

Students' Understanding About Clinical Research and Their Willingness to Participate in
Clinical Trials

by

Divya Pandiri

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Thesis Committee:

Irwin Martin, Ph.D.

Stephen Sonstein, Ph.D.

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Abstract

Drug development is a tedious process involving a huge amount of time and money. Clinical trials are the important part of the drug development process. In clinical trials, subject recruitment is challenging especially when recruiting the Generation Y (millennial) population group. This might be generational or due to few barriers. In the present research, in-class surveys were done in the College of Health and Human Services and the College of Business at Eastern Michigan University to determine whether an educational intervention impacts the willingness of Generation Y to participate in clinical research. This interventional group (active group or exposure group) was compared to a placebo group (without any educational intervention). In both treatment groups, the number of students who were willing to participate in clinical trials was > 90%. This clearly indicates that the intervention used did not work, or it simply means that the students are willing to participate in clinical trials. Between Generation Y (n = 114) and the 35 years or older group (n = 2), far more of Generation Y, almost 98.3%, indicated that they were willing to participate in clinical research. This trend might be different if the sample size were similar. When asked "How knowledgeable are you about clinical research?" participants with science backgrounds clearly indicated more knowledge than non-science professions. Three quarters of participants said they have complete knowledge about clinical research, but upon further analysis it was seen that they answered incorrectly when asked what clinical research is. Therefore, further research is needed on these parameters with a better exposure of the treatment group and with equal sample size in both the comparing groups, since the number of participants older than 35 years in the present study was too limited to make any reliable conclusions.

Keywords: Clinical trials, Generation Y, interventional group

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Chapter 1: Introduction

Clinical research, or clinical trials, is research done on humans to determine the safety and effectiveness of new medicine. According to the World Health Organization (2015):

A clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiological procedures, devices, behavioral treatments, process-of-care changes, preventive care, etc. (para. 1)

Therefore, as per World Health Organization, a clinical trial enrolls humans to study the results of a given product or procedure. Friedman, Furberg, and DeMets (2010), in the *The Fundamentals of Clinical Trials (4th ed.)*, stated, “Clinical trial is a prospective study comparing the effect and value of intervention(s) against a control in human beings” (p. 2). To conduct clinical research, human beings (healthy volunteers or specific patient populations) are to be screened and enrolled in a study based on inclusion and exclusion criteria. Patient or subject recruitment into clinical trials is done at clinical sites, using various recruitment strategies approved by the site institutional review board (IRB) or institutional ethical committee (IEC).

Chapter 2: Background

Trauth, Musa, Siminoff, Jewell, Ricci (2000), stated that the general public understands that biomedical research unfolds new, safe, and effective ways to diagnose, treat, and cure diseases, but they are not aware of the fact that this advancement takes place only with public participation. According to Moorcraft et al. (2016), "Recruiting subjects can be challenging and slower than anticipated." Subject recruitment is a major challenge in clinical trials, especially with the subjects between the ages of 18 and 34 years, termed *Generation Y* (Nelson, Martin, & Getz, 2015). This can be challenging because of barriers such as attitude, religious factors, and knowledge (Brown, Cowdery, & Jones, 2015). Brown et al. (2015) conducted a questionnaire survey of about 82 Michigan high school students and studied how "knowledge" and "attitude" of adolescence affect their participation in clinical trials. The researchers made race/ethnic comparisons to see if educational intervention can make any difference. According this survey, only 33% had heard about clinical trials, and overall understanding about clinical trials was below average (46%). Minority students had low knowledge ($p = .0006$), a more negative attitude ($p = .05$), and more distrust ($p = .15$) about the clinical trials than non-Hispanic Whites, whereas non-Hispanic Whites ($p = .05$) had more self-efficacy. In this survey, participants indicated that they felt more positive towards participating in clinical trials. Therefore, the authors stated that educational intervention is needed to deal with barriers such as knowledge, attitude, and a distrust among adolescents, which may increase their awareness and willingness to participate in clinical trials.

According to Midgley, Isaacs, Weitkamp, Target (2016), "Relatively little research is available on young people's participation in clinical trials generally," and when done, two things should be considered: (a) that important terminology such as "recruitment, randomization, and

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ongoing data collection” is understood, and (b) whether participating in the trial impacted their therapy/treatment (p. 2).

In Winter 2015, an email survey was conducted on active students attending Eastern Michigan University to understand the college-aged population's knowledge of common terminologies used in informed consent forms when enrolling as subjects in clinical trials (Garapati, 2015). Most of the college-aged population couldn't differentiate between clinical research and clinical laboratory practices. Only 45.1% answered correctly when asked, “What is clinical research or clinical trials?”. And only 42.2% selected all the options that apply when asked, “Where clinical research studies are conducted”.

Based on the email survey results of these two questions, the present study tried to further estimate college-aged students' understanding and willingness to participate in clinical research through an in-class paper survey. In the present survey, the age groups were 18–24 years, 25–34 years, and 35 years or older. For most of the analysis, 18–24 and 25–34 years were collapsed to 18–34 years, which represents the Generation Y population in the survey. Any participants 35 or older were considered Generation X.

