

7-14-2015

College student understanding of informed consent terminology

Kishore Garapati

Follow this and additional works at: <http://commons.emich.edu/theses>

 Part of the [Bioethics and Medical Ethics Commons](#), and the [Investigative Techniques Commons](#)

Recommended Citation

Garapati, Kishore, "College student understanding of informed consent terminology" (2015). *Master's Theses and Doctoral Dissertations*. 627.

<http://commons.emich.edu/theses/627>

This Open Access Thesis is brought to you for free and open access by the Master's Theses, and Doctoral Dissertations, and Graduate Capstone Projects at DigitalCommons@EMU. It has been accepted for inclusion in Master's Theses and Doctoral Dissertations by an authorized administrator of DigitalCommons@EMU. For more information, please contact lib-ir@emich.edu.

College Student Understanding of Informed Consent Terminology

by

Kishore Garapati

Thesis

Submitted to the Department of Clinical Research Administration

Eastern Michigan University

in partial fulfillment of the requirements

for the degree of

MASTER OF SCIENCE

in

Clinical Research Administration

Thesis Committee:

Irwin Martin, Ph.D., Chair

Stephen Sonstein, Ph.D.

July 14, 2015

Ypsilanti, Michigan

Acknowledgement

I would like to acknowledge Dr. Sonia Chawla Wright, Research Compliance Officer at office of Reserach Complience, Eastern Michigan University for her help during the survey distribution process.

Abstract

A good, understandable informed consent form (ICF) is key to ethical medical research, and the ICF is necessary according to United States federal regulation. Since they may be written in complex technical language, ICFs are often difficult for subjects to understand. The purpose of this research was to evaluate students' understanding of terminology commonly used in the ICF. An online research survey was sent to active students of Eastern Michigan University (EMU) during the winter 2015 semester. Questions were asked to evaluate the students' understanding of the correct meaning of the terms used in medical research. The majority of students understood common terminology used in informed consents, but they were confused about the meaning of the term "Clinical Research/Trial" and the location where the clinical studies were conducted. Therefore, investigators and Institutional Review Boards (IRBs) need to be aware of these potentially confusing items when writing an ICF.

Table of Contents

Acknowledgement	ii
Abstract.....	iii
Chapter 1: Introduction.....	1
Purpose of the Study.....	3
Research Questions.....	3
Chapter 2: Research Design and Methodology.....	4
Chapter 3: Results.....	5
Chapter 4: Discussion.....	10
Chapter 5: Conclusion.....	12
References.....	13
Appendix A: Approval Letter from EMU Human Subject Review Committee.....	19
Appendix B: Sample Survey Form.....	20

List of Tables

<u>Table</u>		<u>Page</u>
1	Demographic description of the respondents.....	5
2	Comparisons of responses by the participants to various questions	6
3	Responses to the question "Where do you think clinical research studies are conducted?"	8

List of Figures

<u>Figure</u>		<u>Page</u>
1	"Clinical Research/Trial" answers by class year.....	7

Introduction

The American Medical Association defines informed consent as the “process of communication between a patient and physician that results in the patient’s authorization or agreement to undergo a specific medical intervention,” (as cited in Alonso, Alejandro, & Emma, 2013, p. 2). Informed consent has a long history. From the traditional vivisection of condemned men, to the scandalous U.S. Public Health Service Syphilis Study at Tuskegee and the Nazi experimentation on huge numbers of prisoners during World War II, patients have not always known they were being utilized as test subjects (as cited in Dresden & Levitt, 2001). Informed consent of research subjects was first stated as a research standard in 1947 in the Nuremberg Code and later in the Declaration of Helsinki (1964) and the Belmont Report (1978) (as cited in Dresden & Levitt, 2001). In recent decades, there has been far-reaching recognition of the significance of educated assent in medicine and in research (Dawson & Kass, 2005). Lack of obtaining proper informed consent affects patient autonomy (Lo, 2000). Patient autonomy is very important in ethical medical practices. A human subject must have the opportunity to choose what ought to or ought not happen to his/her body, making a decision based on relevant data. No third party may force a patient to act in a specific way. Indeed, even though the physician can assist the subject’s decision making, all the decisions must be made by subject. A good, understandable informed consent form (ICF) is key to ethical medical research and, as such, ICFs are required by US federal regulation.

