbatim transcription accurately captures the words of the informants. Only one person, the lead investigator, collected and transcribed all of the data. The investigator’s involvement in a project as early as the conception stage makes her the most knowledgeable person about what data can
address the best study aims. Another expert in qualitative research methods was consulted across all aspects of the study to ensure adherence to the study design.

Coding was conducted in a systematic manner. Any changes in codes and code definitions, their justifications and causes, as well as any other analytic decisions, were documented, contributing to the transparency in the interpretive process. To ensure credibility of the final conclusions drawn from the data, conclusions were verified by returning to the interview text to evaluate related explanations, making certain that the findings were anchored in sound evidence.

During text analysis, reliability checks were conducted. The coding process was performed twice, each time starting with the raw data and then comparing and documenting the findings. Constant comparison of the data with the code definitions assured stability of the code meaning. The excerpt from the coding scheme appears in Table 2. An expert in qualitative research methods reviewed and examined the qualitative codebook and coding application to the data to assure clarity and stability.

**Table 2**
*Exemplars from the Coding Scheme*

<table>
<thead>
<tr>
<th>Code Label</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Experience</td>
<td>Informant’s experience with the IC process for clinical research</td>
</tr>
<tr>
<td>Success</td>
<td>Communication strategies and practices during IC procedure perceived as successful by informants</td>
</tr>
<tr>
<td>Understanding</td>
<td>Relates to the activities and procedures for establishing comprehension of the discussed consent information to the potential research participant</td>
</tr>
<tr>
<td>Training</td>
<td>Training activities performed to prepare consent administrators for their role</td>
</tr>
</tbody>
</table>

**Results**

Three themes and several subthemes were derived from the key informant interviewees as identified in Table 3 and described in the following paragraphs.
Table 3
Descriptive Coding Scheme Developed to Classify Informants’ Utterances.

<table>
<thead>
<tr>
<th>#</th>
<th>Theme</th>
<th>Subtheme</th>
</tr>
</thead>
</table>
| 1 | R&B communication: process and strategies | a. The IC form and its delivery  
   b. Conveying probability of the R&B  
   c. Using presentation means and supplemental materials  
   d. Reading aloud  
   e. Summarizing and highlighting information  
   f. “Take it home” procedure |
| 2 | Assuring comprehension of the R&B information | a. “We have to ensure they understand”  
   b. Current and recommended practices |
| 3 | Consent administrators - preparation for the role | a. Controversial assumptions  
   b. IC training requirements  
   c. Training - local initiatives  
   d. Envisioning training in IC |

Theme 1 - R&B Communication: Process and Strategies

a. The informed consent form and its delivery. Informants in this study noted that in general, the research community is making efforts to improve the effectiveness of the consent process. However, some informants felt that the current consenting process is not as effective as it should, “I don't think we do a better job explaining consent.” Another stated: “I think it's clear [that] what we are doing now doesn't work and doing more of what we do now is not likely to work any better.”

Some informants believed that improvement has mainly come through simplifying consent forms, for example, by using plain language and an appropriate level for potential participant language. Other informants noted that improving the consent process is about more than creating consent forms in simple sentences. Many expressed concern that current major efforts to improve the IC process is limited to form changes. “We can tweak these consent forms to death, but I don't really know if we know how to explain [R&B] that well.” The preoccupation with the consent form wording might mask a more problematic, but less controllable or enforceable components of the consent encounter. This refers to the process of delivery of the consent information to the potential research participant; the ways and words in which the professionals actually explain it.
So, I would say like this - the consent forms themselves it would be cynical not to make them better, but that's not enough, even the very simple document and easy to understand, and easy to use, easy to read, is meaningless if the process doesn't support it. So, really it has to be connected with a process that make sense and supports the goals of having substantively informed people choosing to be in [research] projects.

Additional concerns were raised specifically about the process of communication of risk information. Some informants shared experiences of describing and explaining risks in simpler terms:

It's hard to figure out how to do this [to simplify risks related information]. Legal department is not going to allow you to simplify those sections [concerning R&B]…at least you should be able to simplify the purpose of the study and the procedures, those areas that are more under the control of the investigator.

Informants expressed their concerns over professionals failing to present the information in a meaningful manner to potential participants. They also noted the lack of the generally accepted or standard procedure of delivering this information during the IC encounter.

You know, we have really lousy, lousy ways of explaining it [risks] and people don’t understand anything. Somehow, we do have trouble of sort of putting risks in an appropriate category for the patient. Like these are important risks, these are not very likely to happen, these are not important, there is some risk we don't know; there is always risk you don't know.

b. Conveying probability of R&B. Informants’ opinions differed on the best ways to convey the probability of experiencing positive or negative effects of participating in the research. They ranged from a focus on numbers to a focus on verbal descriptors.

Some informants believed that it is important to provide research participants with the precise numbers, such as percentages. They argued that, in this evidence-based era, there is an expectation to “give [research participants] some objective data rather than being subjective” and “[we should] encourage [investigators] to break [risks] out by likelihood, and list the things.”
Another informant stated that she would make sure to “put all the numbers that are available both for the benefits and the risks.” Another informant found it difficult to talk about possible harm when its chance of occurring is not known.

One informant suggested numerical information should be included in the supplemental materials only and provided to people who are interested in this type of data. This informant explained that “some mechanism [is needed] for giving basic information, essential information for all subjects…and then for those who want more, those who want the statistics and who want some other details, provide them with that.”

Other informants felt that when using numbers, a verbal description should always be provided to “… somehow define what those [numbers] mean.” Also, they noted that there is a need for guidelines that identify effective communication techniques for the appropriate disclosure of numerical data. “There are some people that do better when you describe things in non-numerical terms.”

Several informants did not support the use of numbers during the consent encounter. They believed that numbers were not as helpful or understandable as some might think they are. They also argued that the number itself does not say anything to the individual about his/her personal risk and is not necessary in the consent discussion. Some informants suggested that only verbal expressions should be used to describe and explain chances of all the potential harms and discomfits of the study.

When [research participants] see…statistics, the percentages, they skip that paragraph…they don't read [numbers]. Because people are innumerate, as they say…people can't assess risk… ‘You gonna feel weak, and you probably will have tingling in your fingers’… 25%? 10%? Who cares?…[research] subjects are not scientists…and they shouldn't be treated like scientists.
c. Using presentation means and educational materials. Most informants noted the importance of presentation methods to enhance R&B comprehension and to assist with potential research participant’s decision-making, such as tables or pictographs, and supplementary educational materials, such as brochures. Adapting the presentation of R&B information to the individual’s capacity by combining different explanatory strategies would possibly improve its comprehension. “You want to show it, say it and have people read it - three different ways of doing it.”

The majority of the experts viewed presentation methods as a relatively new “up-and-coming technique in getting informed consent,” mentioning that some institutions are “starting to encourage people to [use] charts… [and other] visual aids instead of just wording.” However, few of the informants had used graphics themselves. Their impression was that this type of communication aid is rarely used by others in the research field to support the R&B communication and the IC process.

Some informants assumed that this practice is probably limited due to the lack of valid and approved materials. One informant noted that the rare use of educational aids is “mostly because who is going to develop those supplemental materials, you know whose responsibility is it to develop them; and will our IRB allow it?” One informant noted that any additional materials would only add another layer of complexity to the consent process and would not be as helpful as people expect. “I am not sure a pictograph can work because of the amount of information in the informed consent.”

In addition to using presentation aids during the consent meeting, one of the informants suggested developing a kit with graphics and pictorial explanations. This kit for supporting reading comprehension of the information and assisting with the decision about research
participation has to be IRB approved for use along with the consent form. After the consent discussion, potential participants may be given a copy of the kit along with the consent form.

d. **Reading aloud.** A commonly used IC communication strategy is reading aloud the consent information for the potential research participant. This is performed in addition to providing the written consent form. One informant suggested that this strategy should be used in all instances, because “we just assume that [research participants] won't read [the consent form].” Other informants preferred to given participants a choice.

If I'm not certain about a person's reading level, I'll ask them how they like to get their information. Do they like to read it themselves? Do they like to someone to read to them? Do they feel like they're a slow reader or a fast reader? So, I put it in such a way… and I say, because I'm happy to read it to you, and I always say that. And many patients that can't read will always say, please read it to me. They won't say they can't read, but they'll say, read it to me.

Some informants described drawbacks to the read-aloud approach. They witnessed consent encounters where potential research participants became a passive listener. The professionals read the entire form verbatim and did not stop to allow any comments or clarifying questions.

I have seen many people who simply read the consent form to the subject. They just read it through. Twenty pages they read it through. With very little additional explanation. At the end, they say: “Do you have any questions?” And of course, the person says “No” because they have no idea what they just heard, and then say “Okay, then, sign right here.”

e. **Summarizing and highlighting information.** Several informants discussed another common practice that involves giving an oral summary of the R&B sections. This summary is expected to provide major points, describe the main effects that the research participant might experience while omitting details that might not be seem relevant to the participant. This approach is thought to be more meaningful. “They [participants] benefit from it more if you
summarize each section; the most relevant and should be the instrumental information that they make their decision on.”

Informants elaborated on what information should be highlighted for the person who is considering research participation. In their opinion, only R&B that are most likely to happen or which are severe, should be included in the summary.

The most serious things or what is the most likely things should be highlighted… encourage people [consent administrators] to break them [risks] out by likelihood, and list the things… really try to focus the attention either on that which is most serious or that which is most likely.
There has to be some judgment on what the risks that are significant enough… some judgment in developing those informed consent forms about which risk to focus on.

f. “Take it home” procedure. There were varying opinions and attitudes about the “take it home” procedure. This procedure usually involves providing research participants with the consent form for “reading and re-reading and putting it under the pillow… and asking [the opinions of] friends and physicians” to assist with decision about study participation. Potential participants are given a copy of the consent form before or after the consent meeting, which they get in-person, via email, or by regular mail. Some informants argued in support of this commonly used approach. Research professionals who use this procedure believe that it provides individuals with more time to “read each and every word” and to “mark [the consent form] up and write all of their questions” and then “talk over the phone” or “come back again…if they have any questions.”

One informant, who trained consent administrators, shared concerns that research staff are not motivated to consider participants’ questions. One of her trainees said she “was relieved” when a potential participant “came back with no questions, because it's easier.” This informant
interpreted the trainee’s words as follows: “So, the idea is - let's hope you have no questions because if you're gonna have a lot of questions it's gonna take me more time.”

Several informants argued against the “take it home” approach. According to their experience, it does not serve the consent process well and people could not be trusted to really read the information provided in the form. One informant felt strongly that this “infamous” procedure “should not be used at all.” Another skeptic stated that:

Both the investigator and the doctors are busy and they will not do homework on research participants. But the consent process is trying to introduce homework for the subject…and we are assuming and hoping that the subjects will do this.

One informant questioned the effectiveness of this procedure because she does not “feel comfortable giving [participants] the [consent] form” believing that only a professional can convey the consent information properly. Most informants believe that people will not read the consent form at home. It is better to assume that nobody reads it and whoever asks for consent should always explain everything to all potential participants. One informant said “[Participants] won't read [the consent form]” at home “because it goes on and on forever, and [the participants] don't care.” The complexity of the consent form was also reported as a potential problem. “A lot of people use the take-it-home method, which I think is a really poor way of assessing people’s questions… because basically [the consent form is] an overwhelming document that I don't think many people will understand anyway.” He argued that the consent administrator has to go over the consent document details with the person, regardless of the use of the “take it home” strategy.

Theme 2 - Assuring Comprehension of the R&B Information

a. “We have to ensure they understand.” The prevalent impression by the informants was that individuals usually fail to fully appreciate the R&B when they provide consent. There is no confidence that an ordinary person could deal with all the extensive and often times complex
information. One of the informants confessed, “I assume that a large number of times when I use statistics, it falls on deaf ears, and nobody understands.” Others expressed discomfort with the process of assessing comprehension. “I have never specifically asked a patient ‘When I say 40%, can you tell me what that means to you?’; I have not done that. I think I feel that it could be taken as a sign that I’m disrespectful.”

Despite the above comments, all the informants unanimously agreed that people should participate in the research only when they are substantively informed about the study and have a good understanding of R&B. For many, the level of understanding indicated the level of the effectiveness of the consent discussion. Also, informants noted the importance of the usefulness and relevance of the conveyed information for the potential participant and his/her situation. They suggested the need to evaluate “how comfortable [the participants] felt…if they felt able to use it [the information] in making their decision…So, you can ask them, from their perspective, if it was helpful to them.”

An assessment of the R&B comprehension is a critical component of ethical principles and regulatory requirements for clinical research conduct. Therefore, informants believed that the consent administrator must “be able to engage the potential participant in understanding about the study.” However, they also believed that consent administrators “are not so good at making sure that the potential participant really understands.” A favorable outcome of this evaluation process is “…ideally, the person getting IC should be able to say at the end of [the assessment] - this person understands this study as fully as one can expect someone to understand.” One informant suggested that people should not be expected to remember “all of the detailed information [which] may not be that relevant,” but to focus on “demonstration that
they understand the gist of it, the main points.” There is a lack of consensus across informants on the range and depth of the information we should expect people to understand.

According to several informants, evaluating comprehension of the R&B is not routinely done, often depending on the specific situation. Some informants said they would do the checking, for example, when the conversation is not flowing. One informant explained that she assesses understanding “if I am struggling.” One said that “if you're skilled with communication, you need to have tools [to assess comprehension], and so if everything is going swimmingly, I don't need to use them, but in situations where I'm not so sure, then I need to use them.”

b. Current and recommended practices. There are two common ways of assessing comprehension of the consent form used in the field, according to the informants’ experience. One of these practices includes posing evaluation questions after completion of the entire consent discussion, such as “Do you understand what I said?” or “Do you have any questions about this?” Both questions were clearly perceived as “not helpful.” One informant criticized the second question explaining that the problem sometimes is “that [the participant] doesn't even know what questions to ask. Because you say, ‘Do you have any questions?’ and he doesn't even understand what you just said. So, how does he know what questions to ask?”