Generation Y is not clearly explained in the literature, but according to Strauss and Howe (1991), who first coined the term, it is defined as those born between 1982 and 2004. Therefore, the age group that falls under Generation Y (millennials) is 13–34 years, whereas Generation X would include those born prior to 1982, and Generation Z includes those born after 2005.

According to Nelson et al. (2015), Generation Y are less likely to participate in clinical trials than those of older groups. The authors further stated that this difference is considered generational and not simply related to age.

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Brown et al. (2015) conducted a survey to understand the knowledge and attitudes of adolescents towards clinical trials. The authors categorized the survey questions based on barriers such as distrust of medical research, attitudes, knowledge, perceived ability, receptivity, and intention about clinical research. Based on their results, the authors concluded that educational interventions aimed at adolescents may improve clinical trial awareness and can address some of the barriers that inhibit young people from enrolling in clinical trials.

Purpose of the Study

The purpose of this study is to influence the willingness of Generation Y to participate in clinical research by providing a minimal amount of education prior to completion of a questionnaire.

Research Question

1. Does a better understanding of clinical research affect Generation Y's willingness to participate in clinical trials?
2. Does the college of Health and Human Services have better understanding than College of Business?

Chapter 3: Research Design and Methodology

After receiving approval from the University Human Subjects Review Committee at Eastern Michigan University (Appendices A and B), an in-class paper survey was conducted in the Spring 2016 semester. Members of two colleges of undergraduate students at Eastern Michigan University were selected, and individual departments were approached for permission to conduct the survey. This paper includes a detailed analysis of surveys done in the College of Health and Human Services and the College of Business. In the College of Health and Human Services, one undergraduate class was selected ($n = 118$), and in the College of Business, five undergraduate classes were approached ($n = 92$). The survey sheets used were color-coded by college. In each class, students were given either a survey sheet that had a small description of drug development (Active Group; see Appendix C) or a survey sheet that had a standard scientific method definition (Placebo Group; see Appendix D). The survey sheets contained 12 questions that included those related to clinical research and student demographics such as age, gender, college year, and academic major. Students in each class were given these sheets (active or placebo) randomly. Students were informed verbally (Verbal Consent Form; see Appendix E) that they could return the survey sheets filled or blank as per their willingness to participate in the survey. (This was considered the consent to participate in the in-class paper survey.)

Collected data from the in-class paper survey were initially entered into Microsoft Excel. Later these data were translated to SPSS format, in which each question and their options (answers) were categorized into ordinal or nominal (dichotomous, multi-nominal) data. The translated data were analyzed in SPSS v24 to get cross-tabulations on demographics and other possible parameters that better answer the research question. A Fisher's exact and Pearson chi-square testing was done to evaluate the data accordingly to get suitable cross tabulations and p-

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values to check the statistically significant association between the comparing variables. Descriptive analysis was also done to compare each question in the survey with individual demographic data available.

Chapter 4: Results

The present survey included detailed analysis of 210 respondents, where 118 (56.19%) were from College of Health and Human Services (HHS) and 92 (43.80%) from the College of Business (COB). Of these respondents, 109 (51.90%) were provided with an active survey sheet and 101 (48.09%) with the placebo survey sheet. Eleven respondents were completely eliminated from the sample, as they indicated that their majors were from more than one college (e.g., from both COB and HHS or COT and COB), and no further analysis was done on this excluded population.

A descriptive analysis of demographic data (counts and percentages) for all of the students who participated in the survey is presented in Table 1.

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Table 1

Demographics: HHS and COB

Demographics	Groups	<i>n</i>	Percentages
Age	18-24 years	144	68.57%
	25-34 years	57	27.14%
	35 or older	8	3.80%
	Missing	1	0.47%
Gender	Female	131	62.38%
	Male	75	35.71%
	Prefer not to answer	4	1.90%
College year	First	15	7.14%
	Second	33	15.71%
	Third	94	44.76%
	Fourth	57	27.14%
	Graduate	10	4.76%
	Missing	1	0.47%
Majors	HHS	118	56.19%
	COB	92	43.80%

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When the question “How knowledgeable are you about clinical research?” was asked of 210 respondents to assess the knowledge they believe they have about clinical research, 17.61% ($n = 37$) said they are *not at all knowledgeable*, 54.28% ($n = 114$) checked *a little knowledgeable*, 26.19% ($n = 55$) checked *somewhat knowledgeable* and just 1.90% ($n = 4$) said they are they *completely knowledgeable*. (See Table 2.)

Table 2
Participant Knowledge About Clinical Trials

	Not at all knowledgeable	A little knowledgeable	Somewhat knowledgeable	Completely knowledgeable
Students ($n = 210$)	17.61% ($n = 37$)	54.28% ($n = 114$)	26.19% ($n = 55$)	1.90% ($n = 4$)

When chi-square analysis was performed on the first question, “How knowledgeable are you about clinical research?” with age parameter, the association of these variables was not significant ($\chi^2(1) = 9.54$, $df = 6$, $p = .145$). Among those 18–24 years, 20.8% ($n = 30$) checked *not at all knowledgeable*, 56.9% ($n = 82$) checked *a little knowledgeable*, 20.8% ($n = 30$) checked *somewhat knowledgeable*, and 1.4% ($n = 2$) checked *completely knowledgeable*. Among those 25–34 years, 12.3% ($n = 7$) checked *not at all knowledgeable*, 47.4% ($n = 27$) checked *a little knowledgeable*, 36.8% ($n = 21$) checked *somewhat knowledgeable*, and 3.5% ($n = 2$) checked *completely knowledgeable*. Among those 35 or older, 0% checked *not at all knowledgeable*, 62.5% ($n = 5$) checked *a little knowledgeable*, 37.5% ($n = 3$) checked *somewhat knowledgeable* and 0% chose *completely knowledgeable*. (See Figure 1.)