Respect for persons is an important principle of the Belmont Report and is linked to informed consent. As noted in the Belmont Report, "Respect for person incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents and second that persons with diminished capacity are entitled to protection" (as cited in Jonsen, 1999, p. 23).

According to Applebaum, Lidz, and Meisel (1987), an understandable informed consent process will aid in obtaining consent from subjects, which shows their voluntariness.

Many authors reported that the typical ICF is written at a reading level that needs a minimum of a high school education or higher to understand (Baker & Taub, 1983; Gray, Cooke, & Tannenbaum, 1978; Grossman, Piantadosi, & Covahey, 1994; Grunder, 1980; Hammerschmidt & Keane, 1992; Mede & Howser, 1992; Morrow, 1980; Ogloff & Otto, 1991). According to Grossman, Piantadosi, and Covahey (1994), the average person can read an ICF written at the eighth grade reading level. However, some researchers reported that participants do not fully understand the disclosure information provided in ICFs (Bergler, Pennington, Metcalfe, & Freis, 1980; Joffe, Cook, Cleary, Clark, & Weeks, 2001; Miller, Searight, Grable, Schwartz, Sowell, & Barbarash, 1994). Education plays an vital role in understanding and recall of the information given at the time of informed consent procedure (Waggoner & Sherman, 1996; Lawson & Adamson, 1995). ICFs are often difficult to understand since they are written with complex technical language that is difficult for many patients to understand (Hopper, TenHave, & Hartzel, 1995; Paasche-Orlow, Taylor, & Brancati 2003). Some authors reported that participant understanding may be raised if the ICF is easy to read (Beardsley, Jefford, & Mileskin 2007; Bjorn, Rossel, & Holm, 1999; Paris, Chaves, Cornu, Maison, & Salvat-Méris 2007; Taub, Baker, Kline, & Sturr 1987; Young, Hooker, & Freeberg 1990). Situations where participants did not understand the ICF have provoked calls for investigators along with institutional review boards (IRBs) to search for methods to advance research participants' understanding of the ICF (Lavori, Sugarman, Hays, & Feussner 1999; Siminoff, 2003). Data from various western countries, including the United States, showed that research subjects regularly do not understand placebo treatment or randomization (Elbourne, Snowdon, & Garcia

1997; Snowdon, Garcia, & Elbourne 1997), and deliberations to expand patient understanding of research utilizing distinctive methodologies to informed consent have mixed results (Dunn, Lindamer, Palmer, Schneiderman, & Jeste, 2001; Sorrell, 1991; Stiles, Poythress, Hall, Falkenbach, & Williams, 2001). It is also interesting to note that simplified information, when provided to patients, results in reduced anxiety about consent and increased understanding with the ICF (Coyne, Xu, Raich, Plomer, & Dignan, 2003).

In this aspect, it is very important to know whether the terminology used in ICF is understandable. Therefore, this study examined to what extent university students understand terms often used in an ICF.

Purpose of the Study

The purpose of this research was to investigate college students' comprehension of terminology commonly used in informed consent forms. Based on the results, suggestions were made to researchers and Institutional Review Boards regarding Informed Consent terminology.

Research Questions

- How well do college students understand the terms often used in Informed Consent Forms?
- Which sub-population of college students understands and which sub-population was not able to understand the terminology used in ICF?
- Does year in school or graduate student status affect the understanding of the terms used in ICF among college students?

Research Design and Methodology

An online research survey was sent to all active students of Eastern Michigan University (EMU) in the winter 2015 semester by EMU's Office of Institutional Research and Information Management (IRIM) using Qualtrics online survey software. A total of 20,006 students were invited to participate in the survey. The research survey posed a series of questions related to common terminology used in ICF. Demographic data were collected, including age range, sex, ethnic group, class year and college major of the students. Correlation was examined between these demographic characteristics and familiarity with the terminology most commonly used in the ICFs. The survey was distributed after receiving approval from the University Human Subjects Review Committee (UHSRC) of EMU (Appendix A). The survey remained active online for two weeks. A copy of the survey, including the online consent form, may be found in Appendix B. The results were examined for any large ($\geq 10\%$) incorrect responses. These responses were then examined by cross tabulation with demographic data. Any possible relationship with demographic data was examined using appropriate statistical tests.