A second common practice refers to some implicit or intuitive ways of judging participant’s comprehension status, such as “just guessing by their questions that they understood” or “assessing them...from their nods of understanding.” In this connection, one informant commented, “the way that comprehension is assessed basically is the ‘gut’ of the researcher saying - well, I think [the participant] understood.” Another informant, who felt very confident in her intuitive capacities, explained:
I'm a very intuitive person, I try to read the body language and eye contact…but those aren't very objective measures, I totally understand that there are flaws in those methods, but personally I usually rely on things like that.

Some informants described additional ways to ensure R&B comprehension, such as by asking specific study related questions. In some instances, these questions are asked at the initiative of the investigators. In other cases, the questions are part of the formal requirements of the institution where the research is conducted. Two informants felt it was important to them to ask the following questions: “What are three things that I told you should watch out for in terms of risk? What are three things that are most important?” “What is the worst side effect that you could get?” Another informant shared a different approach. She said that for “one of our complicated studies” they developed and administered a study-specific 20 multiple-choice item questionnaire to potential participants. “After we went over the consent…I could assess how much they understood…if they missed any of questions…we would focus on that question and we'd explain it before we had them sign the consent form.” From this informant’s point of view, the questionnaire was “incredibly helpful” in ensuring comprehension, but also “doubled the length of the informed consent discussion.”

The most commonly recommended strategy to ensure and improve R&B understanding was by using a teach-back. As one informant stated - “we know it's the best thing.” This is a strategy where potential research participants are asked to relay the information they have been provided in their own words and then a professional “[tries] to assess their comprehension by what they're then saying back to you.” Teach-back was reported as useful for several reasons: “It tells what the [participant] himself is thinking and you have the opportunity to correct anything that wasn't correctly communicated.”
Despite the positive features of the method, it is not routinely used. Some informants noted that they are “not sure that [teach-back] happens” and “certainly not on a daily basis in a research.” One informant noted that even though the topic of teach-back is sometimes “mentioned in lectures” about consent, people are not trained to apply this method and develop appropriate skills.

To choose the appropriate timing for a teach-back, one informant suggested considering the complexity of the study protocol in the following way: “If it's a simple study with very low risk, I'd probably do the teach-back at the very end of the whole discussion. If it's a complicated study, I’d stop at the end of each section and do the teach-back.” Another informant supported this chunk-and-check communication strategy, regardless of the complexity of the delivered information.

Theme 3 - Consent Administrators - Preparation for the Role

a. Controversial assumptions. Several informants noted that normally, investigators believe that ICs for their study will be obtained appropriately, though they did not seek evidence to confirm this expectation. Also, investigators expect that professionals who were delegated the responsibility to obtain IC, “know how to do it,” are “able to engage the potential participant in understanding about the study,” and are “able to judge the level of comprehension of the person,” even though “there’s no way that… [these professionals were] tested about [their] proficiency in how to do it.” Some informants were certain that the issue of the consent information process is never brought up by the investigators in preparing their research team for the IC procedure.

So, in many studies where consent is being obtained by the project coordinator, or the research assistant, depending on the nature of the study, or co-investigators, who may be physicians, not a PI him or herself, how consent is obtained is often not discussed at all.
There is no explicit discussion of how to do [the disclosure of R&B]. I think it's just ignored... That question is just ignored.

Some of the informants criticized assumptions concerning the consent process made by the IRBs and other officials at the institution where the research study takes place. Institutions assume that the investigators they have hired have the skills needed for appropriate IC. Another informant noted that there is no systematic supervision on the way the consent procedure is actually performed which creates a dangerous situation where the lack of monitoring over the consent process leads to “people starting to cut corners, and it erodes the [consent] process.”

b. Informed consent training requirements. One of the major disappointments shared by the informants was insufficient training opportunities to support the development of skills of the research staff, including investigators themselves. “There actually is no training for physicians or research staff about how to do [IC] and in fact, the way that they do it is pretty crappy.” Other informants explained that IC “is learned by doing, there is no learning process in any official way.”

Informants mentioned that there are general requirements across the United States, which include taking “basic training on research ethics” to be on a research team that involves human participants. The two most common training requirements are completed online and directed by the National Institutes of Health (NIH) and by the Collaborative Institutional Training Initiative (CITI) program. The main issue about these programs is that they do not “provide skills.” The NIH and CITI basic training programs only provide “a basic kind of understanding of certain [consent] elements, but it's not sufficient…to help develop skills.” Another informant commented that “if it was like – ‘This is what you need to do in informed consent and this is how you best do it’ - then it would be useful.” Concerning training in risk communication, one
informant stated “I don't think anybody has any training in risk communication. That's true whether you are clinician, researcher, whatever. Nobody has training in risk communication...We simply don't know how.”

c. Training local initiatives. Informants described several initiatives that provide training courses and workshops in IC in which they took an active part in the developmental and operational stages. In some cases, attendance for these training programs was mandatory for individuals who want to work on research teams in their institution.

One informant shared that training at her work place used “role modeling and… videos… [of a] consent process that [research staff] observe and then [are] asked to rate the quality of the process.” Another informant said that she was a part of a group that developed a training module in IC for research coordinators in their facility. They developed a 40-minute didactic section describing the regulatory aspects and gave tips on how to lead an effective IC process. They also created several IC scenarios accessible online. Although there was positive feedback from the training participants, the training did not become mandatory. She also did not have “a good feeling for how many people take advantage of that [course].” Another informant described that in her academic research facility, the institution offered an hour-long monthly workshop on obtaining informed consent. At the beginning, it was a short lecture. Over time the workshop became more skills based. Workshop participants were required to bring their consent forms to obtain feedback from peers.

Training in IC for a specific study protocol is not standardized. “There are no standards for that, it's really…the investigator’s personal way of how they train individuals to do [the consent procedure].” Another informant investigator’s explanation helped to illustrate the previous point. She said that on her team, it is the duty of her project director to coordinate
training for the research staff. In this training, she described, “we first explain the study really well, and then… we do mock consents. So, we show them what it would sound like to be consented and then we ask them to do that back…That's my standard, as an investigator.”

**d. Envisioning training in informed consent.** Informants believed that every professional who is going to seek consent for research must undergo hands-on training in the IC process. “If your role in the study would be to do informed consent, to be listed on that study with that task…you have [to have these] additional educational requirements.” Another informant noted, “the training [in IC] really needs to be very much integrated into institutions that are consenting individuals at an ongoing basis.” She also recommended integration in terms of “any time you have a research project, there'll be an opportunity to continue with training staff.” One informant reinforced the need for the development of “actual skills related to informed consent and communication… skills development should require some simulation and feedback, where you actually practice and get feedback to people about how you're communicating.” Standard training should be provided by “someone who does it well” and who can document “[the research staff] expertise in doing [consent].” IC training should include guidance on “how do you compare and contrast standard treatment with clinical research, how do you explain R&B, how do you explain the rights of the patient, and how do you assess comprehension. All those things need to be tested.”

**Discussion**

The in-depth interviews with 17 key informants provided a unique opportunity to identify and describe various communication strategies that are currently in use. It allowed us to expand on related issues for discussion, considering the relative importance of the methods, the extent of their use and their effectiveness in the process of gaining ethical IC to research. In addition, three
major themes were identified: (a) communication strategies; (b) assessment of comprehension; and (c) preparation for the role of consent administrator.

Concerning the process of delivering R&B information, all of the informants underscored the need for encouraging the use of educational aids to facilitate understanding of this information. The interviews also revealed that there is an awareness among the consent administrators about several recommended practices. These practices include reading the information aloud for potential research participant, employing the “take it home” procedure, and conveying numerical information accompanied by an explanation of what these expressions mean. However, the informants criticized the way in which the “reading aloud” practice is commonly implemented and questioned the necessity and overall effectiveness of the other strategies in increasing the comprehension of the prospective participant.

The informants pointed to the “teach-back” as the most effective strategy for evaluating comprehension during IC encounter. This supports results of previous studies indicating that an assessment of understanding of the consent information has not been carried out routinely. This ineffective practice continues despite increasing emphasis on the value and the importance of potential research participant’s understanding as indicated by ethical guidelines. Furthermore, the most common way to assess potential participant’s comprehension, as indicated by informants, is by asking at the end of the consent meeting “Do you understand what I said?” This kind of question was referred as to the “worst question you can ask during the consent process” by Michaels (2011).

The informants also commented that the current mandatory training for researchers and research staff on human subjects’ protection, such as those run by CITI and NIH, are not intended to provide practical tools and skills necessary for conducting an adequate IC process. In
addition, local training programs that focused on the IC procedure are often isolated to a specific institution or single research team. These programs are mostly not mandatory and do not specifically consider the uniqueness and complexity of conveying R&B and their related uncertainties. Informants also emphasized that research professionals involved in the IC process are insufficiently prepared for carrying out their related duties.

There are potential limitations of this study related to its methodology that might restrict the transferability of its findings. The study results are rooted in the opinions and attitudes of the diversity of professionals who hold different roles and positions that surround clinical research. However, we were not able to discern salient inter-professional variations in perceptions probably because of the limited number of informants belonging to each professional category. In addition, even though the informant’s origin included ten states and numerous academic institutions, it is possible the voices of professionals employed in private research industry and from additional states could enrich the findings.

Seventeen expert informants’ opinions could be indicative of some of the contributing factors that are likely to lead to a poor quality of the IC process and communication of the R&B in particular. The prevalence and validity of such attitudes should be further examined eliciting responses from a larger number of professionals involved in the consent process. Future studies need to verify whether expert opinions from this study reflect current consent communication procedures and to determine whether the issues identified are broadly comparable to those faced by the consent administrators in the field. Accordingly, our next step in this endeavor is to use the results from this study to develop a quantitative survey. This survey will particularly focus on attitudes, training received and desired, and practices related to R&B communication strategies.
Conclusion

Qualitative interviews with experts in this study succeeded in generating an important discussion about communication strategies used in the IC process with the emphasis on delivering R&B to potential research participants. Inconsistencies in opinions, attitudes, and critique with respect to certain widely used communication practices should be a cause of concern necessitating further consideration and research. This qualitative study was essential for the development of a survey about research nurses’ experiences with IC process.
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CHAPTER FOUR

Research Nurses’ Attitudes and Practices Regarding Communication of Risks and Benefits
during the Research Informed Consent Process

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Abstract

**Background:** Many potential clinical research participants do not understand the risks and benefits (R&B) of the studies they are considering to join, despite communication strategies intended to improve disclosure of this key information during the informed consent (IC) process. Since research nurses are often involved in obtaining IC, investigating their attitudes and practices about communication of R&B can help identify ways to improve this important process.

**Objective:** To determine the self-reported attitudes and practices of research nurses regarding communication of research R&B to potential participants during the research IC process.

**Methods:** A survey was developed and then administered online to a national convenience sample of 107 research nurses with experience in obtaining IC for clinical trials. Univariate and bivariate analyses were conducted of survey responses, stratified by selected work related characteristics.

**Results:** The majority of research nurses (87%) reported using a teach-back method to assess potential research participant comprehension and almost three-quarters (72%) indicated that they often rely on their gut feelings as an indicator of understanding. About one-third reported they did not feel prepared to communicate statistics related to R&B in a clear way. About one out of five did not feel prepared to tailor R&B information to potential research participants’ needs and half did not feel competent using supplemental instructional materials to enhance comprehension of R&B information. Only 70% had received training in the IC process and the formats for that training included in-person training (84%), case studies (69%), online courses (57%), feedback during practice sessions (54%), simulation, such as a role playing (49%), and viewing videos of
the IC process (45%). Perceived preparedness to perform selected IC related tasks were significantly associated with greater IC related experience and training.

**Conclusion:** Although comprehension by potential research participants of R&B is an integral component of the research IC process and required by ethical and regulatory human research guidelines worldwide, our results suggest that research nurses may not have adequate training to encourage, support, and reinforce the communication of this information. We recommend that research nurses involved in the IC process be adequately prepared through purposeful education and training about R&B communication which also may help to improve and standardize the research IC process.

**Keywords:** informed consent, risks, benefits, research nurses, attitudes, practices, survey.
Introduction

Each year millions of people are enrolled in clinical trials worldwide. This immense clinical research effort is needed to inform evidence-based treatments, health practices, and policies. However, research participation introduces potential risk of harm. International ethical and regulatory requirements stipulate that research professionals need to discuss information about the study, including any risks, discomforts, and benefits, prior to obtaining informed consent (IC) for research participation (45 C.F.R. §46, 2009; CIOMS, 2016; WMA, 2013).

In recent years, research nurses have become increasingly involved in providing consent information and ensuring its comprehension by the potential research participants (Cresswell & Gilmour, 2014). According to the International Council of Nurses position statement “Nurses and Human Rights,” nurses are “obliged to ensure that patients receive appropriate information in understandable language prior to consenting” for research (ICN, 2011, p. 1).

Meaningful informed consent for clinical trials requires effectively communicating information that represent each of the essential elements of the study consent form (Cohn, Jia, Smith, Erwin, & Larson, 2011). Ensuring that a potential participant fully understands the risks and potential benefits of the study is imperative because this information can have a major impact on their decision to participate, or not, in a clinical trial (82 FR 7149, 2017).