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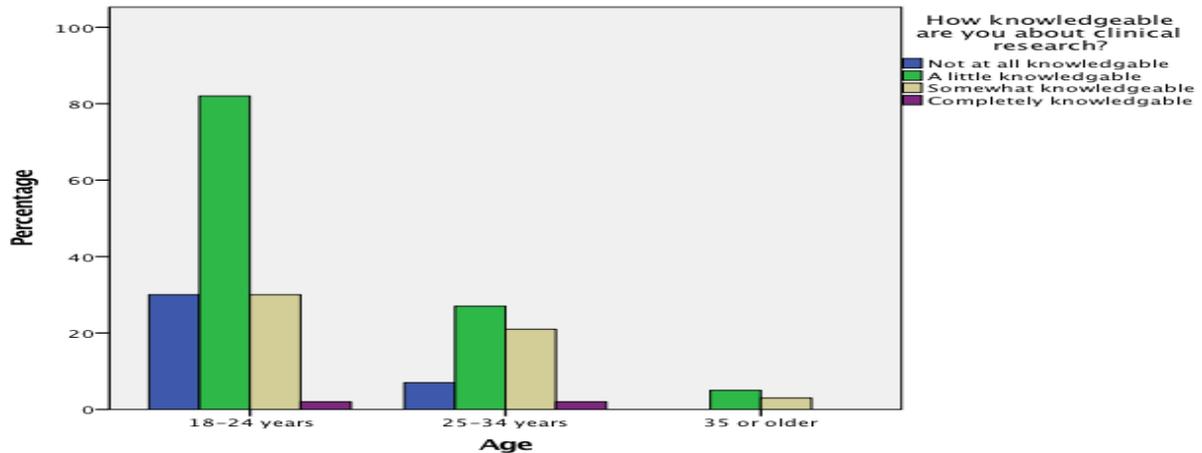


Figure 1. Participants' knowledge about clinical trials vs. age groups.

Nelson (2015) defined *millennial* as those aged 18–34 years in the Center for Information and Study on Clinical Research Participation (CISCRP). The response from the groups when age variable was collapsed (18–24 and 25–34 years as 18–34 years) and compared to 35 or older is presented in Figure 2.

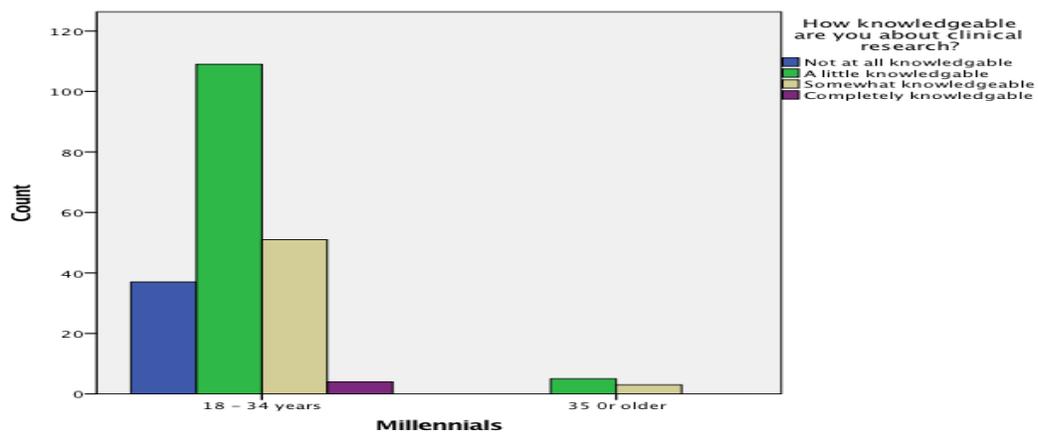


Figure 2. Generation Y (18–34 years) vs. Generation X (35 or older) about clinical trials.

Figure 2 shows more Generation Y (18–34 years) respondents than Generation X, and most of age 18–34 year participants listed themselves as *a little knowledgeable*.

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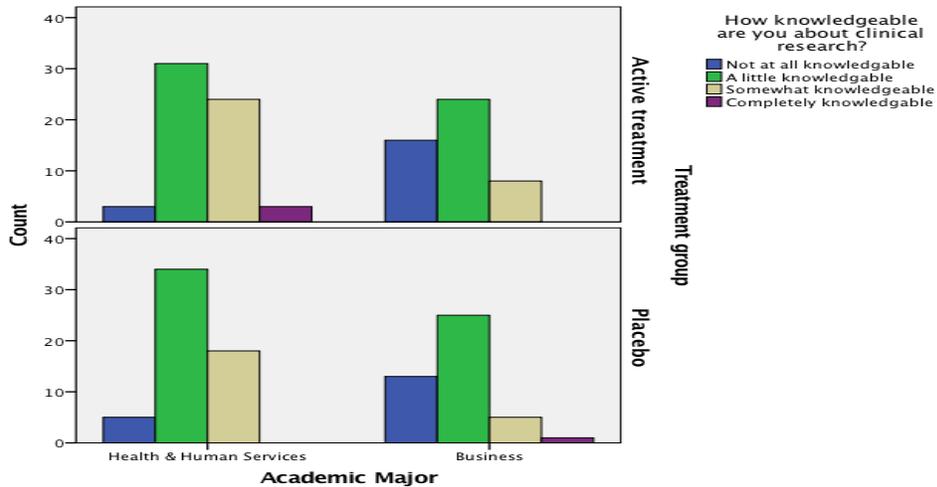