Results

The survey was sent to 20,006 students, of which 1,899 (10.70%) participated in the study. However, only 1,869 (10.53%) provided answers to the survey questions. The data used in this study were extracted from the participants who answered survey questions. The other respondents were excluded from all analysis, including demographics. The response rate appears typical for a survey of this type. Demographic results are presented in Table 1.

Table 1
Demographic description of the respondents

			Percent
Response Rate	<i>Valid</i>	1869	10.7%
	<i>Missing</i>	30	
	<i>Total</i>	1899	
Age	<i>18-24</i>	1109	59.3%
	<i>25-34</i>	430	23.0%
	<i>35 or Older</i>	330	17.7%
Sex	<i>Female</i>	1291	69.1%
	<i>Male</i>	578	30.9%
Ethnic Group	<i>White</i>	1408	75.5%
	<i>Black or African-American</i>	202	10.8%
	<i>Native Hawaiian or other Pacific Islander</i>	3	0.2%
	<i>Asian</i>	108	5.8%
	<i>American Indian or Alaska Native</i>	6	0.3%
	<i>Other/ multi-ethnic</i>	137	7.3%
College year	<i>First year</i>	283	15.2%
	<i>Second Year</i>	208	11.2%
	<i>Third Year</i>	318	17.1%
	<i>Fourth Year or beyond</i>	548	29.4%
	<i>Graduate Student</i>	504	27.1%
College Major or Program	<i>Arts & Science</i>	665	35.6%
	<i>Business</i>	238	12.7%
	<i>Education</i>	280	15.0%
	<i>Health & Human Services</i>	457	24.5%
	<i>Technology</i>	171	9.2%
	<i>Others</i>	57	3.1%

Ten questions were chosen to evaluate the students' understanding of the correct meaning of terms commonly used in medical research. However, only eight questions were included in the survey due to an error by the EMU Research group. As a result, questions 3 ("Randomization") and 6 ("Reimbursement") in Appendix B were not included in the survey, and no results are available. The number of correct responses to the eight survey terms are presented in Tables 2 and 3. The terms "placebo," "biopsy," and "consent" were understood by >90% of the respondents, and no further analysis were conducted for these terms.

Table 2

Comparisons of responses by the participants to various questions

	1 Clinical Research	2 Placebo	3 Biopsy	4 Consent	5 Clinical investigator	6 Efficacy
Correctly answered	797 (45.1 %)	1639 (92.7%)	1682 (95.2%)	1627 (92.1%)	1319 (74.7%)	1273 (72.1%)

See **Appendix B** for the options offered.

When the question on "Clinical research" or "Clinical trial" was asked, 797 participants (45.1 %) responded correctly (i.e., *Scientific investigations using humans to study treatment of human disease*), but 80 participants (4.5%) said they were 'not sure' what the term means. While 71 participants (4.0%) chose *Scientific investigations using animals to study treatment of human disease*, 819 participants (46.6%) chose *Scientific investigations using laboratory studies to study treatment of human disease*. Cross tabulations were examined for this question. The only answer that showed any relationship to a demographic variable was the term "clinical research/trial" by class year. Figure 1 presents the percent answering correctly for "clinical research/trial" by class year.