Despite these clear requirements and expectations, results from many studies suggest that research participants do not sufficiently appreciate the R&B of the studies to which they agreed to join (Buchanan, 2013; Koh, Goh, Yu, Cho, & Yang, 2012; Montalvo & Larson, 2014; Rowbotham, Astin, Greene, & Cummings, 2013; Smith & Fogarty, 2016). This miscommunication of key information indicates unmet ethical standards and regulatory
requirements, a failure of the IC process, and possible exposure of participants to situations and conditions they did not want to take part in.

Providing comprehensive, accurate risk information is a difficult task. It requires informing individuals about the potential for unwanted effects from research involvement, giving a clear description about the nature and form of the risks, explaining the possible seriousness or severity of the effect(s) on the person, and also the chances that the harm(s) might actually happen to the individual (Ahmed, Naik, Willoughby, & Edwards, 2012). The description of chances or the probability of any event occurring has its own unique challenges. Several options exist to present this information. Probability communication can involve using numeric (e.g., percentages, frequencies), verbal (e.g., unlikely, rare), and/or visual (e.g., graphical) formats. The interpretation and perception of the conveyed risks by the study participant depends on several factors. For example, personal factors (such as age or fatigue), educational background, and statistical literacy might influence an individual’s ability to interpret numbers or graphical displays (Lipkus, 2007). As noted by Cadman and her colleagues (2014), the effectiveness of the risk message also heavily relies on the degree of preparedness and interpersonal communication skills of the professionals who convey this complex information.

In addition to the communication issues described above, various general communication strategies are suggested to help enhance the IC process. These strategies include, but are not restricted to, simplifying IC forms (Paasche-Orlow, Taylor, & Brancati, 2003), explaining concepts using plain language, reading aloud the consent form, asking if the person has questions (AHRQ, 2009), providing bulleted summarized information (Kass, Taylor, Ali, Hallez, & Chaisson, 2015), repeating important information (Pick, Gilbert, & McCaul, 2014), using supplemental materials and aids to support understanding (Drake et al., 2016), using a “teach-
back” method to assess comprehension of the consent form content (AHRQ, 2009), and testing the person’s overall knowledge and understanding at the completion of the consent encounter (Kass et al., 2015).

While most of the aforementioned research focuses on the development and testing of interventions to improve IC process communication, little is known about how these strategies are applied in the daily practice of clinical trials (Ferguson, 2003). Even less is understood about procedures and communication strategies that research nurses actually use in the consent process or those that they perceive as effective (Sabik et al., 2005). As critical professionals in this field, research nurses’ attitudes and practices may provide valuable insight in understanding current communication strategies and establishing their relevance to the disclosure of the R&B information. Also, research nurses’ opinions may suggest additional directions to advance these strategies to assist in the continuous effort to convey information in a clear and understandable way to ensure ethical research processes that meet regulatory requirements.

To address this gap, we designed and conducted a survey to examine the self-reported attitudes and practices of research nurses about communication of R&B to potential research participants during the IC encounter. We surveyed research nurses to answer the following research questions.

1. What are the attitudes, practices, and preparedness of nurses regarding selected communication strategies?

2. Is there a relationship between the nurses’ attitudes and practices for selected communication strategies?

3. Is there a relationship among the nurses’ attitudes and practices in relation to nurses’ research work related characteristics, and preparedness?
4. Is there a relationship among the nurses’ research work related characteristics and their
   preparedness for R&B communication?

Methods

A cross sectional study design was utilized. A survey was developed to answer the research questions and administered online to a convenience sample of research nurses, who are or have been, involved in the IC process for clinical trials. Survey responses were analyzed and interpreted.

Survey Development

A thorough systematic review of relevant peer-reviewed publications and data from personal semi-structured qualitative interviews with experts in IC informed the development and content of the survey (Nusbaum, Douglas, Damus, Estrella-Luna, and Paasche-Orlow, 2016). The data found three general themes of important dimensions of the IC communication process that were used to identify as key domains for survey questions. The domains are: (a) strategies for R&B communication, (b) methods to ensure comprehension of information, and (c) preparation for the role of consent administrator.

The final survey included a total of 30 items. Three main sections parallel the three domains and included nine items to assess specific R&B communication strategies and methods to ensure comprehension (n=54 questions), and perceived preparedness (n=7) as well as the type of training regarding the IC administration (n=20). An additional five items addressed demographics, and eight work and research experience. The total number of variables was 94.

To best capture the desired information and encourage survey completion, the survey items were designed in a variety of formats including Likert-type scales, multiple choice, yes/no, and open-ended questions which prompted respondents (research nurses who completed the
survey) to elaborate on their responses and share information that was not included in the fixed response categories. To facilitate comprehension, the survey items were designed using short sentences and simple wording with crucial words highlighted for emphasis.

Several measures were taken to assure the reliability and validity of the survey. First, four survey and three content experts reviewed the instrument for usability and validity, looking at clarity and format, and item representativeness within each domain. After refining the survey, a pilot was conducted with two research nurses. Pilot results revealed that the survey assessed the intended information, its format was easy to follow and, on average, it took 15 minutes to complete.

**Sampling and Data Collection Procedure**

A national convenience sample of eligible research nurses was sought. Inclusion criteria required each participant be a research nurse working in a clinical trial setting with experience in obtaining IC from potential research participants. There were no exclusion criteria. No incentive was offered for participation.

The survey participants were recruited from a variety of sources. Initial recruitment efforts included manually searching for research nurses from a publicly available list of clinical trials and their contacts on the ClinicalTrials.gov website. Of the 385 research nurses who were identified and contacted via email, 65 returned the survey. Recruitment of additional research nurses was accomplished through emailing members of the U.S. chapters of the International Association of Clinical Research Nurses, nursing members of the Public Responsibility in Medicine and Research organization, and nursing members of the LinkedIn professional network. Using a snowball sampling procedure to increase the sample size, recipients were permitted to share the survey invitation with a colleague. Out of a total return of 127 surveys, 20
surveys were excluded from the database (six did not match the inclusion criteria and 14 were incomplete.) The final sample included 107 eligible research nurses who completed the survey between July and September, 2015.

Each potential survey participant received an initial email invitation to participate with a reminder email a week after the initial contact. The email invitation explained the purpose of the research study, that participation was voluntary, and that participants could decide which questions to answer and could stop the survey at any time. The invitation further explained how the participant’s identity would be protected and provided contact information for questions. Interested, eligible, self-selected individuals accessed the survey through a URL included in the email which was supported by the Qualtrics survey management platform (Qualtrics, 2012). Survey participants provided informed consent by clicking “accept” below the unsigned consent form when it first appeared on the survey. The Institutional Review Board of the Northeastern University, Boston, MA, reviewed and approved the study.

**Data Analysis**

Descriptive statistical analyses were done for all survey responses providing total counts, frequencies, and percentages for categorical variables. Measures of central tendency and variability were calculated for continuous variables (such as age, years of research and informed consent experience). Likert scale data were analyzed using both categorical and continuous methods. A review of the univariate frequency distributions identified which could be truncated into fewer categories for additional analysis. Cross tabulation bivariate analyses were followed by stratification of significant associations by selected work related characteristics to identify potential confounding and mediating factors. Open text responses were categorized according to domains.
The Number Cruncher Statistical System v. 9 (NCSS, 2013) was used to perform statistical analyses and the significance level was set at $p<0.05$.

**Results**

**Demographic and Professional Profiles**

The final sample included 107 research nurses working in 31 U.S. states. Out of 78 research nurses who reported their main location of work, 36% (28) were from the South, 32% (25) were from the Northeast, 17% (13) were from the Midwest, and 15% (12) from the West (Figure 1).

![U.S. States Distribution Map of Survey Responses](image)

Figure 1 *U.S. States Distribution Map of Survey Responses*

The majority of respondents were White/Caucasian (87%), female (89%), with an average of 14 years of experience in the clinical research setting. Respondents primarily worked in academia (72%), but 14% were from community settings, 12% from research centers/institutes, and one from a pharmaceutical company. The majority (92%) had baccalaureate or advanced degrees in nursing. Most of the respondents (85%) reported they were currently involved in administering the research IC process as the main focus of their position. On average, the research nurses reported having 12 years experience in obtaining IC and
performing a mean of 43 consent procedures (sd=63, median=25) during the past 12 months.

Selected demographic and professional characteristics of the respondents are presented in Table 1.

**Table 1**

*Demographic and Professional Characteristics*

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>n (%)</th>
<th>Mean/Median</th>
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<tr>
<td>Age, years (n=97)</td>
<td></td>
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<tr>
<td>Mean (sd)</td>
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<td>Gender</td>
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<tr>
<td>Race</td>
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<tr>
<td>Other</td>
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<td>Years of experience as RN</td>
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<td>25.3 (12.7)</td>
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<td>Highest degree in nursing</td>
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<td>Masters/DNP/PhD</td>
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<td>Years of experience working in research</td>
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<td>≤ 10</td>
<td>45 (42.1)</td>
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</tr>
<tr>
<td>&gt; 10</td>
<td>62 (57.9)</td>
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<td>Years of experience obtaining IC**</td>
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<td>12.4 (8.3)</td>
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<td>Median (range)</td>
<td></td>
<td>11.0 (0.5-36.0)</td>
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<tr>
<td>≤ 10</td>
<td>52 (49.1)</td>
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<tr>
<td>&gt; 10</td>
<td>54 (51.0)</td>
<td></td>
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</tbody>
</table>

sd - standard deviation.

*One respondent also identified herself as Hispanic.

**1 missing response.

The majority (n=75, 71%) reported they had received training in the informed consent process. The average number of trainings were 8 (sd=13.8, median = 4.0) and the average interval since training was 3.4 years (sd=4.0, median 2.0). The training formats and content of trainings are provided in Table 2. The most common training formats were in-person (83.8%)
and case studies (69.3%). More than half had also received training by an online course. Notably, less commonly used training formats were using simulation and receiving appraisal feedback on a practice of obtaining IC. In the open-ended responses, some respondents reported their training included shadowing other providers and observing experienced staff obtain IC before performing the consent procedure under supervision. Almost all were trained on general approaches in communicating IC and how to explain that participants can withdraw from the research at any time. However, slightly more than half were trained on how to tailor R&B information to an individual’s needs (52%), how to compare study risks to common everyday risks (49.3%), how to convey numerical information (46.7%), and how to use instructional aids to assist with sharing R&B information with potential research participants (36%) (see Table 2).

**Table 2**

<table>
<thead>
<tr>
<th>Training Formats and Content</th>
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<tbody>
<tr>
<td>Statements (n=75)</td>
</tr>
<tr>
<td><strong>Training formats</strong></td>
</tr>
<tr>
<td>In-person training*</td>
</tr>
<tr>
<td>Presentation of case studies</td>
</tr>
<tr>
<td>Online course</td>
</tr>
<tr>
<td>Feedback on a practice administration of IC*</td>
</tr>
<tr>
<td>Simulation (such as a role-playing)*</td>
</tr>
<tr>
<td>Video of the consent process</td>
</tr>
<tr>
<td><strong>Topics addressed in the training</strong></td>
</tr>
<tr>
<td>General approaches in communicating IC</td>
</tr>
<tr>
<td>How to explain that subjects have the right to withdraw from the study at any time</td>
</tr>
<tr>
<td>IC process for a specific research study</td>
</tr>
<tr>
<td>How to compare the risks of research to the risks of the standard treatment, when relevant</td>
</tr>
<tr>
<td>How to expand on risks which are of special concern to subjects</td>
</tr>
<tr>
<td>How to simplify an explanation of R&amp;B</td>
</tr>
<tr>
<td>How to convey R&amp;B with reference to their time and duration</td>
</tr>
<tr>
<td>How to personalize risk communication</td>
</tr>
<tr>
<td>How to compare study related risks to common everyday risks</td>
</tr>
<tr>
<td>How to convey numbers (such as the chance of harms and benefits)</td>
</tr>
<tr>
<td>How to use pictures, graphs or other aids for conveying risks and benefits information</td>
</tr>
</tbody>
</table>

*1 missing response.

**Research question 1 results:** What are the attitudes, practices, and preparedness of nurses regarding selected communication strategies?

Some of the strategies that were perceived as useful and were frequently used by almost all respondents included encouraging participants to ask questions during and after the consent
discussion (100%), describing common as well as serious risks of research participation (97%) and discussing the consent form with significant others (96%). The least commonly used strategy was giving a test to assess comprehension of the R&B after the IC discussion (23%) (Table 3). Less than one-quarter (22%) of the research nurses provided additional strategies they viewed as useful. These included: using a team approach for consent administration; suggesting the potential research participant review the IC form prior to the consent visit to write down questions to discuss during the IC process; allowing more time for discussion and consideration of all the information on R&B; giving only the information that pertains to the specific person; pointing out in the consent form where it lists or includes the risks so the person not only hears the information but also sees the information; addressing potential distractors prior to the IC process; and marking important areas on the IC form for review.