Figure 3. Participants' majors vs. their knowledge of clinical trials in two groups.

Health and Human Services majors rated their knowledge as more at a higher percentage in both treatment groups than participants from the College of Business (Figure 3).

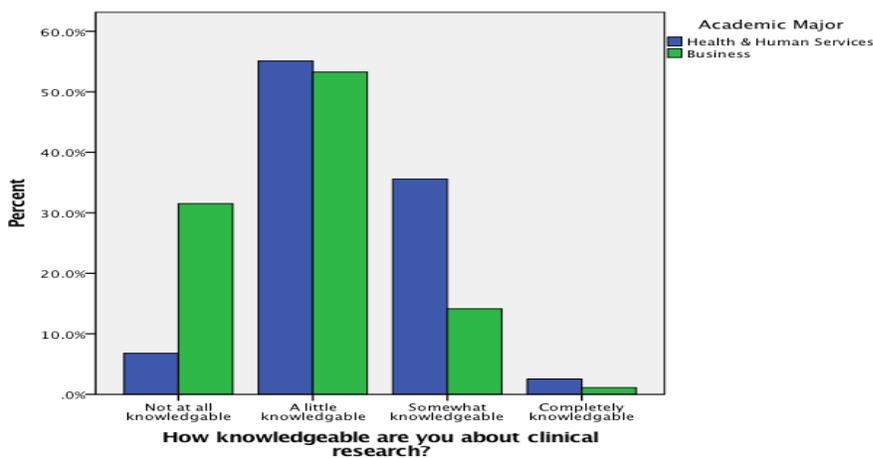


Figure 4. Academic major response compared with knowledge of participants.

When a Fisher's exact test was done to compare students' academic majors and how knowledgeable they are about clinical research, it indicated a statistically significant association ($p < .001$, Pearson Chi-square = 27.66, $df = 3$). Out of 118 HHS participants, only 6.8% said they were *not at all knowledgeable*, 55.1% said they are *a little knowledgeable*, 35.6% said they are *somewhat knowledgeable*, and 2.5% said they were *completely knowledgeable*. Of 92 COB

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participants, 31.5% said they were *not at all knowledgeable*, 53.3% said they were *a little knowledgeable*, 14.1% said they were *somewhat knowledgeable*, and 1.1% said they were *completely knowledgeable* (Figure 4).

The participants were asked a multiple-choice question with four possible responses, one of which contained the correct definition of clinical research or clinical trials. Of 210 participants, only 38.09% ($n = 80$) correctly defined clinical research as scientific investigations using humans to study treatment of human disease. Of the rest, 8.09% ($n = 17$) thought that clinical research was scientific investigations using animals to study treatment of human disease, 36.1% ($n = 76$) thought that clinical research was scientific investigations using laboratory studies to study treatment of human disease, and 8.5% ($n = 18$) were not sure; the remaining 10% 1.42% ($n = 3$) thought they were tests done on humans and animals; 6.66% ($n = 14$) thought they were done on humans, animals, and in laboratories; and 0.95% ($n = 2$) thought they were done on humans and through laboratory studies. There is only one correct answer to this question, but a few students chose multiple options.

An exact chi-square testing was conducted to compare correct and incorrect responses for the definition of clinical research or clinical trials with treatment groups, and there was no statistically significant impact of the treatment group on correct response, $\chi^2(1) = 0.022, p = .88$. Among the placebo group, 61.4% ($n = 62$) answered incorrectly, and 38.6% ($n = 39$) answered correctly, whereas among the active group, 62.4% ($n = 68$) answered incorrectly, and 37.6% ($n = 41$) answered correctly.

When comparing the treatment group with correct and all incorrect responses, of 101 placebo group participants, 61.4% answered incorrectly, and 38.6% selected the correct answer. However, of 109 active group participants, 62.4% gave an incorrect response and only 37.6%

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gave a correct response, with a $p = .88$, indicating no association and no statistically significant impact of the treatment group on the correct response.

Figure 5 shows responses by academic year for the correct response for Question 2 from the survey.