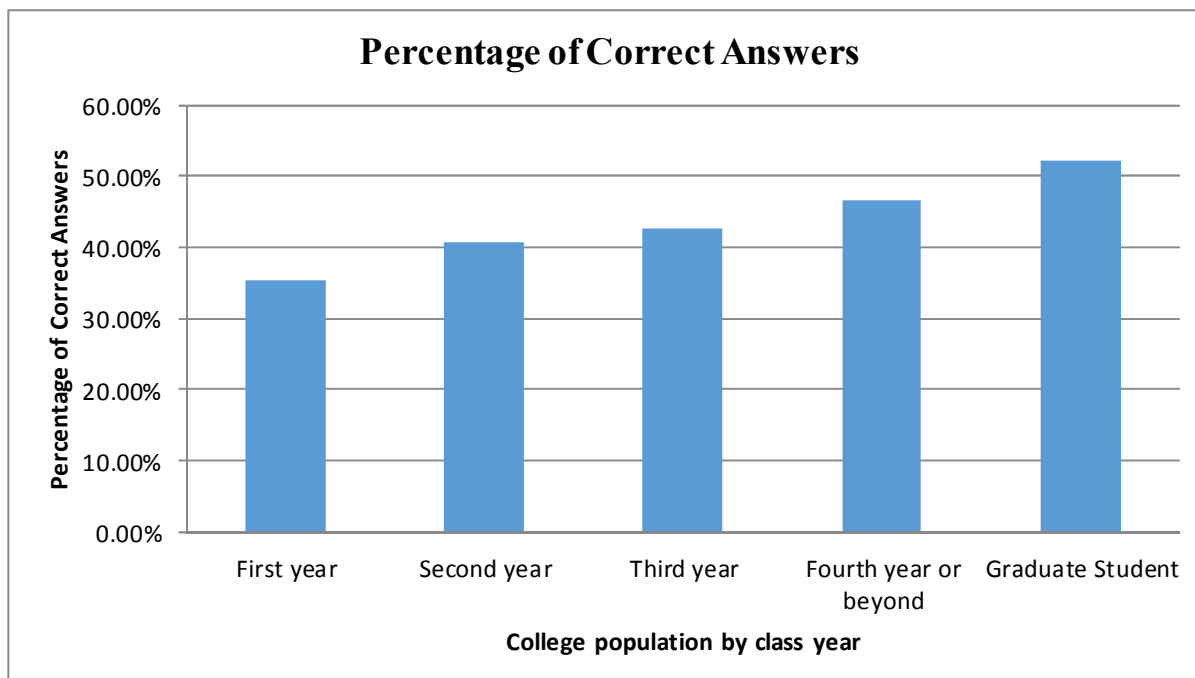


Figure 1. "Clinical Research/Trials" answers by class year

Using the Cochran-Armitage Trend Test (Agresti, 2002), the increasing trend of correct answers was tested for statistical significance. The results of the Cochran-Armitage Trend Test yielded a Z Statistic of 4.6463. The corresponding p -value is $< .0001$, rejecting the null hypothesis of no difference and accepting the alternative hypothesis that there is a statistically significant increasing trend in the population proportions.

When asked to define the term "placebo", 1639 participants (92.7%) gave the correct answer, 73 participants (4.1%) said they were not sure what is meant by "placebo" while the rest (3.2%) chose incorrectly. When the meaning of "biopsy" was asked, 1682 participants (95.2%) chose the correct answer, and 61 participants (3.5%) said they were not sure, while the remaining (1.3%) chose wrong answers. When the meaning of the term "consent" was asked, 1627 participants (92.1%) chose the correct answer, while 17 participants (1.0%) said they were not sure of the meaning of the term, and the rest (6.9%) chose wrong answers. When asked about

the meaning of the term "clinical investigator", 1319 participants (74.7%) responded correctly (i.e., *Someone in charge of carrying out a research study in a hospital*), while 172 participants (9.7%) said they were 'not sure' of the term. Additionally, 88 participants (5.0%) chose *Someone who finds criminal activities in hospitals*, and 187 participants (10.6%) chose *Someone who works in a laboratory in a hospital*. When asked about the word "Efficacy", 1273 participants (72.1%) responded correctly (i.e., *The ability of a drug to produce the desired effect*), 346 participants (19.6%) said they were 'not sure' of what the term means, 72 participants (4.1%) chose *The ability of a drug to produce no adverse effects*, and 75 participants (4.2%) chose *The ability of a drug to be used by the patient*. No meaningful demographic differences were observed when "placebo," "biopsy," "consent," "clinical investigator," or "efficacy" were examined in cross-tabulations.

Table 3

Responses to the question "Where do you think clinical research studies are conducted?"