Table 3
Research Nurses Attitudes and Practices Regarding Communication Strategies

<table>
<thead>
<tr>
<th>Specific R&amp;B communication strategies</th>
<th>Perceived effectiveness (n=107)</th>
<th>Frequency of use (n=104)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Effective* %</td>
<td>Not effective* %</td>
</tr>
<tr>
<td>Describe only common risks and discomforts</td>
<td>42.1</td>
<td>58.0</td>
</tr>
<tr>
<td>Describe common as well as serious risks, regardless of their chance of occurrence</td>
<td>88.8</td>
<td>11.2</td>
</tr>
<tr>
<td>Describe every known risk and discomfort</td>
<td>33.6</td>
<td>66.4</td>
</tr>
<tr>
<td>Compare study related risks to common everyday risks (e.g. chance of being in a car accident or chance of being hit by lightning)</td>
<td>69.2</td>
<td>30.8</td>
</tr>
<tr>
<td>Describe risks and benefits with reference to their time and duration</td>
<td>82.2</td>
<td>17.8</td>
</tr>
<tr>
<td>Offer to read aloud the consent form along with the subject</td>
<td>47.7</td>
<td>52.3</td>
</tr>
<tr>
<td>Repeat all important information</td>
<td>92.0</td>
<td>8.4</td>
</tr>
<tr>
<td>Discuss the consent with the subject when significant others can participate, either in person or remotely (such as by phone or Skype)</td>
<td>85.1</td>
<td>15.0</td>
</tr>
<tr>
<td>Encourage subjects to discuss the consent form with significant others after you reviewed it with the subject</td>
<td>89.7</td>
<td>10.3</td>
</tr>
<tr>
<td>Encourage subjects to ask questions during the discussion</td>
<td>99.1</td>
<td>1.0</td>
</tr>
<tr>
<td>Summarize the information for subjects</td>
<td>91.6</td>
<td>8.4</td>
</tr>
<tr>
<td>Encourage subjects to take notes during the consent discussion</td>
<td>64.5</td>
<td>35.5</td>
</tr>
</tbody>
</table>
Specific R&B communication strategies  | Perceived effectiveness (n=107) | Frequency of use (n=104)  
--- | --- | ---  
|  | Effective | Not effective | Mean (sd) | Frequently | Not frequently | Mean (sd)  
Encourage subjects to follow-up with you regarding their questions and concerns | 93.5 | 6.5 | 4.7 (0.6) | 100.0 | 0 | 4.9 (0.4)  
Use a checklist that contains key risks and benefits | 72.0 | 28.0 | 4.0 (0.9) | 39.4 | 60.6 | 2.3 (1.2)  
Use supplemental materials (such as pictures, tables, graphs, videos) | 63.6 | 36.5 | 3.8 (1.0) | 38.5 | 61.5 | 2.3 (1.1)  
Relate subjects’ personal life (e.g. occupation, family status, goals, challenges) to the risks and benefits discussion | 54.2 | 45.9 | 3.5 (1.1) | 51.9 | 48.1 | 2.5 (1.2)  

Strategies to assess comprehension

1. Ask subjects to repeat the risks and the benefits in their own words | 81.3 | 18.7 | 4.2 (0.9) | 86.5 | 13.5 | 3.7 (1.1)  
2. Ask subjects if they have any questions | 92.5 | 7.5 | 4.7 (0.7) | 100.0 | 0 | 4.9 (0.4)  
3. Ask prepared questions about study related risks and benefits | 59.8 | 40.2 | 3.7 (1.0) | 46.1 | 53.9 | 2.6 (1.2)  
4. Rely on your intuition (gut feelings) to determine subjects’ understanding | 48.6 | 51.4 | 3.3 (1.3) | 72.1 | 27.9 | 3.2 (1.3)  
5. Give a short test after the discussion | 29.0 | 71.0 | 2.9 (1.2) | 23.1 | 76.9 | 1.8 (1.2)  

|   | Effective | Not effective | Mean (sd) | Frequently | Not frequently | Mean (sd)  
--- | --- | --- | --- | --- | --- | ---  
Encourage subjects to follow-up with you regarding their questions and concerns | 93.5 | 6.5 | 4.7 (0.6) | 100.0 | 0 | 4.9 (0.4)  
Use a checklist that contains key risks and benefits | 72.0 | 28.0 | 4.0 (0.9) | 39.4 | 60.6 | 2.3 (1.2)  
Use supplemental materials (such as pictures, tables, graphs, videos) | 63.6 | 36.5 | 3.8 (1.0) | 38.5 | 61.5 | 2.3 (1.1)  
Relate subjects’ personal life (e.g. occupation, family status, goals, challenges) to the risks and benefits discussion | 54.2 | 45.9 | 3.5 (1.1) | 51.9 | 48.1 | 2.5 (1.2)  

Although most (87%) of the research nurses reported using a teach-back strategy such as asking potential participants to repeat the R&B in their own words, only 56% asked potential participants to explain the meaning of a number in terms of the risks for harmful events. About one-half (49%) of the research nurses relied on their “gut” feelings to assess potential participant R&B comprehension and almost three fourths (72%) frequently used this strategy during the IC process. Less than one-half (46%) of respondents asked specific questions about R&B and less than one-quarter (23%) frequently used a structured test at the end of the IC discussion to assess comprehension (Table 3).  

About three out of five (57%) of the respondents indicated that the best time to evaluate comprehension of R&B is immediately after completing the R&B information however, one out of four (24%) reported that it should be done either when questions were asked or when the person was perceived as having difficulty understanding the information. Almost one-fifth (19%) selected the “other” response category and added written comments that the best time for
evaluating R&B understanding is at all the provided points of time, at the end of each page of the consent form, or at the end of the consent encounter.

Although about two-thirds (65%) of the research nurses thought supplemental materials might help to enhance comprehension of R&B, only 39% of the sample used them in their daily work (Table 3). Further exploration of supplemental instructional material usage indicated that most did not agree that these materials make describing R&B easier (96%), they would not be willing to use supplements if they were available to them (95%), and it would not be helpful to provide potential study participants with any additional materials to enhance comprehension of R&B (95%). One of the respondents noted that, “Often supplemental materials are overwhelming to the patient if they don’t contain graphics or pictures to provide clarification to the IC form, since the IC form is narrative only.”

For the question regarding the best method for describing the probabilities or likelihood of experiencing R&B using numerical information, the majority (65%) indicated using a combination of words and numbers (e.g., rare or occasional, along with percentages or ratios) was preferable to using only words (33%) or only numbers (3%). Two-thirds (67%) of research nurses asked potential participants whether they understood presented numbers, 38% used the person’s education level to decide whether or not to use numbers or statistics, and one-third (34%) used pictures or graphic representations to illustrate the number.

Most research nurses (more than 90%) felt well prepared performing various IC process related tasks such as engaging participants in learning about R&B and ensuring that they understood the topic (Table 4). However, about one-third (32%) reported that they did not feel well prepared to provide a description and explanation of statistics related to R&B in a simplified and clear way, about one-half (52%) did not feel competent using supplemental instructional
materials, and about one-fifth (18%) self-identified as not being prepared to select and adapt the information to meet the personal goals and preferences of the prospective research participant.

Table 4
Perception of Preparedness to the Informed Consent Related Tasks

<table>
<thead>
<tr>
<th>Selected R&amp;B communication strategies (n=106)</th>
<th>Prepared* %</th>
<th>Not prepared* %</th>
<th>Mean (sd)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Engage subjects in learning about risks and benefits</td>
<td>94.3</td>
<td>5.7</td>
<td>4.5 (0.6)</td>
</tr>
<tr>
<td>Describe and explain concepts related to the risks and benefits in a simplified and clear way</td>
<td>94.3</td>
<td>5.7</td>
<td>4.5 (0.6)</td>
</tr>
<tr>
<td>Describe and explain statistics related to the risks and benefits in a simplified and clear way</td>
<td>67.9</td>
<td>32.1</td>
<td>3.9 (0.9)</td>
</tr>
<tr>
<td>Provide alternative explanations or examples when the subject seems confused</td>
<td>93.4</td>
<td>6.6</td>
<td>4.5 (0.6)</td>
</tr>
<tr>
<td>Use supplemental instructional materials</td>
<td>48.1</td>
<td>51.9</td>
<td>3.4 (1.3)</td>
</tr>
<tr>
<td>Select and adapt the information to meet the personal goals and preferences of the subject</td>
<td>82.1</td>
<td>17.9</td>
<td>4.2 (1.0)</td>
</tr>
<tr>
<td>Ensure that the subjects understand study related risks and benefits</td>
<td>93.4</td>
<td>6.6</td>
<td>4.6 (0.6)</td>
</tr>
</tbody>
</table>

* 5 point Likert scale: 5=very much prepared, 4=quite a bit prepared, 3=somewhat prepared, 2=a little prepared, 1=not at all prepared; truncated to 4-5 (prepared), 1-3 (not prepared).

Research question 2 results: Is there a relationship between the nurses’ attitudes and practices for selected communication strategies?

Statistically significant relationships were identified between perceived effectiveness of the strategies and frequency of their use for seventeen strategies (Table 3). Non-significant associations were found for three additional communication strategies: describing common as well as serious risks regardless of their chance of occurrence; summarizing the information for participants; and using a checklist that contains key R&B during the IC discussion. In general, respondents who frequently used a specific communication strategy were likely to perceive it as effective.

Research question 3 results: Is there a relationship among the nurses’ attitudes and practices in relation to nurses’ research work related characteristics, and preparedness?

Several statistically significant relationships were found among selected communication strategies and the respondents’ work related characteristics (Table 5). For example, research nurses with more than 10 years of experience in research and IC administration were more likely than those with less experience to compare research participation related risks to common
everyday risks and to suggest that potential participants write their comments about the discussed R&B. More experienced research nurses were also less likely to believe that offering to read the consent form out loud was a helpful measure to enhance comprehension. Respondents who frequently used supplemental instructional material or thought that it was an effective measure to help with comprehension were likely to feel prepared to do this task (75% and 56%, respectively), contrasted to respondents who did not routinely use additional educational materials or thought that this strategy was not effective (30% and 34%, respectively).

### Table 5

**Selected Attitudes by Research and Informed Consent Experience**

<table>
<thead>
<tr>
<th>Attitudes about R&amp;B communication strategies (n=107)</th>
<th>Research work experience ≤10yrs n(%)</th>
<th>&gt;10yrs n(%)</th>
<th>Informed consent related experience ≤10yrs n(%)</th>
<th>&gt;10yrs n(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Comparing study related risks to common everyday risks</td>
<td>29(39.7)</td>
<td>44(60.3)</td>
<td>23(69.7)</td>
<td>10(30.3)</td>
</tr>
<tr>
<td>Effective</td>
<td>23(69.7)</td>
<td>10(30.3)</td>
<td>23(69.7)</td>
<td>10(30.3)</td>
</tr>
<tr>
<td>Ineffective</td>
<td>23(69.7)</td>
<td>10(30.3)</td>
<td>23(69.7)</td>
<td>10(30.3)</td>
</tr>
<tr>
<td>2 Comparing study related risks to common everyday risks</td>
<td>20(31.7)</td>
<td>43(68.3)</td>
<td>24(38.1)</td>
<td>39(61.9)</td>
</tr>
<tr>
<td>Frequently used</td>
<td>24(58.5)</td>
<td>17(41.5)</td>
<td>27(67.5)</td>
<td>13(32.5)</td>
</tr>
<tr>
<td>Not routinely used</td>
<td>24(58.5)</td>
<td>17(41.5)</td>
<td>27(67.5)</td>
<td>13(32.5)</td>
</tr>
<tr>
<td>3 Offering to read aloud the consent form</td>
<td>29(56.9)</td>
<td>22(43.1)</td>
<td>33(64.7)</td>
<td>18(35.3)</td>
</tr>
<tr>
<td>Effective</td>
<td>16(28.6)</td>
<td>40(71.4)</td>
<td>19(34.5)</td>
<td>36(65.5)</td>
</tr>
<tr>
<td>Ineffective</td>
<td>16(28.6)</td>
<td>40(71.4)</td>
<td>19(34.5)</td>
<td>36(65.5)</td>
</tr>
<tr>
<td>4 Encourage subjects to take notes during the consent discussion</td>
<td>24(34.3)</td>
<td>46(65.7)</td>
<td>29(42.0)</td>
<td>40(58.0)</td>
</tr>
<tr>
<td>Frequently used</td>
<td>20(58.8)</td>
<td>14(41.2)</td>
<td>22(64.7)</td>
<td>12(35.3)</td>
</tr>
<tr>
<td>Not routinely used</td>
<td>20(58.8)</td>
<td>14(41.2)</td>
<td>22(64.7)</td>
<td>12(35.3)</td>
</tr>
</tbody>
</table>

All the comparisons are statistically significant (p < .05 by Fisher’s Exact test, two-tailed).

*b* 5 point Likert scale: 5=effective, 4=somewhat effective, 3=neither effective nor ineffective, 2=somewhat ineffective, 1=ineffective; truncated to 4-5 (effective), 1-3 (not effective).

*c* 5 point Likert scale: 5=always, 4=often, 3=sometimes, 2=rarely, 1-never; truncated to 3-5 (frequent use), 1-2 (not routinely used).

*4 missing responses.

**Research question 4 results:** *Is there a relationship among the nurses’ research work related characteristics and their preparedness for R&B communication?*

Research nurses were more likely to feel prepared to describe and explain statistics related to the R&B in a simplified and clear way if they had more than 10 years of research experience (77% vs 56%), participated in 25 or more IC encounters in the past 12 months (80% vs 58%), and had been trained on methods of communicating probabilities (80% vs 54%). Perceived preparedness of the respondent to select and adapt information to meet the personal...
goals and preferences of the potential participant was statistically significantly associated with IC related experience. Research nurses with more than 10 years of experience obtaining IC were likely to feel prepared to personalize R&B information as opposed to research nurses with less than 10 years (93% vs 73%, respectively). In this sample, participation in training was not associated with research nurses’ perceived preparedness to communicate R&B information.

**Discussion**

Our survey results provide a rich database about research nurses’ attitudes, practices, and preparedness to convey R&B information during the research IC process. Since research nurses are major players in administering IC, this information is key to a better understanding of the current communication strategies used and how they can be enhanced. These findings shed light on why many participants do not understand the R&B associated with research participation, and help to identify opportunities for improvements in the IC process.