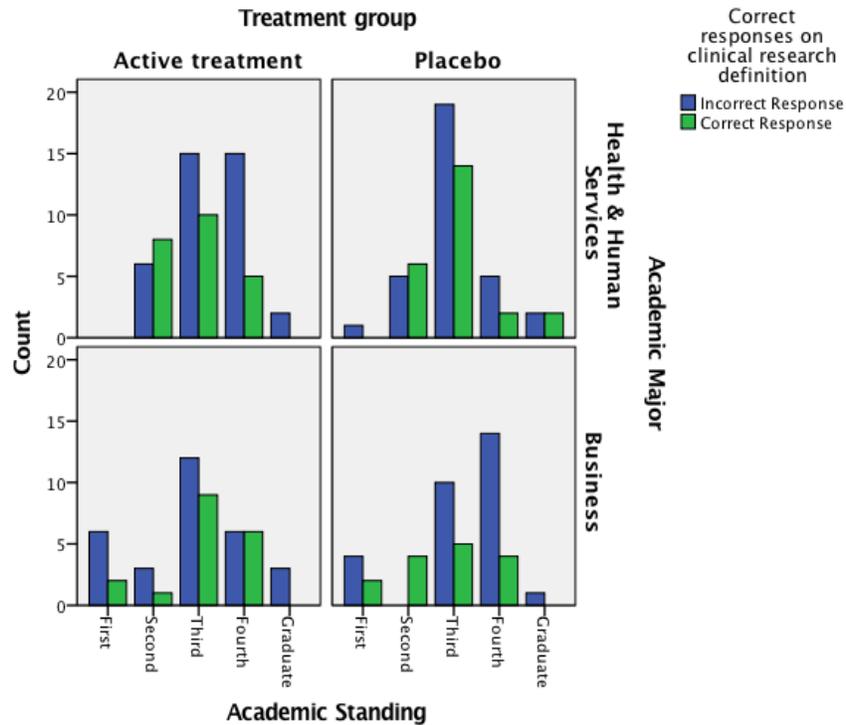


Figure 5. Correct response to clinical research/clinical trials by students of different college years in the HHS and COB in both treatment groups.

The trend of giving the correct response did not increase with academic standing/college years. Among HHS students ($p = .22$), 1.4% of first-year, 15.7% of second-year, 48.6% of third-year, 28.6% of fourth-year, and 5.7% of graduate students answered Question 2 incorrectly. On the contrary, 0% of first-year, 29.8% of second-year, 51.1% of third-year, 14.9% of fourth-year, and 4.3% of graduate students answered correctly. However, among COB student participants ($p = .23$), 16.9% of first-year, 5.1% of second-year, 37.3% of third-year, 33.9% of fourth-year, and 6.8% of graduate students answered incorrectly. Only 12.1% of first-year, 15.2% of second-year,

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42.4% of third-year, 30.3% of fourth-year, and 0% of graduate students answered correctly.

When exact chi-square testing ($p = .48$, $\chi^2(1) = 27.66$, $df = 3$) was done on participants to compare the correct response to questions on clinical research definition and how knowledgeable they were about clinical research, the ones who said they were completely knowledgeable answered incorrectly when asked the definition of clinical research. (The sample size for that group is disproportionately low.) See Table 3.

Table 3

Clinical Research Definition vs. How Knowledgeable About Clinical Research?

Correct responses on clinical research definition	Not at all knowledgeable % (n)	A little knowledgeable % (n)	Somewhat knowledgeable % (n)	Completely knowledgeable % (n)
Incorrect Response	70.3 (26)	62.3 (71)	54.5(30)	75.0(3)
Correct Response	29.7(11)	37.7(43)	45.5 (25)	25.0 (1)

When the chi square test was done to compare “willingness to participate in clinical trials” with “age” ($p = .063$, $\chi^2(1) = 3.44$, $df = 1$), among the active group ($n = 108$), of the 57 participants who answered *yes*, all were from the 18–34 years age group, and of 51 participants who answered *no*, 48 (94.1%) were from the 18–34 years age group, and 3 (5.9%) were from the 35 or older age group. In the placebo group ($n = 100$), of the total 59 participants who answered *yes*, 57 (96.6%) were from the 18–34 year old age group, and 2 (3.4%) were from 35 or older age group. Of the 41 participants who answered *no*, 37 were from the 18–34 years age group, and 5 were from the 35 or older age group, with no statistically significant association ($p = .37$, $\chi^2(1) =$

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0.785, $df = 1$).

When the Pearson chi-square test was performed, 53.2% ($n = 58$) of 108 active group participants said *yes*, they are willing to participate in clinical research, and 46.8% ($n = 51$) said *no*. Out of 100 placebo group participants, 59% ($n = 59$) said *yes* and 41% ($n = 41$) said *no*, without a statistical significant association ($p = .4$, $\chi^2(1) = 0.709$, $df = 1$).

The Pearson chi-square test was done on academic majors and willingness to participate, Question 3 from the survey sheet ($p = .017$, $\chi^2(1) = 5.696$, $df = 1$).

Table 4

Willingness to Participate in Clinical Trials

Willingness to participate in the clinical research	<i>Yes</i> <i>% (n)</i>	<i>No</i> <i>% (n)</i>
College of Health & Human Services	63.2 (74)	46.7 (43)
College of Business	36.8 (43)	53.3 (49)

Table 5 lists reasons given to participate and not to participate in clinical trials by the enrolled students within this survey.