Where do you think clinical research studies are conducted?	Hospitals	University Medical centers	Clinics	Private Physician's office	Not sure
	896 (47.2%)	1346 (70.9%)	660 (34.8%)	302 (15.9%)	87 (4.6%)

When the question "Where do you think clinical research studies are conducted?" was asked, 896 participants (47.2%) chose "hospitals" while 1346 participants (70.9%) chose "university medical centers," 660 participants (34.8%) chose "clinics," 302 participants (15.9%) chose "private physician's office," and 87 participants (4.6%) said they were not sure about where the clinical research studies were conducted (Table 3). Only 42.2 % correctly chose all 4 possible locations. When participants' college majors or programs were considered, among all

the participants, students in the College of Arts and Science chose the highest number of correct answers (>30%) which included hospital (37.2%), university medical centers (36.3%), clinics (35.3%) and private physician's office (33.1%). No other college major answered this question above 30%.

When the question "You must have the disease being studied to volunteer for a clinical study?" was posed, 1168 participants (66.1%) correctly chose the answer "false", while 404 participants (22.9%) incorrectly chose "true", and 196 participants (11.1%) chose "Not sure." No significant demographic differences were observed for this question.

Discussion

Understanding the terminology of informed consent used in research has a high value since it determines the research subjects' understanding of research and their volunteering in research participation. For seven out of eight questions posed to a college population, the majority of the students understood the terms. For the term clinical research/trial, however, only 45.1% understood the meaning. Upon further examination, it was discovered that understanding improved with educational level, yet still only 52.1% of graduate students understood the meaning of the term "clinical research/trial." Therefore, it is clear that the understanding of this term was greater in more highly educated students in the survey population (graduate students). Whether this increase by class year is due to increased formal education or simply age cannot be determined by this survey. The understanding level is still low in graduate students as they were confused the term "clinical research/trial" with "clinical laboratory."

This study was not conducted in a typical clinical research population; this population has attained a higher educational level than that normally found in research study populations. Thus, the results would likely be skewed towards more knowledgeable respondents and correct responses in a more typical population would likely be lower. Investigators should be aware of the population used in a clinical study. Educational level has previously been shown to correlate with a better understanding of terms used in informed consent (Waggoner & Sherman, 1996). As participants' age and/or level of education increased, the level of understanding of the term "clinical research/trial" increased in college students, but this may not be true in the general population as a clinical study population may not be as highly educated. The students responded to "placebo," "biopsy," and "consent" with a high level of understanding (>90% correct). Fewer students understood "clinical investigator" and "efficacy," but the results still showed a good

understanding of these terms (>70% correct). The results of these questions showed no relationship to any demographic variable.

In response to the statement "You must have the disease being studied to volunteer for a clinical study," 66.1 % of participants chose "false." For the participation of Phase I clinical trials, the volunteer may or may not have to have the disease. Phase I clinical studies are conducted mostly on healthy volunteers to determine safety. College students often make up a large percent of Phase I volunteers, and a large number of students (66.1 %) in the survey understand that disease-free volunteers may participate in Phase I clinical trials.

By observing the overall findings, most of the terms used in the survey were understood by the college students who participated. Graduate students only understood the term "clinical research/trial" better than the undergraduate students. No demographic differences were observed for the rest of the words tested. However, for question 7 concerning the location of clinical students, students in the College of Arts and Science answered better than the rest, although it is unlikely that this difference is meaningful. This means that regardless of age, sex, ethnicity, college major, and college class, most of the questions were understood by the majority of the students. Since the participants were college students, they would be considered better educated than the general clinical research population. It is therefore recommended that when the term "clinical research/trial" or similar terminology is used in patient recruitment activities, the usage is quickly followed by an explanation that the study will be in patients or volunteers. Otherwise, perspective participants may believe the activity is related to the clinical laboratory. The potential for misunderstanding the other terms used in this survey in a more typical clinical research population cannot be determined here, although investigators are cautioned not to extrapolate these findings too broadly.