For example, ethical and research guidelines specify that research team members who obtain IC must be proficient in the role through adequate training and experience in consent administration (CIOMS, 2016; WMA, 2013) which includes understanding the research process and being able to address participant’s questions about the study for which they are seeking IC. Yet our results revealed significant deficiencies related to the training and preparedness of the research nurses for the IC process, and in particular, communication of R&B.

It is concerning, but not surprising, that one-third of the research nurses reported no training in IC administration with many not being trained on specific, well accepted, communication strategies. In fact, previous research indicates that principal investigators often guide research staff members on how to obtain IC and use widely varying training methods (Larson, Cohn, Meyer, & Boden-Albala, 2009). Without training and practice that includes, clear
communication is difficult to apply (Oates & Paasche-Orlow, 2009). We found that only about one-half of the respondents were trained in methods for presenting and discussing R&B numbers with potential participants with very limited use of highly recommended training methods, such as role-play and feedback (Jackson & Back, 2011). Our data also revealed that participation in IC administration training was not associated with the R&B communication strategies in terms of their perceived effectiveness or usage. This finding suggests that many of the training programs in which respondents participated probably did not target the communication strategies presented in this survey. Instead those research nurses who used these strategies in their professional repertoire may have acquired them through on-the-job experience. Our finding that one third of the respondents felt they were not prepared to deliver numerical information associated with R&B in a simplified and clear way is concordant with other studies where explaining this information was found to be particularly challenging by the research staff (Breitsameter, 2010; Sabik et al., 2005).

Deficiencies in training and guidance might constitute a possible explanation for the variation in patterns of use of the examined strategies. For example, the pattern of use of selected strategies differed among the research nurses with some strategies used by the majority while others were used by a relatively few. The surveyed research nurses seemed well trained in describing the magnitude and severity of risks and discomforts, as the majority (97%) reported describing both common as well as serious risks regardless of their chance of occurring, a strategy supported by the National Cancer Institute (NCI, 2013). In contrast to our results, a study by Sabik et al. (2005) reported that only 57% of researchers surveyed indicated the same level of importance in communicating common and serious risks.
The need for better training was supported by our finding that only half of the research nurses reported including personal preferences and goals of the specific research participant during the R&B discussion, and one-fifth felt unable to adapt the R&B discussion to meet the personal needs of individuals. This was an issue particularly in research nurses with less experience in the IC process. Yet studies have shown that tailoring information to participant’s preferences makes study information personally relevant (Brown, Butow, Butt, Moore, & Tattersall, 2004). Having a tool to systematically assess and address specific participant’s needs and provide training to use this tool might be helpful in identifying areas that require special attention and adaptation of the consent information (CTTI, 2015).

Our research also affirmed some reported gaps between some strongly recommended R&B communication strategies that are not followed by the research community, such as the recommendation by the Agency for Health Care Research and Quality to offer to read the consent information out loud to all potential participants as (AHRQ, 2009). We found that offering to read R&B messages out loud was not perceived as useful and was not frequently used by about half of the respondents, with more experienced research nurses being less likely to follow the recommendation. Our survey results were consistent with the results from our qualitative interviews of experts in the IC process (Nusbaum, et. al., 2016) that showed opposing opinions concerning the usefulness of this strategy.

Although teach-back is considered a preferred strategy for assessment of comprehension of R&B information, 72% of the research nurses reported frequently using their intuition to determine comprehension. Intuition is a prevalent decision-making tool in nursing practice, and its use seems to increase with experience (Pretz & Folse, 2011). Yet, “gut” feelings and other
implicit judgments are not a reliable tool and can lead to an incorrect estimation of a participant’s comprehension of study R&B.

Other results raised concerns including those related to supplemental materials. Less than 40% of respondents reported frequent use of supplemental instructional materials, even though two-thirds of the sample thought that employing this strategy could be a helpful method to foster understanding of R&B. One half of the sample felt they were not prepared to use supplemental instructional materials to aid potential participants’ understanding of R&B. This finding is not surprising as only 27 (36%) respondents were exposed to this topic in their training. Interestingly, when research nurses were asked whether they would use supplements if available, they almost unanimously declined. These findings are consistent with another study that examined trial researchers’ perspectives on this topic (Verheggen, Jonkers, & Kok, 1996). In that study, several reasons for not using instructional aids were found including a concern that extra information will cause additional questions and possible confusion; the belief that they are good communicators and that oral presentation is the best way to inform potential participants; they forget to use it; and the belief that the potential research participants do not want to add more information for their consideration. Since it is recognized that the use of simple charts, pictographs, and other graphics is an important means to improve comprehension (CIOMS, 2016; NCI, 2013; Tait, Voepel-Lewis, Brennan-Martinez, McGonegal, & Levine, 2012), these findings indicate barriers to the use of instructional aids that need to be investigated.

We believe that our results are likely indicative of shortcomings in the training of the research nurses who participated in this survey. It is argued that inadequate training has become a serious barrier to improving the IC process and one of the reasons for unmet needs of research participants (CTTI, 2015). This underscores the need for improved and appropriate training in IC
administration that includes R&B communication however, others have found that existing training programs for research staff are not directed at practicing or reinforcing communication skills (Brown, Butow, Boyle, & Tattersall, 2007; Cadman et al., 2014).

Using educational techniques to engage the learner, such as role-playing, provision of different types of scenarios and case studies, bringing in research participants to tell their stories, and providing opportunities to practice and receive feedback on performance could help to improve these training programs. A person who obtains IC needs to understand how to communicate clearly; consider the participant’s education background, learning style and preferences as to the level of information desired; and use accepted teaching techniques to help participants understand the information and apply it to themselves. A trained evaluator should observe the research nurse or other research team member obtaining IC, provide feedback and approve those eligible to serve in this role based on observed competency in obtaining IC.

**Future Research Directions**

Since we surveyed research nurses working mainly in academia initiated clinical trials, future research might consider, but not be limited to, examining R&B communication in a larger more diverse sample of research nurses engaged in clinical trials representative of pharmaceutical companies and private sector research as well as different trial phases and clinical specialties. The sample could also be expanded to different groups of consent administrators with clinical and non-clinical educational backgrounds. Future research could also focus on determining the best training content and format for research nurses involved in the research IC process. It could examine research nurses’ experience and skills related to IC process delivery, including R&B communication, their perception of barriers for becoming an effective
communicator of this information and their specific training needs, and define the communication skills gap to be addressed in the training.

Additional research efforts might include potential clinical research participants’ opinions about the usefulness of various communication strategies to foster comprehension of the R&B and satisfaction with the overall IC process. Participant centric research should include diverse participants with respect to language, culture, racial/ethnic background, nationality, literacy, and decisional competency. It is also important to evaluate the impact of the communication strategies on enrollment and retention of research participants (Sugarman & Paasche-Orlow, 2006). To stay current, the growing trend to recruit participants for clinical trials while obtaining consent using electronic systems and processes (eConsent) (81 FR 90855, 2016) needs to be examined along with developing and evaluating training programs for research staff using this new process. In short, there are many aspects of R&B communications strategies that still need to be investigated.

Limitations

The national convenience sample was relatively small which prevents generalizing results to specific states, types of research settings, or specific characteristics of research nurse IC administrators. The survey methodology is always subject the bias of self-reported information but this was the only practical and feasible method to collect the data needed to address the research questions. Despite these limitations, our research provided a database of information about the breadth of use of multiple communication strategies by research nurses. In addition, we developed a survey that other investigators can use to expand knowledge on attitudes, training and practices related to R&B communication strategies in the research IC process.
Conclusions

Although the need for clear and meaningful communication of R&B to potential research participants should be an integral component of the research IC process and is required by ethical and regulatory human research guidelines worldwide, our results suggest that research nurses may need additional training to encourage, support, and reinforce effective communication of this information. More research is needed to confirm and compare our results among diverse clinical research settings and consent administrators with a range of educational backgrounds and research related experience. We recommend that research nurses as consent administrators be adequately prepared and receive purposeful education and training about R&B communication, which may help to standardize and improve the research IC process. We also recommend that to help bridge the skills gap, relevant educational content and basic training in the research IC process be included in graduate nursing programs and that training on R&B communication strategies be mandatory for nurses hired into research related positions. A model of supervision and feedback is warranted to provide evaluation criteria for research staff performance and to ensure soundness of the educational efforts. This would entail professional development for the supervisors of the research professionals engaged in the IC process. Regular employment of supervision and feedback mechanisms will promote self-evaluation and self-reflection, and contribute to a commitment to developing, improve and applying effective communication skills.
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CHAPTER FIVE

Summary and Conclusions

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Northeastern University
Ethical recruitment of individuals into clinical trials requires obtaining informed consent (IC) from potential research participants. Research guidelines emphasize that IC is a process and not just a signature on a form (FDA, 2015; OHRP, 1993). It should encompass an exchange of information that involves a detailed, comprehensible, and meaningful explanation of the research study and its risks and benefits (R&B), so the individual can determine if they wish to participate. However, a signature on an IC form does not always imply that the participant was adequately informed nor that they comprehended the information delivered during the consent process. Specifically, information about R&B provided during the IC process was found by many participants to be difficult to understand (Beadle, Mengersen, Moynihan, & Yates, 2011; Montalvo & Larson, 2014), and difficult for providers to adequately convey (Breitsameter, 2010; Sabik et al., 2005). These difficulties indicate communication deficiencies that need to be addressed (Ssali, Poland, & Seeley, 2016).

There is increasing involvement of research nurses in the enrollment efforts for clinical trials where they are responsible for obtaining IC and judging potential participants’ understanding of the information delivered (Bristol & Hicks, 2014; Cantini & Ells, 2007; Kleiderman et al., 2012; Poston & Buescher, 2010). There is a lack of literature, however, that addresses what research nurses do to fully inform and ensure comprehension of a study’s R&B by research participants (Cresswell & Gilmour, 2014). This study was intended to address this gap by contributing a greater understanding of the research nurses’ attitudes, practices, and preparedness in relation to R&B communication during the research IC process.

In this study, the results of a systematic literature review of nurse-led studies indicate that there is insufficient research of the views and practices of nurses who obtain IC and bear the
responsibility for the quality and ethics of the process. The paucity of nursing research evidence on this important topic, suggest areas for future nursing research.

Further exploration of current R&B communication practices was performed using qualitative in-depth interviews with seventeen experts in the research IC process. The experts indicated that today’s efforts are mainly directed at improving the IC form and its structure, versus how the consent information is delivered to potential research participants. Concern was expressed about research professionals failing to present R&B information in a meaningful manner, although opinions differed concerning effective communication strategies. Experts not only criticized some of the common strategies used to assess participant comprehension of R&B, but also indicated insufficient use of other recommended strategies to ensure an effective IC process and the lack of supervision to verify the quality of implementation of the IC process. From the experts' perspective, deficiencies of the IC process and R&B communication most likely reflect inadequate education and training of those responsible for obtaining IC. Three major themes emerged in the analysis: (a) strategies for R&B communication; (b) methods to ensure comprehension; and (c) preparation for the role of the consent administrator. These themes informed the development of items for a survey about the communication of R&B in the IC process from the consent providers’ perspective.

Survey results revealed variable practices by research nurses in conveying R&B information and also identified critical deficiencies in research nurses’ educational preparation to obtain IC. For example, two commonly employed strategies used by nurses to check potential participant’s comprehension were reported. The majority of research nurses surveyed in this study used the teach-back strategy (Eder, Yamokoski, Wittmann, & Kodish, 2007) however, about three fourths of the nurses also reported the frequent use of their “gut” feeling as a strategy
to measure comprehension. While the former is well established as an effective strategy, there is inadequate literature support for using ‘gut’ feeling which may pose a threat to the reliability of the assessment outcome.

Although the majority of the research nurses who responded to the survey reported obtaining IC as a primary responsibility of their job, findings show that one-third did not have specific training in the IC process. Training in the IC process was described as lacking in content related to communications strategies, including how to simplify and personalize R&B explanations, convey numerical information, and use educational aids to assist in explaining information. The survey findings echo the results from our qualitative interviews, which uncovered shared frustration among the experts in IC around insufficient training opportunities to support the development of IC process related skills. The survey findings also contradict assumptions presented by the experts that institutions rely on researchers’ skills for appropriate IC process. Collectively, this result reveals an overall deficiency in research nurses’ preparation for the role of consent administrator.

Tait and colleagues (2003) found that the clarity of information conveyed during the IC process was statistically significantly associated with understanding of the IC document, and understanding was lower among those who refused to join the study. Tait’s findings suggest that clear communication may be important to achieve better understanding and higher enrollment rates. Current survey findings demonstrated that many research nurses did not feel prepared to explain numerical information related to R&B in a simple and clear way, nor to adapt this information to the goals and preferences of the potential participant. Organized educational efforts directed at research nurses responsible for the IC process must be developed to meet these critical deficiencies to improve IC outcomes.
There were some limitations to this research. Although a national convenience sample was obtained, it was relatively small preventing generalization of results to diverse research settings and specific characteristics of IC administrators. In addition, the self-reported information employing survey methodology has an inherent bias. There is also a risk for response bias, particularly social desirability. This bias might influence self-reported views by urging survey respondents to provide socially desirable or professionally correct responses. If this bias exists, it would blur the reporting of the actual attitudes and practices of research nurse. In this context, social desirability bias should make us cautious about good practices or preparedness that are reported at higher rates because they may mask the existence of actual deficiencies in practice or preparedness level. Steps have been taken to alleviate the effect of this social desirability bias in our survey responses by avoiding direct confrontation with the researcher through the use of an on-line survey and by promising and granting of anonymity to all the respondents.

The survey methodology is always subject the bias of self-reported information but this was the only practical and feasible method to collect the data needed to address the research questions. Despite these limitations, our research provided a database of information about the breadth of use of multiple communication strategies by research nurses. In addition, we developed a survey that other investigators can use to expand knowledge on attitudes, training and practices related to R&B communication strategies in the research IC process.