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Table 5

Reasons for Participating in Clinical Trials

Reason for participating	n(%)
If I get paid	125 (43.40)
To help future generations	54 (18.75)
An interesting thing to do	43 (14.93)
To get help with my illness	66 (22.91)

Table 6

Reasons for not Participating in Clinical Trials

Reason for not participating	n(%)
I do not want to be used as a guinea pig	27 (10.93)
I do not know if it would be safe	111 (44.93)
I simply prefer not to	26 (10.52)
I am concerned about taking an experimental drug	83 (33.60)

When enrolled students were asked if they would take a drug that was not tested on animals or humans, 197 out of 208 (94.7%) said *no* and 5.3% said *yes*. Two responses are missing as they did not answer this question.

When a question “How a participant prefers be informed of an active clinical trial?” was asked, 67% of participants chose “From a Physician” and 6% chose “Through Facebook or other social media” (Figure 6).

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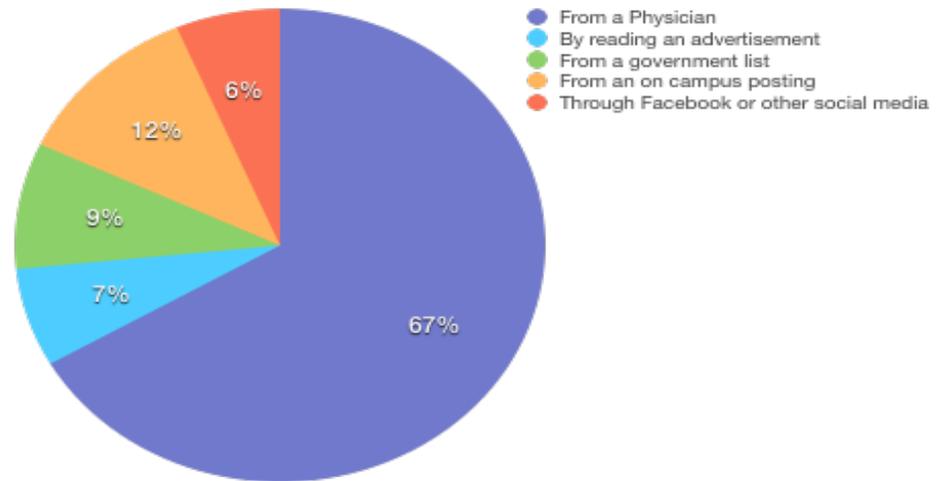


Figure 6. How a participant prefers to be informed of an active clinical trial.

When “Where do you think clinical research is conducted?” was asked, the highest percentage of participants chose “University Medical Centers” (See Table 7).

Table 7

Where Clinical Research Was Conducted

Hospitals	University Medical Centers	Clinics	Private Physicians' Offices	Not sure
28.85%	34.45%	19.01%	9.39%	8.3%

Chapter 5: Discussion

Clinical research studies are done at various medical sites (hospitals, university medical centers, clinics, and private physicians' offices). These studies enroll diverse sets of the population. In the present survey, EMU students were asked 12 questions, four of which were related to the demographics of the sample. Of the other eight questions asked, the main aim was to understand how the intervention of the paragraph about "drug development" in active survey sheets and a paragraph about "scientific method" in the placebo group affected the pattern of students' responses to the survey questions and their willingness to participate in clinical research. The College of Health and Human Services (HHS) major students who participated clearly indicated that they have more knowledge about clinical research than participants from the College of Business (COB), with a statistically significant association, a $p < .001$ (Figure 4). When exact chi-square testing was done to determine how knowledgeable participants were about clinical research with "What is clinical research?" 75% who said they had complete knowledge gave an incorrect response (Table 3). However, here the sample size is disproportionately low (*completely knowledgeable* was selected by just three participants). However, among other participants who chose incorrectly, 70.3% said they were *not at all knowledgeable*, 62.3% said they were *a little knowledgeable*, and 54.5% said they were *somewhat knowledgeable* ($p = .44$). This analysis clearly indicates that the students assessed their own knowledge about clinical research incorrectly.

When the age variable was collapsed (18–24 years and 25–34 years to one group, 18–34 years), the findings indicated that there were more participants among the Generation Y group and most of them listed themselves as *a little knowledgeable* (Figure 2); this trend is because there were only 8 participants under the Generation X category compared to the 201 Generation

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Y participants. No comparison is generalizable with a very small sample size. To get more accurate or reliable, results for a comparison between these two generations, more participants, approximately 201, should be enrolled in the 35 and older age group.

In this survey, done in a few classes of HHS and COB, only 38.1% of participants knew that clinical research is scientific investigations using humans to study treatment of human disease. The number of correct responses does not increase with academic year, as had been seen by Garapati (2015). This survey was conducted in undergraduate classes (1–5 classes), and distribution of the sample was not diverse (among all college years); this has affected the response trends among participants of HHS and COB. The challenge here is that these results do not indicate a specific direction or trend. This direction or trend might have been more significant if the intervention had been more effective with slightly more exposure in the active group by giving an oral but brief presentation prior to conducting the survey. In the case of placebo group, students assessed their knowledge incorrectly because of the intervening paragraph. Garapati (2015) also stated that most of the participants (46.6%) in his survey thought that clinical research was scientific investigations using laboratory studies to treat human diseases, but in this survey, the highest number of participants (irrespective of class years, treatment groups, or academic backgrounds) knew it was done with humans. This could be due to the structure of the options to this question, where all of the options included “for treating human disease.” Therefore, for this question, answering correctly could be due to two reasons: either students had the correct knowledge about clinical trials or they misinterpreted the meaning of clinical trial. Another interesting finding for above question among the treatment groups is that 37.6% of the active group answered correctly, and 38.6% of the placebo group answered correctly. These findings indicate that by percentage, there was not much difference between the