Conclusion

Eight terms often used in clinical studies and in informed consent forms were tested for comprehension by a college-aged population. Six terms were fairly well understood by this population. The survey revealed, however, that this population did not accurately differentiate the terms clinical research from clinical laboratory. The population also was generally not aware of the diverse locations for clinical research. Researchers and Institutional Review Boards are cautioned to keep these findings in mind when writing study recruitment or informed consent documents, especially if the study population is less educated than this group of college students.

References

- Agresti, A. (2002). *Categorical data analysis* (2nd ed.). New York, NY: John Wiley and Sons.
- Alonso, C., Alejandro G. A., & Emma, V. (2013). Who decides? Informed consent for cancer patients in Mexico. In H. Nuria & U. Antonio (Eds.), *Clinical trials in Latin America: Where ethics and business clash* (pp. 237-249). Switzerland: Springer Science & Business Media.
- Applebaum, P., Lidz, C., & Meisel, A. (1987). *Informed consent: Legal theory and clinical practice*. New York, NY: Oxford University Press.
- Baker, M.T., & Taub, H. A. (1983). Readability of informed consent forms for research in a veterans administration medical center. *The Journal of the American Medical Association*, 250(19), 2646-2648.
- Beardsley, E., Jefford, M., & Mileshekin, L. (2007). Longer consent forms for clinical trials compromise patient understanding: So why are they lengthening? *Journal of Clinical Oncology*, 25(9), e13-e14.
- Bergler, J., Pennington, A., Metcalfe, M., & Freis, E. (1980). Informed consent: How much does the patient understand? *Clinical Pharmacology and Therapeutics*, 27(4), 435-440.
- Bjorn, E., Rossel, P., & Holm, S. (1999). Can the written information to research subjects be improved? An empirical study. *Journal of Medical Ethics*, 25(3), 263-267.
- Coyne, C., Xu, R., Raich, P., Plomer, K., Dignan, M., & Wenzel, L. (2003). Randomized, controlled trial of an easy-to-read informed consent statement for clinical trial participation: A study of the Eastern Cooperative Oncology Group. *Journal of Clinical Oncology*, 21(5), 836-842.

- Dawson., L. & Kass., N. E. (2005). Views of US researchers about informed consent in international collaborative research. *Social Science & Medicine*, 61(6), 1211-1222.
- Dresden, G. M. & Levitt, M. A. (2001). Modifying a standard industry clinical trial consent form improves patient information retention as part of the informed consent process. *Academic Emergency Medicine*, 8(3), 246-252.
- Dunn, L., Lindamer, L., Palmer, B., Schneiderman, L., & Jeste, D. (2001). Enhancing comprehension of consent for research in older patients with psychosis: A randomized study of a novel consent procedure. *The American Journal of Psychiatry*, 158(11), 1911–1913.
- Elbourne, D., Snowden, C., & Garcia, J. (1997). Informed consent: Subjects may not understand concept of clinical trials. *British Medical Journal*, 315(7102), 248-249.
- Gray, B., Cooke, R., & Tannenbaurn, A. (1978). Research involving human subjects: The performance of Institutional Review Boards is assessed in this empirical study. *Science*, 201(4361), 1094-1101.
- Grossman, S., Piantadosi, S., & Covahey, C. (1994). Are informed consent forms that describe clinical oncology research protocols readable by most patients and their families? *The Journal of Clinical Oncology*, 12(10), 2211-2215.
- Grundner, T.M. (1980). On the readability of surgical consent forms. *The New England Journal of Medicine*, 302(16), 900-902.
- Hammerschmidt, D., & Keane, M. (1992). Institutional Review Board review lacks impact on readability of consent forms for research. *The American Journal of the Medical Science*, 304(6), 348-351.