Based on the results of the study, we suggest that training and continuing education should be a requirement to improve and update current practices for the entire community of research staff who responsible for obtaining research IC. This training should include effective communication strategies, be readily accessible on an ongoing basis, and be developed to meet
the needs of both novice and experienced research nurses. Training that is modulated for those at varying levels of skill and experience will be able to address self-identified needs. Training programs that provide opportunities to observe experts in the practice of obtaining IC and receive individualized feedback can further reinforce learning. In addition, the use of interactive teaching methods such as case studies, videos, problem-solving tasks, role-playing, and small group discussions can promote effective learning. Further examination to understand the reasons why nurses may not feel well prepared to convey statistical information or to use best practice strategies could improve training programs.

The IC process has implications for nursing practice and research as well as for academic nursing. We should not only focus on improving IC process training for nurses who conduct IC in clinical research but also how to better prepare future nurses who, at a minimum, need to understand the IC process, particularly ethical and legal aspects in a patient-centered care environment. This preparation is needed across the education spectrum for both pre-licensure nursing students as well as nurses in graduate programs as both may be engaged in obtaining IC for research studies. Graduate students in particular need to know about the IC process for their own projects and also for potential future practice where they may work on their own research or as part of a research team. Nursing graduate programs need to ensure that graduate students have hands-on training in effective communication, including key IC elements, such as potential risks and possible benefits of research. Graduate students also need to know how to describe the IC process in publications when they report on studies in professional literature. These training experiences must equip graduate students with critical skills required to be responsible investigators using ethical standards of conduct for human subjects’ research. Nursing faculty must also be knowledgeable about the IC process and may require training or continuing
education to ensure that students receive the most effective learning experiences and to ensure that they are applying expected IC process in their own research efforts.

This study’s findings reinforce the importance of the integrating effective communication strategies in the IC process by research nurses. Nurses skilled in the process ensure potential research participants’ comprehension and satisfaction in making an informed consent decision to participate in a research study and facilitate higher study enrollments. Using effective communication strategies supports research teams in their endeavor to conduct ethical research and provide research evidence for better healthcare outcomes.
References


APPENDICES

Lidia Lika Nusbaum

Northeastern University
Appendix A: Northeastern University IRB Approvals

Northeastern

Notification of IRB Action

Date: August 1, 2013    IRB #: 13-06-17

Principal Investigator(s): Karla Damus
                          Lidia Lika Nusbaum

Department: School of Nursing

Address: 401 C Robinson Hall
         Northeastern University

Title of Project: Communication of Risks and Benefits in Informed Consent for Clinical Research: Perspectives from Members of the Research Team

Participating Sites: N/A

Informed Consent: One (1) signed consent for interviews
                  One (1) unsigned consent for online survey

NOTE: Approval of the online survey is forthcoming once survey questions are developed

As per CFR 46.117(c)(2) signed consent is being waived as the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required.

DHHS Review Category: Expedited #6, #7

Monitoring Interval: 12 months

Approval Expiration Date: JULY 31, 2014

Investigator's Responsibilities:

1. Informed consent form bearing the IRB approval stamp must be used when recruiting participants into the study.
2. The investigator must notify IRB immediately of unexpected adverse reactions, or new information that may alter our perception of the benefit-risk ratio.
3. Study procedures and files are subject to audit any time.
4. Any modifications of the protocol or the informed consent as the study progresses must be reviewed and approved by this committee prior to being instituted.
5. Continuing Review Approval for the proposal should be requested at least one month prior to the expiration date above.
6. This approval applies to the protection of human subjects only. It does not apply to any other university approvals that may be necessary.

C. Randall Colvin, Ph.D., Chair
Northeastern University Institutional Review Board

Nan C. Regina, Director
Human Subject Research Protection

Northeastern University FWA #: 4630
NOTIFICATION OF IRB ACTION
RENEWAL APPROVAL

Date: June 27, 2014
IRB #: 13-06-17
Principal Investigator(s): Karla Damus
Lidia Lika Nushbaum
Department: School of Nursing
Bouvé College of Health Sciences
Address: 102 Robinson Hall
Northeastern University
Title of Project:
Communication of Risks and Benefits in Informed Consent for Clinical Research: Perspectives from Members of the Research Team
Approval Status: Phase I interviews: closed to enrollment - ongoing analysis only
Phase II online survey: under development - research will submit for review and approval by the NU IRB prior to implementation.
Participating Sites: N/A
Original Protocol Approved: August 1, 2013
DHHS Review Category: Expedited #6, #7
Informed Consents:
One (1) unsigned consent form as preface to online survey - forthcoming
As per CFR 45 46.117(c)(2) Signed consent is being waived as the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required.
Monitoring Interval: 12 months

APPROVAL EXPIRATION DATE: JUNE 26, 2015

Investigator’s Responsibilities:
1. The informed consent form bearing the IRB approval stamp must be used when recruiting participants into the study.
2. The investigator must notify IRB immediately of unexpected adverse reactions, or new information that may alter our perception of the benefit-risk ratio.
3. Study procedures and files are subject to audit any time.
4. Any modifications of the protocol or the informed consent as the study progresses must be reviewed and approved by this committee prior to being instituted.
5. Continuing Review Approval for the proposal should be requested at least one month prior to the expiration date above.
6. This approval applies to the protection of human subjects only. It does not apply to any other university approvals that may be necessary.

C. Randall Colvin, Ph.D., Chair
Northeastern University Institutional Review Board

Jan C. Regina, Director
Human Subject Research Protection

Northeastern University FWA #4630
NOTIFICATION OF IRB ACTION
RENEWAL APPROVAL

Date: June 16, 2015
IRB #: 13-06-17

Principal Investigator(s): Brenda Douglas
Lidia Lika Nussbaum

Department: School of Nursing
Bouvé College of Health Sciences

Address: 103 Robinson Hall
Northeastern University

Title of Project: Communication of Risks and Benefits in Informed Consent for Clinical Research: Perspectives from Members of the Research Team

MODIFICATION:
2. Addition of Phase II online survey.

Approval Status: Phase I interviews: closed to enrollment - ongoing analysis only
Phase II online survey: open to enrollment

Participating Sites: N/A

Original Protocol Approved: August 1, 2013

DHHS Review Category: Expedited #6, #7

Informed Consents: One (1) unsigned consent form as preface to online survey

As per CFR 45.117(c)(2) Signed consent is being waived as the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required.

Monitoring Interval: 12 months

APPROVAL EXPIRATION DATE: JUNE 15, 2016

Investigator's Responsibilities:
1. The informed consent form bearing the IRB approval stamp must be used when recruiting participants into the study.
2. The investigator must notify IRB immediately of unexpected adverse reactions, or new information that may alter our perception of the benefit-risk ratio.
3. Study procedures and files are subject to audit any time.
4. Any modifications of the protocol or the informed consent as the study progresses must be reviewed and approved by this committee prior to being instituted.
5. Continuing Review Approval for the proposal should be requested at least one month prior to the expiration date above.
6. This approval applies to the protection of human subjects only. It does not apply to any other university approvals that may be necessary.

C. Randall Colvin, Ph.D., Chair
Northeastern University Institutional Review Board

Nan C. Regina, Director
Human Subject Research Protection

Northeastern University FWA #4630
NOTIFICATION OF IRB ACTION
RENEWAL APPROVAL

Date: May 31, 2016  IRB #: 13-06-17
Principal Investigator(s): Brenda Douglas
                        Lidia Lika Nusbaum
Department: School of Nursing
            Bouvé College of Health Sciences
Address: 103 Robinson Hall
          Northeastern University
Title of Project: Communication of Risks and Benefits in Informed
                Consent for Clinical Research: Perspectives from
                Members of the Research Team
Approval Status: Closed to Enrollment - Ongoing Analysis Only
Participating Sites: N/A
Original Protocol Approved: August 1, 2013
Most Recent Approval Date: August 4, 2015 - modification
DHHS Review Category: Expedited #6, #7
Informed Consents: N/A
Monitoring Interval: 12 months

APPROVAL EXPIRATION DATE: MAY 30, 2017

Investigator's Responsibilities:
1. The informed consent form bearing the IRB approval stamp must be used when recruiting
   participants into the study.
2. The investigator must notify IRB immediately of unexpected adverse reactions, or new
   information that may alter our perception of the benefit-risk ratio.
3. Study procedures and files are subject to audit any time.
4. Any modifications of the protocol or the informed consent as the study progresses must
   be reviewed and approved by this committee prior to being instituted.
5. Continuing Review Approval for the proposal should be requested at least one month prior
   to the expiration date above.
6. This approval applies to the protection of human subjects only. It does not apply to any
   other university approvals that may be necessary.

C. Randall Colvin, Ph.D., Chair
Northeastern University Institutional Review Board

Nan C. Regina, Director
Human Subject Research Protection

Northeastern University FWA #4630
Appendix B: Informed Consent Form (qualitative interviews)

Signed Informed Consent to Participate in a Research Study

Northeastern University, Bouvé College of Health Sciences, School of Nursing
Name of Investigators: Dr. Karla Damus, & Lidia Lika Nusbaum
Title of Project: Communication of risks and benefits in informed consent for clinical research: Perspectives from members of the research team.

Dr. Karla Damus is an academic advisor and the principal investigator of the study. Lidia Lika Nusbaum is a doctoral student in the School of Nursing at the Bouvé College of Health Sciences School of Nursing at the Northeastern University. We are inviting you to take part in a research study. This form will tell you about the study, but the researcher will explain it to you first. You may ask this person any questions that you have. When you are ready to make a decision, you may tell the researcher if you want to participate or not. You do not have to participate if you do not want to. If you decide to participate, the researcher will ask you to sign this statement and will give you a copy to keep.

Why am I being asked to take part in this research study?
We are asking you to be in this study because of your expertise in the studied issue.

Why is this research study being done?
You are invited to participate in a dissertation research project that aimed to better understand research team members' views and experiences related to the communication of risks and benefits in the informed consent process for clinical research in order to propose possible ways to improve this process.

What will I be asked to do?
Your participation in this study will involve one interview that asks questions about your opinions, experiences related to informed consent process to research, the possible ways to address these issues in a future survey on the topic, and also will include some questions about you, such as your age, professional experience, and training. Our discussion will be audio-recorded. You can choose to turn off the recorder at any time during the discussion. For the discussion you will select a fake name so your real name will not be mentioned in a recording.

Where will this take place and how much of my time will it take?
You will be interviewed at a time and place that is convenient for you. The interview will last for no more than a 60-minute time period.

Will there be any risk or discomfort to me?
We believe this interview does not involve any risk to you. In a case of feeling discomfort while discussing any issues, you can always choose not to respond to specific questions and/or terminate the interview at any time.

Will I benefit by being in this research?
There is no direct benefit to you anticipated from participation in the study. However, the information learned from you may contribute to a greater body of knowledge and help better understand and improve risk and benefit communication to advance informed consent process to clinical research. We are offering you a copy of the final report of the study.

Who will see the information about me?
The research will be confidential. The interview information will be held in a manner that protects your identity and may be accessed only by the researchers. No reports or publications will use information that can identify you in
any way. Lika Nusbaum will transcribe the de-identified audio into text. To protect your privacy, there will be no identifying you information on the interview transcript: it will have a fake name you choose and a code number (like 01, 02, etc.). The transcript and the record link between the identifying information and the fake name will be stored in a different password protected files on the researcher’s personal computer. This fake name and a code number will be used instead of your name on any researcher’s written notes about the interview and to label the audio-file. Lika Nusbaum will permanently delete audio-file upon its transcription. Interview transcription file will be deleted following completion of the presentation/publication of the study findings. The investigators will store your original consent form in a locked fireproof file cabinet in a locked Principal Investigator’s office, which is in a suite with an additional locked door to the suite. The form will be shredded three years following the study activities completion (per federal regulations) and disposed in a secure locked container to be further shredded by a company contracted by the university for the secure disposal of documents with confidential information.

In rare instances, for the oversight or monitoring purposes only, authorized people may request to see research information about you and other people in this study. This is done only to be sure that the research is done properly. We would only permit people who are authorized by the Northeastern University Institutional Review Board to see this information.

**Can I stop my participation in this study?**

It is your free choice to be in a study. You can participate and still refuse to answer certain question. You can choose to stop audio recording, to terminate the whole interview, and to leave the study at any time you wish without any bad effects on you.

**Who can I contact if I have questions or problems?**

If you have any questions, comments or concerns about this study, please feel free to contact Lidia Lika Nusbaum at lidianster@gmail.com, the person mainly responsible for the research. You can also contact Dr. Karla Damus, at k.damus@neu.edu, the principle investigator of the study.

**Who can I contact about my rights as a participant?**

If you have any questions about your rights as a research participant, you may contact Nan C. Regina, Director, Human Subject Research Protection, 960 Renaissance Park, Northeastern University, Boston, MA 02115. Tel: 617.373.4588, Email: n.regina@neu.edu. You may call anonymously if you wish.

**Will I be paid for my participation?**

You will not be paid for being in this study.

**Will it cost me anything to participate?**

The participation in the study will not have any costs for you.

**Is there anything else I need to know?**

Dr. Karla Damus and Lika Nusbaum will not use the information you provide for any other reason than those stated in the consent form.

Thank you for considering your participation in this study.

I agree to take part in this research.

__________________________________________\nSignature of person agreeing to take part

__________________________________________\nDate

__________________________________________\nSignature of person who explained the study to the

__________________________________________\nDate participant above & obtained consent

__________________________________________\nPrinted name of person above

06-11-13
Appendix C: Online Survey Invitation

Email “Subject” Line:

A survey of Nurses’ Opinions regarding the Informed Consent Process in Research.