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two treatment groups, though the answer was within the paragraph given to the active group and not the placebo group, who had no idea. In general, when a survey sheet is given, there is no assurance that a student has read the paragraph to which they were exposed. Many college students may simply skip the instructions to finish the survey. Sometimes a group of people may be exposed to something and not be aware of this exposure. This could be more effective if the students were asked to read the paragraph aloud, or if it was read aloud to them (by conducting the survey separately for comparing groups), or if they were asked to circle a few letters or certain words to ensure that they have absorbed that minimal knowledge and are exposed properly to the intervention.

When we compare within the treatment groups, 53.2% in the active group and 59% in placebo group said they would participate in clinical trials. This clearly suggests that the intervention did not influence the active group to participate in clinical trials. When we compare the age parameter with willingness to participate, in the active group, all the respondents who said "yes" are all from Generation Y, and even in the placebo group, 92.7% who said "yes" are from Generation Y. Though the percentages are higher for willingness to participate in clinical trials for Generation Y, irrespective of the treatment group, these percentages might have been more reliable if there had been more participants among the 35 or older group. This is also because of age diversity at Eastern Michigan University, which has about 19,077 students between 18 and 34 years and only 2741 who are 35 or older (College Factual, 2016).

According to a survey done by Moorcraft et al. (2016), a majority of subjects participate in clinical trials because these trials offer the best therapy available and also to help future generations. But most of the enrolled students in the present survey said that they would participate in a clinical trial if they got paid. According to Midgley et al. (2016), who

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interviewed all of the adolescents who participated in a multi-center, randomized controlled trial, the Improving Mood through Psychoanalytic and Cognitive-Behavioural Therapy (IMPACT) study, 36 of the 76 participants said they participated to help the future generation/others, whereas 13 of the 76 said they participated to get help with their treatment. One young person stated that young people should not be paid for participating in the trial, whereas five others stated that the money paid for taking part in the trial was a source of motivation. In the present survey, of all the students enrolled, 125 (43.40%) said they would participate in trials if they were paid, 54 (18.75%) said to help the future generation, and 111 (44.93%) said they would not participate because they are not sure it would be safe (Table 5).

Luring subjects with monetary compensation is a common practice in clinical research (Phillips, 2011). But students should be informed that these monetary compensations are not the only factors to be considered while participating in a clinical trial. Subjects should fall into suitable inclusion/exclusion criteria to participate in any clinical research study, and it is not ethical to participate in a clinical trial just for money.

Even in this era where social media such as Facebook, Instagram, and Twitter play a very important role in any college student's life, the majority of participants in this survey still preferred being informed through a physician about any trial they are suitable for. (Figure 6)

Similar to the survey conducted by Garapati (2015), in the present survey, the highest percentage of participants said that clinical research is done at university medical centers, the second highest percentage said at hospitals, the third at clinics, and the lowest at private physicians' offices. Only 16.19% selected all of the correct responses, and 17.61% indicated that they are *not sure* (Table 6).

Similar surveys were conducted in two other colleges (College of Arts and Sciences and

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College of Technology) within the university, by another researcher. These colleges also did not see a difference between active and placebo groups. This indicates that even in these colleges, the intervention did not influence the participants' willingness to volunteer for clinical trials (Pathakamudi, 2017). These results are therefore independent of the colleges selected and are found to be more generalized.

Chapter 6: Conclusion

In conclusion, students' understanding about clinical research and their willingness to participate in it were examined using 12 questions within two treatment groups: active and placebo. In both the College of Health and Human Services and the College of Business, the intervention used in the survey, that of providing minimal education, did not impact the willingness of the Generation Y group to participate in clinical trials.

The claim that the intervention would improve the understanding and willingness of Generation Y to participate in clinical research would be more likely if the comparison group (i.e., 35 years or older) had an equal sample size. Using strategies such as conducting the survey separately (for active and placebo groups), reading the paragraph aloud or asking students to circle certain words, or giving a brief oral presentation prior to the survey and making sure the students had absorbed all the knowledge would ensure that the exposure was more effective, which plays a major role in determining accurate and reliable results. Therefore, this survey provides valuable insight for future researchers considering a wider population and equal sample size in comparing groups (Generation Y and older age groups). They should also consider doing a pilot study to understand (or to test assumptions like) the following: whether the education was adequate, whether we can change minds with written information, whether the assumption that the information provided in the placebo survey sheet was unknown, and whether cognitive power plays a role in processing (i.e., reading, understanding, and relating it with the questions) the given information within the time provided in these kind of surveys.

Limitations of the Research

- Only a small sample size confined to one university of a single region was evaluated.
- The sample number in different groups is not equal.

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- It remains unknown whether any simple educational intervention can change a student's willingness to participate in clinical studies. Perhaps some of the extended educational efforts previously noted might have impacted the results. We can only state that requiring participants to read a simple statement does not influence willingness to participate in clinical trials.