- Hopper, K., TenHave, T., & Hartzel, J. (1995). Informed consent forms for clinical and research imaging procedures: How much do patients understand? *American Journal of Roentgenology*, *164*(2), 493-496.
- Joffe, S., Cook, E., Cleary, P., JW, C., & Weeks, J. (2001). Quality of informed consent in cancer clinical trials: A cross-sectional survey. *Lancet*, *358*(9295), 1772-1777.
- Jonsen, A. R. (1999). The Belmont report: Ethical principles and guidelines for the protection of human subjects of research. In A. R. Jonsen, R. M. Veatch & L. Walters (Eds.), *Source book in bioethics* (22-28). Washington, D.C.: Georgetown University Press.
- Lavori, P., Sugarman, J., Hays, M., & Feussner, J. (1999). Improving informed consent in clinical trials: A duty. *Controlled Clinical Trials*, *20*(2), 187-193.
- Lawson, S.L., and Adamson H.M. (1995). Informed consent readability: Subject understanding of 15 common consent form phrases. *Institutional Review Board*, *17*(5), 16-19.
- Lo, B. (2000). *Resolving ethical dilemmas: A guide for clinicians* (2nd ed.). Philadelphia, PA: Lippincott Williams & Wilkins.
- Meade, C., & Howser, D. (1992). Consent forms: How to determine and improve their readability. *Oncology Nursing Forum*, *19*(10), 1523-1528.
- Miller, C., Searight, H., Grable, D., Schwartz, R., Sowell, C., & Barbarash, R. (1994). Comprehension and recall of the informational content of the informed consent document: An evaluation of 168 patients in a controlled clinical trial. *Journal of Clinical Research and Drug Development*, *8*(4), 237-248.
- Morrow, G. (1980). How readability are subject consent forms? *The Journal of the American Medical Association*, *244*(1), 56-58.

- Ogloff, J., & Otto, R. (1991). Are research participants truly informed? Readability of informed consent forms used in research. *Ethics and Behavior, 1*(4), 239-252.
- Paasche-Orlow, M., Taylor, H., & Brancati, F. (2003). Readability standards for informed-consent forms as compared with actual readability. *The New England Journal of Medicine, 348*(8), 721-726.
- Paris, A., Nogueira ga Gama Chaves, D., Cornu, C., Maison, P., Salvat-Melis, M., Ribuot, C., & Cracowski, J. (2007). Improvement of the comprehension of written information given to healthy volunteers in biomedical research: A single-blind randomized controlled study. *Fundamental & Clinical Pharmacology, 21*(2), 207-214.
- Siminoff, L. (2003). Toward improving the informed consent process in research with humans. *Institutional Review Board, 25*(5), S1-S3.
- Snowdon, C., Garcia, J., & Elbourne, D. (1997). Making sense of randomization: Responses of parents of critically ill babies to random allocation of treatment in a clinical trial. *Social Science and Medicine, 45*(9), 1337-1355.
- Sorrell, J. (1991). Effects of writing/speaking on comprehension of information for informed consent. *Western Journal of Nursing Research, 13*(1), 110-122.
- Stiles, P., Poythress, N., Hall, A., Falkenbach, D., & Williams, R. (2001). Improving understanding of research consent disclosures among persons with mental illness. *Psychiatry Services, 52*(6), 780-785.
- Taub, H., Baker, M., Kline, G., & Sturr, J. (1987). Comprehension of informed consent information by young-old through old-old volunteers. *Experimental Aging Research, 13*(4), 173-178.

Reisen, S. J., Dyck, A. J., & Curran, W. J. (Eds.). (1977). Historical perspectives and contemporary concerns. In *Ethics in medicine* (p. 257). Cambridge, MA: MIT Press.

Waggoner, W.C., & Sherman, B.B (1996). Who understandds? II: A survey of 27 words, phrases or symbols used in proposed clinical research consent forms. *Institutional Review Board, 18(3)*, 8-10.

Young, D., Hooker, D., & Freeberg, F. (1990). Informed consent documents: Increasing comprehension by reducing reading level. *Institutional Review Board, 12(3)*, 1-5.

APPENDICES

Appendix A: Approval Letter from EMU Human Subject Review Committee

RESEARCH @ EMU

UHSRC Determination: **EXEMPT**

DATE: **February 5, 2015**

TO: **Kishore Garapati
Eastern Michigan University**

Re: **UHSRC: # 715162-1
Category: Exempt category 2
Amendment Approval Date: February 5, 2015**

Title: **Survey to Determine Understanding of Terminology Used in Inform Consent**

Your research project, entitled **Survey to Determine Understanding of Terminology Used in Inform Consent**, has been determined **Exempt** in accordance with federal regulation 45 CFR 46.102. UHSRC policy states that you, as the Principal Investigator, are responsible for protecting the rights and welfare of your research subjects and conducting your research as described in your protocol.