Email Message:

Dear Research Nurse,

We are conducting a survey of nurses involved in obtaining informed consent for clinical trials. The survey is anonymous, will take about 15 minutes to complete and can be accessed on any internet-enabled device, such as iPad, laptop, or desktop.

You are eligible to take this survey if you answer “Yes” to each of the following questions:

1) Are you a registered nurse who currently or who has ever been a member of a clinical trial research team?

2) Have you ever participated in obtaining informed consent from the potential research subject?

3) Are you able to speak, read, write, and comprehend English?

If you have answered Yes to all three questions, please click on link below to take survey and thank you in advance for your participation.

https://bouve.co1.qualtrics.com/SE/?SID=SV_1LKRuMCCBz7Fzjn

If you answered No to any of the questions, please don’t take the survey, but we would appreciate if you forward this email to a colleague who might be eligible for this study. Thank you very much for your time.

Sincerely,

Lika Nusbaum, Student Researcher,
Brenda Douglas, Principal Investigator, Associate Clinical Professor.

This research study and this email message have been approved by the Institutional Review Board, under federal regulations, at Northeastern University, Boston (NU IRB# 13-06-17).
## Appendix D: Frequency Distributions of Survey Responses

<table>
<thead>
<tr>
<th>No</th>
<th>List of survey sections</th>
<th>pages</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Communication strategies</td>
<td>123</td>
</tr>
<tr>
<td>2.</td>
<td>Preparedness</td>
<td>126</td>
</tr>
<tr>
<td>3.</td>
<td>Training</td>
<td>126</td>
</tr>
<tr>
<td>4.</td>
<td>Professional characteristics</td>
<td>127</td>
</tr>
<tr>
<td>5.</td>
<td>Demographics</td>
<td>128</td>
</tr>
</tbody>
</table>
## Communication Strategies

Q1. What is your opinion about the following strategies to promote comprehension of R&B? (n=107)

<table>
<thead>
<tr>
<th>List of Strategies</th>
<th>5 Effective (%)</th>
<th>4 Somewhat effective (%)</th>
<th>3 Neither Effective nor Ineffective (%)</th>
<th>2 Somewhat ineffective (%)</th>
<th>1 Ineffective (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q1.1 Describe only common risks and discomforts</td>
<td>17.8</td>
<td>24.3</td>
<td>15.9</td>
<td>18.7</td>
<td>23.4</td>
</tr>
<tr>
<td>Q1.2 Describe common as well as serious risks, regardless of their chance of occurrence</td>
<td>57.9</td>
<td>30.8</td>
<td>2.8</td>
<td>8.4</td>
<td>0</td>
</tr>
<tr>
<td>Q1.3 Describe every known risk and discomfort</td>
<td>14.0</td>
<td>19.6</td>
<td>15.0</td>
<td>25.2</td>
<td>26.2</td>
</tr>
<tr>
<td>Q1.4 Compare study related risks to common everyday risks (e.g. chance of being in a car accident or chance of being hit by lightning)</td>
<td>29.0</td>
<td>40.2</td>
<td>12.2</td>
<td>9.4</td>
<td>9.4</td>
</tr>
<tr>
<td>Q1.5 Describe risks and benefits with reference to their time and duration</td>
<td>34.6</td>
<td>47.7</td>
<td>8.4</td>
<td>6.6</td>
<td>2.8</td>
</tr>
<tr>
<td>Q1.6 Offer to read aloud the consent form along with the subject</td>
<td>28.0</td>
<td>19.7</td>
<td>26.2</td>
<td>16.0</td>
<td>10.3</td>
</tr>
<tr>
<td>Q1.7 Repeat all important information</td>
<td>59.8</td>
<td>31.8</td>
<td>4.7</td>
<td>3.7</td>
<td></td>
</tr>
<tr>
<td>Q1.8 Discuss the consent with the subject when significant others can participate, either in person or remotely (such as by phone or Skype)</td>
<td>57.9</td>
<td>27.1</td>
<td>13.1</td>
<td>0.9</td>
<td>0.9</td>
</tr>
<tr>
<td>Q1.9 Encourage subjects to discuss the consent form with significant others after you reviewed it with the subject</td>
<td>67.2</td>
<td>22.4</td>
<td>4.7</td>
<td>4.7</td>
<td>0.9</td>
</tr>
<tr>
<td>Q1.10 Encourage subjects to ask questions during the discussion</td>
<td>91.6</td>
<td>7.5</td>
<td>0.9</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Q1.11 Ask subjects to repeat the risks and the benefits in their own words</td>
<td>47.7</td>
<td>33.6</td>
<td>13.1</td>
<td>4.7</td>
<td>0.9</td>
</tr>
<tr>
<td>Q1.12 Ask subjects if they have any questions</td>
<td>80.4</td>
<td>12.2</td>
<td>5.61</td>
<td>0.9</td>
<td>0.9</td>
</tr>
<tr>
<td>Q1.13 Summarize the information for subjects</td>
<td>70.1</td>
<td>21.5</td>
<td>6.5</td>
<td>1.8</td>
<td>0</td>
</tr>
<tr>
<td>Q1.14 Encourage subjects to take notes during the consent discussion</td>
<td>37.4</td>
<td>27.1</td>
<td>21.5</td>
<td>11.2</td>
<td>2.8</td>
</tr>
<tr>
<td>Q1.15 Encourage subjects to follow-up with you regarding their questions and concerns</td>
<td>72.9</td>
<td>20.6</td>
<td>5.6</td>
<td>0.9</td>
<td>0</td>
</tr>
<tr>
<td>Q1.16 Use a checklist that contains key risks and benefits</td>
<td>33.6</td>
<td>38.3</td>
<td>25.2</td>
<td>1.9</td>
<td>0.9</td>
</tr>
<tr>
<td>Q1.17 Use supplemental materials (such as pictures, tables, graphs, videos)</td>
<td>31.8</td>
<td>31.8</td>
<td>27.1</td>
<td>6.5</td>
<td>2.8</td>
</tr>
<tr>
<td>Q1.18 Relate subjects’ personal life (e.g. occupation, family status, goals, challenges) to the risks and benefits discussion</td>
<td>17.8</td>
<td>36.5</td>
<td>31.8</td>
<td>8.4</td>
<td>5.6</td>
</tr>
<tr>
<td>Q1.19 Ask prepared questions about study related risks and benefits</td>
<td>23.3</td>
<td>36.5</td>
<td>30.8</td>
<td>6.5</td>
<td>2.8</td>
</tr>
<tr>
<td>Q1.20 Rely on your intuition (gut feelings) to determine subjects’ understanding</td>
<td>20.6</td>
<td>28.0</td>
<td>26.2</td>
<td>8.4</td>
<td>16.8</td>
</tr>
<tr>
<td>Q1.21 Give a short test after the discussion</td>
<td>9.4</td>
<td>19.6</td>
<td>34.6</td>
<td>19.6</td>
<td>16.8</td>
</tr>
</tbody>
</table>

Q2: Do you recommend any other communication strategies that were not listed above to promote R&B comprehension? If yes, describe: ________________
Q3: When do you usually assess potential subjects’ understanding about risks and benefits? Check the best response. (n=70)

<table>
<thead>
<tr>
<th>Response choices</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 After presenting all the study related risks and benefits</td>
<td>57.1</td>
</tr>
<tr>
<td>2 When subjects ask me questions about risks and benefits</td>
<td>12.9</td>
</tr>
<tr>
<td>3 When I feel subjects have difficulties with comprehending the information</td>
<td>10.0</td>
</tr>
<tr>
<td>4 Other</td>
<td>20.0</td>
</tr>
</tbody>
</table>

Q4. How often do potential subjects follow up on your recommendations such as: (n=107)

<table>
<thead>
<tr>
<th>List of recommendations</th>
<th>1 Never (%)</th>
<th>2 Rarely (%)</th>
<th>3 Sometimes (%)</th>
<th>4 Often (%)</th>
<th>5 Always (%)</th>
<th>6 Don’t know (%)</th>
<th>7 Doesn’t apply (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q4.1</td>
<td>1.9</td>
<td>8.4</td>
<td>29.9</td>
<td>49.5</td>
<td>10.3</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Q4.2</td>
<td>0.9</td>
<td>13.7</td>
<td>40.2</td>
<td>33.6</td>
<td>4.7</td>
<td>7.5</td>
<td>0</td>
</tr>
<tr>
<td>Q4.3</td>
<td>10.3</td>
<td>38.3</td>
<td>42.1</td>
<td>1.9</td>
<td>7.5</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Q5. Some informed consent forms use numbers such as percentages or ratios to describe chances of experiencing risks and benefits. How often do you use each of the following methods?

<table>
<thead>
<tr>
<th>List of methods</th>
<th>1 Never (%)</th>
<th>2 Rarely (%)</th>
<th>3 Sometimes (%)</th>
<th>4 Often (%)</th>
<th>5 Always (%)</th>
<th>6 Don’t know (%)</th>
<th>7 Doesn’t apply (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q5.1</td>
<td>15.2</td>
<td>18.1</td>
<td>27.6</td>
<td>26.7</td>
<td>12.4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q5.2</td>
<td>24.5</td>
<td>37.7</td>
<td>17.9</td>
<td>12.3</td>
<td>7.6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q5.3</td>
<td>18.1</td>
<td>25.7</td>
<td>32.4</td>
<td>15.2</td>
<td>8.6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q5.4</td>
<td>30.5</td>
<td>35.2</td>
<td>23.8</td>
<td>8.6</td>
<td>1.9</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Q6: Select the method you think works best for describing to subjects their chance of experiencing R&B. (n=107)

<table>
<thead>
<tr>
<th>Response choices</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Use words (such as rare, occasional, common)</td>
<td>32.7</td>
</tr>
<tr>
<td>2 Use numbers (such as percentages, ratios)</td>
<td>1.9</td>
</tr>
<tr>
<td>3 Use a combination of both words and numbers</td>
<td>64.5</td>
</tr>
<tr>
<td>4 Other (please specify):</td>
<td>0.9</td>
</tr>
</tbody>
</table>
Q7. What is your opinion about the following statements regarding the use of supplemental materials (such as a table, picture, graph) to communicate R&B? (n=107)

<table>
<thead>
<tr>
<th>List of statements</th>
<th>1 Agree strongly (%)</th>
<th>2 Agree (%)</th>
<th>3 Neither agree nor disagree (%)</th>
<th>4 Disagree (%)</th>
<th>5 Disagree strongly (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q7.1 Supplemental materials may make describing R&amp;B easier</td>
<td>1.9</td>
<td>1.9</td>
<td>29.0</td>
<td>55.1</td>
<td>12.2</td>
</tr>
<tr>
<td>Q7.2 I would be willing to use supplemental materials if they were available to me</td>
<td>1.9</td>
<td>3.7</td>
<td>18.69</td>
<td>56.1</td>
<td>19.6</td>
</tr>
<tr>
<td>Q7.3 It would be helpful to provide subjects with supplemental materials to enhance comprehension of R&amp;B of the research</td>
<td>1.9</td>
<td>2.8</td>
<td>29.0</td>
<td>47.7</td>
<td>18.7</td>
</tr>
</tbody>
</table>

Q8. For each of the following activities, indicate how often you use them when communicating R&B information. (n=104)