Your exempt amendment request has been approved for the following: *Addition of modified informed consent form.*

Renewals: Exempt protocols do not need to be renewed. When the project is completed, please submit the **Human Subjects Study Completion Form** (access through IRBNet on the UHSRC website).

Modifications: You may make minor changes (e.g., study staff changes, sample size changes, contact information changes, etc.) without submitting for review. However, if you plan to make changes that alter study design or any study instruments, you must submit a **Human Subjects Approval Request Form** and obtain approval prior to implementation. The form is available through IRBNet on the UHSRC website.

Problems: All major deviations from the reviewed protocol, unanticipated problems, adverse events, subject complaints, or other problems that may increase the risk to human subjects or change the category of review must be reported to the UHSRC via an **Event Report** form, available through IRBNet on the UHSRC website

Follow-up: If your Exempt project is not completed and closed after **three years**, the UHSRC office will contact you regarding the status of the project.

Please use the UHSRC number listed above on any forms submitted that relate to this project, or on any correspondence with the UHSRC office.

Good luck in your research. If we can be of further assistance, please contact us at 734-487-3090 or via e-mail at human.subjects@emich.edu. Thank you for your cooperation.

Sincerely,

Jennifer Kellman Fritz
Chair
University Human Subjects Review Committee

Appendix B: Sample Survey Form*

Health Terminology Familiarity

Q1. Age Range:

18 - 24 years old

25 - 34 years old

35 - or older

Q2. Sex: Female () Male ()

Q3. In which ethnic group do you classify yourself?

1. White

2. Black or African-American

3. Native Hawaiian or other Pacific Islander

4. Asian

5. American Indian or Alaska Native

6. Other / multi-ethnic

Q4. What is your class year in college?

1. First year

2. Second year

3. Third year

4. Fourth year or beyond

5. Graduate

Q5. In which college is your major or with which are you most closely associated?

1. Arts & Sciences
2. Business
3. Education
4. Health & Human Services
5. Technology
6. Others

Please choose the answer(s) that best represents your understanding of the meaning of each term:*

Q1. Clinical research or clinical trials

- 1. Scientific investigations using humans to study treatment of human disease**
2. Scientific investigations using animals to study treatment of human disease
3. Scientific investigations using laboratory studies to study treatment of human disease
4. Not Sure

Q2. Placebo

1. A method to test new drugs
- 2. An inactive or fake drug given in research**
3. Any drug given in research
4. Not sure

Q3. Randomization

1. A type of health insurance
2. A method of assigning patients into study groups by the order of study enrollment
- 3. A method of assigning patients into study groups by chance**
4. Not sure

Q4. Biopsy

1. **The removal of tissue, cells, or fluids from someone's body to check for illness**
2. It is a type of treatment given to improve side effects
3. It is a branch of psychology that analyzes behaviors, thoughts and feelings
4. Not sure

Q5. Consent

1. **Agreement to enter a proposed study**
2. Understanding a proposed study
3. Signing an explanation of a proposed study.
4. Not sure

Q6. Reimbursement

1. Method of paying fees to physician
2. **Method of paying expenses to a patient**
3. Insurance
4. Not sure

Q7. Clinical Investigator

1. Someone who finds criminal activities in hospitals
2. **Someone in charge of carrying out a research study in a hospital**
3. Someone who works in a laboratory in a hospital
4. Not sure

Q8. Efficacy

1. **The ability of a drug to produce the desired effect**
2. The ability of a drug to produce no adverse effects
3. The ability of a drug to be used by the patient
4. Not sure

Q9. Where do you think clinical research studies are conducted?

1. **Hospitals**
2. **University Medical Centers**
3. **Clinics**
4. **Private Physician's Office**
5. Not sure

Q10. You must have the disease being studied to volunteer for a clinical study.

1. True
2. **False**
3. Not sure

Correct answers in **bold*