<table>
<thead>
<tr>
<th>List of activities</th>
<th>1 Never (%)</th>
<th>2 Rarely (%)</th>
<th>3 Sometimes (%)</th>
<th>4 Often (%)</th>
<th>5 Always (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q8.1 Describe only common risks and discomforts</td>
<td>36.6</td>
<td>29.8</td>
<td>15.4</td>
<td>13.5</td>
<td>4.8</td>
</tr>
<tr>
<td>Q8.2 Describe common as well as serious risks, regardless of their chance of occurrence</td>
<td>1.0</td>
<td>1.9</td>
<td>6.7</td>
<td>34.6</td>
<td>55.8</td>
</tr>
<tr>
<td>Q8.3 Describe every known risk and discomfort</td>
<td>14.4</td>
<td>31.7</td>
<td>16.4</td>
<td>19.2</td>
<td>18.3</td>
</tr>
<tr>
<td>Q8.4 Compare study related risks to common everyday risks (e.g. chance of being in a car accident or chance of being hit by lightning)</td>
<td>23.1</td>
<td>16.4</td>
<td>31.7</td>
<td>23.1</td>
<td>5.8</td>
</tr>
<tr>
<td>Q8.5 Describe R&amp;B with reference to their time and duration</td>
<td>6.7</td>
<td>13.5</td>
<td>29.8</td>
<td>36.6</td>
<td>13.5</td>
</tr>
<tr>
<td>Q8.6 Offer to read aloud the consent form along with the subject</td>
<td>12.5</td>
<td>31.7</td>
<td>25.0</td>
<td>15.4</td>
<td>15.4</td>
</tr>
<tr>
<td>Q8.7 Repeat all important information</td>
<td>1.0</td>
<td>3.9</td>
<td>11.5</td>
<td>39.4</td>
<td>44.2</td>
</tr>
<tr>
<td>Q8.8 Discuss the consent with the subject when significant others can participate, either in person or remotely (such as by phone or Skype)</td>
<td>1.9</td>
<td>5.8</td>
<td>32.7</td>
<td>51.0</td>
<td>8.7</td>
</tr>
<tr>
<td>Q8.9 Encourage subjects to discuss the consent form with significant others after you reviewed it with the subject</td>
<td>1.0</td>
<td>2.9</td>
<td>8.7</td>
<td>32.7</td>
<td>54.8</td>
</tr>
<tr>
<td>Q8.10 Encourage subjects to ask questions during the discussion</td>
<td>0</td>
<td>0</td>
<td>1.0</td>
<td>8.7</td>
<td>90.4</td>
</tr>
<tr>
<td>Q8.11 Ask subjects to repeat the risks and the benefits in their own words</td>
<td>6.7</td>
<td>6.7</td>
<td>24.0</td>
<td>37.5</td>
<td>25.0</td>
</tr>
<tr>
<td>Q8.12 Ask subjects if they have any questions</td>
<td>0</td>
<td>0</td>
<td>1.9</td>
<td>5.8</td>
<td>92.3</td>
</tr>
<tr>
<td>Q8.13 Summarize the information for subjects</td>
<td>0</td>
<td>1.9</td>
<td>7.7</td>
<td>25.0</td>
<td>65.4</td>
</tr>
<tr>
<td>Q8.14 Encourage subjects to take notes during the consent discussion</td>
<td>13.5</td>
<td>19.2</td>
<td>22.1</td>
<td>18.3</td>
<td>26.9</td>
</tr>
<tr>
<td>Q8.15 Encourage subjects to follow-up with you regarding their questions and concerns</td>
<td>0</td>
<td>0</td>
<td>1.0</td>
<td>11.5</td>
<td>87.5</td>
</tr>
<tr>
<td>Q8.16 Use a checklist that contains key R&amp;B</td>
<td>32.7</td>
<td>27.9</td>
<td>22.1</td>
<td>9.6</td>
<td>7.7</td>
</tr>
<tr>
<td>Q8.17 Use supplemental materials (such as pictures, tables, graphs, videos)</td>
<td>25.0</td>
<td>36.5</td>
<td>20.2</td>
<td>15.4</td>
<td>2.9</td>
</tr>
<tr>
<td>Q8.18 Relate subjects’ personal life (e.g. occupation, family status, goals, challenges) to the R&amp;B discussion</td>
<td>26.9</td>
<td>21.2</td>
<td>27.9</td>
<td>19.2</td>
<td>4.8</td>
</tr>
<tr>
<td>Q8.19 Ask prepared questions about study related R&amp;B</td>
<td>19.2</td>
<td>34.6</td>
<td>19.2</td>
<td>18.3</td>
<td>8.7</td>
</tr>
<tr>
<td>List of activities</td>
<td>1 Never (%)</td>
<td>2 Rarely (%)</td>
<td>3 Sometimes (%)</td>
<td>4 Often (%)</td>
<td>5 Always (%)</td>
</tr>
<tr>
<td>-----------------------------------------------------------------------------------</td>
<td>-------------</td>
<td>--------------</td>
<td>----------------</td>
<td>-------------</td>
<td>--------------</td>
</tr>
<tr>
<td>Q8.20 Rely on your intuition (gut feelings) to determine subjects’ understanding</td>
<td>14.4</td>
<td>13.5</td>
<td>31.7</td>
<td>21.2</td>
<td>19.2</td>
</tr>
<tr>
<td>Q8.21 Give a short test after the discussion</td>
<td>56.6</td>
<td>17.3</td>
<td>11.5</td>
<td>6.7</td>
<td>4.8</td>
</tr>
</tbody>
</table>

Q9: Do you use any other communication strategies that were not listed above? If yes, describe: ____

**Preparedness**

Q10. How prepared are you to do the following tasks that are sometimes used in the IC process? (n=106)

<table>
<thead>
<tr>
<th>List of tasks</th>
<th>1 Not at all prepared (%)</th>
<th>2 A little prepared (%)</th>
<th>3 Somewhat prepared (%)</th>
<th>4 Quite-a-bit prepared (%)</th>
<th>5 Very much prepared (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q10.1 Engage subjects in learning about R&amp;B</td>
<td>0</td>
<td>0</td>
<td>5.7</td>
<td>37.7</td>
<td>56.6</td>
</tr>
<tr>
<td>Q10.2 Describe and explain concepts related to the R&amp;B in a simplified and clear way</td>
<td>0</td>
<td>0.9</td>
<td>4.7</td>
<td>34.0</td>
<td>60.4</td>
</tr>
<tr>
<td>Q10.3 Describe and explain statistics related to the R&amp;B in a simplified and clear way</td>
<td>0</td>
<td>6.6</td>
<td>25.5</td>
<td>34.9</td>
<td>32.0</td>
</tr>
<tr>
<td>Q10.4 Provide alternative explanations or examples when the subject seems confused</td>
<td>0</td>
<td>0</td>
<td>6.6</td>
<td>36.8</td>
<td>56.6</td>
</tr>
<tr>
<td>Q10.5 Use supplemental instructional materials</td>
<td>11.3</td>
<td>14.2</td>
<td>26.4</td>
<td>21.7</td>
<td>16.4</td>
</tr>
<tr>
<td>Q10.6 Select and adapt the information to meet the personal goals and preferences of the subject</td>
<td>3.8</td>
<td>3.8</td>
<td>10.4</td>
<td>33.0</td>
<td>49.1</td>
</tr>
<tr>
<td>Q10.7 Ensure that the subjects understand study related R&amp;B</td>
<td>0</td>
<td>0.9</td>
<td>5.7</td>
<td>22.7</td>
<td>70.8</td>
</tr>
</tbody>
</table>

**Training**

Q11: Have you had formal training in informed consent administration? (n=106)

<table>
<thead>
<tr>
<th>Response choices</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Yes</td>
<td>70.8</td>
</tr>
<tr>
<td>0 No</td>
<td>29.3</td>
</tr>
</tbody>
</table>

If ‘Yes,’ go to Q12. If ‘No,’ go to Q17.

Q12: About how many training programs have you completed? (n=75)

<table>
<thead>
<tr>
<th>Mean</th>
<th>Median</th>
<th>SD</th>
<th>Min</th>
<th>Max</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.7</td>
<td>4.0</td>
<td>13.8</td>
<td>1</td>
<td>100</td>
</tr>
</tbody>
</table>

Q13: What year was your last training? (n=75) Range: 1989-2015

Q14. Which of these topics were addressed in the training/s? (n=75)

<table>
<thead>
<tr>
<th>List of topics</th>
<th>1 Yes</th>
<th>2 No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q14.1 General approaches in communicating IC</td>
<td>98.7</td>
<td>1.3</td>
</tr>
<tr>
<td>Q14.2 IC process for a specific research project</td>
<td>73.3</td>
<td>26.7</td>
</tr>
<tr>
<td>Q14.3 How to simplify an explanation of R&amp;B</td>
<td>62.7</td>
<td>37.3</td>
</tr>
<tr>
<td>Q14.4 How to convey numbers (such as the chance of harms and benefits)</td>
<td>46.7</td>
<td>53.3</td>
</tr>
</tbody>
</table>
Q14.5 How to use pictures, graphs or other aids for conveying risks and benefits information 36.0 64.0
Q14.6 How to compare the risks of research to the risks of the standard treatment, when relevant 72.0 28.0
Q14.7 How to convey R&B with reference to their time and duration 61.3 38.7
Q14.8 How to compare study related risks to common everyday risks 49.3 50.7
Q14.9 How to personalize risk communication 52.0 48.0
Q14.10 How to expand on risks which are of special concern to subjects 66.7 33.3
Q14.11 How to explain that subjects have the right to withdraw from the study at any time 98.7 1.3

Q15. Which of the following were used in the training(s)?

<table>
<thead>
<tr>
<th>List of training modes</th>
<th>1</th>
<th>2</th>
</tr>
</thead>
<tbody>
<tr>
<td>15.1 In-person training (n=74)</td>
<td>83.8</td>
<td>16.2</td>
</tr>
<tr>
<td>15.2 Video of the consent process (n=75)</td>
<td>45.3</td>
<td>54.7</td>
</tr>
<tr>
<td>15.3 Presentation of case studies (n=75)</td>
<td>69.3</td>
<td>30.7</td>
</tr>
<tr>
<td>15.4 Online course (n=75)</td>
<td>57.3</td>
<td>42.7</td>
</tr>
<tr>
<td>15.5 Simulation (such as a role-playing) (n=74)</td>
<td>48.6</td>
<td>5145</td>
</tr>
<tr>
<td>15.6 Feedback on a practice administration of informed consent (n=74)</td>
<td>54.1</td>
<td>46.0</td>
</tr>
</tbody>
</table>

Q16: Were any other training tools or modes were used? If yes, describe: __________

**Professional characteristics**

Q17: Which one of the following best describes your involvement in the informed consent process? (n=107)

<table>
<thead>
<tr>
<th>Response choices</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>I am currently involved in obtaining research IC</td>
</tr>
<tr>
<td>2</td>
<td>I was involved in obtaining research IC in the past</td>
</tr>
<tr>
<td>3</td>
<td>I am/was supervising/managing those who involved in seeking consent for research</td>
</tr>
</tbody>
</table>

Q18: How many years have you been a registered nurse? (n=107)

<table>
<thead>
<tr>
<th>Mean</th>
<th>Median</th>
<th>SD</th>
<th>Min</th>
<th>Max</th>
</tr>
</thead>
<tbody>
<tr>
<td>25.3</td>
<td>28.0</td>
<td>12.7</td>
<td>1.0</td>
<td>50.0</td>
</tr>
</tbody>
</table>

Q19. How many years have you worked in research? (n=107)

<table>
<thead>
<tr>
<th>Mean</th>
<th>Median</th>
<th>SD</th>
<th>Min</th>
<th>Max</th>
</tr>
</thead>
<tbody>
<tr>
<td>13.9</td>
<td>14.0</td>
<td>8.9</td>
<td>0.5</td>
<td>38.0</td>
</tr>
</tbody>
</table>

Q20. For how long have you been obtaining research informed consent? (n=106)

<table>
<thead>
<tr>
<th>Mean</th>
<th>Median</th>
<th>SD</th>
<th>Min</th>
<th>Max</th>
</tr>
</thead>
<tbody>
<tr>
<td>12.4</td>
<td>11.0</td>
<td>8.3</td>
<td>0.5</td>
<td>36.0</td>
</tr>
</tbody>
</table>

Q21: How many times do you estimate that you have been involved in the IC process for a clinical trial in the past 12 months? (n=106)

<table>
<thead>
<tr>
<th>Mean</th>
<th>Median</th>
<th>SD</th>
<th>Min</th>
<th>Max</th>
</tr>
</thead>
<tbody>
<tr>
<td>42.7</td>
<td>25.0</td>
<td>62.3</td>
<td>0</td>
<td>500</td>
</tr>
</tbody>
</table>
Q22: Which one of the following describes your responsibility related to the consent process?
Involvement in the IC process is/was: (n=107)

<table>
<thead>
<tr>
<th>Response choices</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 My primary job</td>
<td>6.5</td>
</tr>
<tr>
<td>2 A key component of my job</td>
<td>78.5</td>
</tr>
<tr>
<td>3 A limited aspect of my job</td>
<td>14.0</td>
</tr>
<tr>
<td>4 Other (please describe)</td>
<td>0.9</td>
</tr>
</tbody>
</table>

Q23: What is your primary institutional affiliation? (n=105)

<table>
<thead>
<tr>
<th>Response choices</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Hospital/Medical (Academia)</td>
<td>73.4</td>
</tr>
<tr>
<td>2 Hospital/Medical (Community)</td>
<td>14.3</td>
</tr>
<tr>
<td>3 Public/Community Services (Community Health Center, Home Health, Hospice)</td>
<td>11.4</td>
</tr>
<tr>
<td>4 Company (Pharmaceutical/Biotechnology)</td>
<td>1.0</td>
</tr>
<tr>
<td>5 Other, please specify</td>
<td></td>
</tr>
</tbody>
</table>

Q24: The majority of your work is done in which state? (n=78)

Demographics

Q25: What is your gender? (n=107)

<table>
<thead>
<tr>
<th>Response choices</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 Female</td>
<td>88.8</td>
</tr>
<tr>
<td>1 Male</td>
<td>11.2</td>
</tr>
<tr>
<td>2 Other</td>
<td>0</td>
</tr>
<tr>
<td>3 Prefer not to answer</td>
<td>0</td>
</tr>
</tbody>
</table>

Q26: What is your age? (n=97)

<table>
<thead>
<tr>
<th>Mean</th>
<th>Median</th>
<th>SD</th>
<th>Min</th>
<th>Max</th>
</tr>
</thead>
<tbody>
<tr>
<td>50.5</td>
<td>52.0</td>
<td>10.5</td>
<td>28.0</td>
<td>72.0</td>
</tr>
</tbody>
</table>

Q27: How do you classify your race? (n=107)

<table>
<thead>
<tr>
<th>Response choices</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Black/African American</td>
<td>5.6</td>
</tr>
<tr>
<td>2 Asian</td>
<td>1.9</td>
</tr>
<tr>
<td>3 White/Caucasian</td>
<td>86.0</td>
</tr>
<tr>
<td>4 American Indian</td>
<td>0.9</td>
</tr>
<tr>
<td>5 Pacific Islander</td>
<td>0</td>
</tr>
<tr>
<td>6 Other (specified as European)</td>
<td>0.9</td>
</tr>
<tr>
<td>7 Prefer not to answer</td>
<td>4.7</td>
</tr>
</tbody>
</table>

Q28: Are you Hispanic/Latino? (n=107)
Response choices  %
1  Yes  0.9
2  No  94.4
3  Prefer nor to answer  4.7

Q29: What is your highest degree in nursing? (n=107)

Response choices  %
1  Associate Degree  7.5
2  BA/BS/BSN  44.9
3  MA/MS/MSN  38.3
4  DNP  0.9
5  PhD  7.5
6  Other, specify  0.9

Q30: If there is anything else you would like to tell us about the informed consent process or your related experiences, provide comments below: __________________________