References

- Brown, D. L., Cowdery, J. E., Jones, T. S., Langford, A., & Gammage, C. (2015). Adolescent knowledge and attitudes related to clinical trials. *Sage Journals: Clinical Trials*, 12(3), 212–4. <http://dx.doi.org/10.1177/1740774515571443>.
- College Factual. (2016). How diverse is Eastern Michigan University? Explore ethnic, age, male to female and geographic diversity. Retrieved from: <http://www.collegefactual.com/colleges/easternmichigan-university/student-life/diversity/>
- Friedman, L. M., Furberg, C., & DeMets, D. L. (2010). *Fundamentals of clinical trials*, 4th Ed. New York: Springer.
- Garapati, K. (2015). *College student understanding of informed consent terminology*. ProQuest Dissertations Publishing. 10010539. Retrieved from <https://search.proquest.com/docview/1768252067?pq-origsite=summon>.
- Midgley, N., Isaacs, D., Weitkamp, K., & Target, M. (2016). The experience of adolescents participating in a randomised clinical trial in the field of mental health: A qualitative study. *Trials*, 17(1), pages doi:10.1186/s13063-016-1474-2.
- Moorcraft, S. Y., Marriott, C., Peckitt, C., Cunningham, D., Chau, I., Starling, N., & Rao, S. (2016). Patients' willingness to participate in clinical trials and their views on aspects of cancer research: results of a prospective patient survey. *Trials*, 17(1), pages. doi:10.1186/s13063-015-1105-3.
- Nelson, A., Martin, I., & Getz, K. (2015). Generational value differences affecting public perceptions of and willingness to participate in clinical trials. *Therapeutic Innovation & Regulatory Science*, 49(6), 940–946. <http://dx.doi.org/10.1177/2168479015583727>.
- Pathakamudi, S. K. (2017). Students' understanding about clinical research and their

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willingness to participate in clinical trials. Unpublished manuscript.

Phillips, T. (2011). Exploitation in payments to research subjects. *Bioethics*, 25(4), 209–19

<http://dx.doi.org/19.10.1111/j.1467-8519.2009.01717.x>.

Strauss, W. A., Howe, N., & Strauss, B. (1991). *Generations: The history of America's future,*

1584 to 2069. New York: William Morrow & Company.

Trauth, J. M., Musa, D., Siminoff, L., Jewell, I. K., & Ricci, E. (2000). Public attitudes

regarding willingness to participate in medical research studies. *Journal of Health &*

Social Policy, 12(2), 23–43. http://dx.doi.org/10.1300/j045v12n02_02.

World Health Organization. (2015). Retrieved from

http://www.who.int/topics/clinical_trials/en/

Students' Willingness to Participate in Clinical Trials

Appendix A: IRB Approval Letter

RESEARCH @ EMU

UHSRC Determination: EXPEDITED INITIAL APPROVAL

DATE: March 7, 2016

TO: Divya Pandiri, MS
Eastern Michigan University

Re: UHSRC: # 871645-1
Category: Expedited category 7
Approval Date: March 7, 2016
Expiration Date: March 6, 2017

Title: Students Understanding About Clinical Research and Their Willingness to Participate in Clinical Research

Your research project, entitled **Students Understanding About Clinical Research and Their Willingness to Participate in Clinical Research**, has been approved in accordance with all applicable federal regulations.

This approval included the following:

1. Enrollment of 240 subjects to participate in the approved protocol.
2. Use of the following study measures: *Active group survey; Placebo group survey*
3. Use of the following stamped recruitment materials: *N/A*
4. Use of the stamped: *Informed consent form*

Renewals: This approval is valid for one year and expires on March 6, 2017. If you plan to continue your study beyond March 6, 2017, you must submit a Continuing Review Form by February 4, 2017 to ensure the approval does not lapse.

Modifications: All changes must be approved prior to implementation. If you plan to make any minor changes, you must submit a **Minor Modification Form**. For any changes that alter study design or any study instruments, you must submit a **Human Subjects Approval Request Form**. These forms are 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 Expedited research project is not completed and closed after **three years**, the UHSRC office requires a new **Human Subjects Approval Request Form** prior to approving a continuation beyond three years.

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.

Appendix B: IRB Approval Letter After Sample Size Modification

RESEARCH @ EMU

UHSRC Determination: EXPEDITED MODIFICATION APPROVAL

DATE: March 11, 2016

TO: Divya Pandiri, MS
Eastern Michigan University

Re: UHSRC: # 871645-2
Category: Expedited
Approval Date: March 11, 2016
Expiration Date: March 6, 2017

Title: Students Understanding About Clinical Research and Their Willingness to Participate in Clinical Research

Your requested modifications for the project entitled **Students Understanding About Clinical Research and Their Willingness to Participate in Clinical Research** have been approved in accordance with all applicable federal regulations.

This approval includes the following: *increase the sample size to 500 participants.*

Renewals: This approval does not change the original expiration date. This study expires on March 6, 2017. If you plan to continue your study beyond March 6, 2017, you must submit a Continuing Review Form by February 4, 2017 to ensure the approval does not lapse.

Modifications: All additional changes must be approved prior to implementation. If you plan to make any minor changes, you must submit a **Minor Modification Form**. For any changes that alter study design or any study instruments, you must submit a **Human Subjects Approval Request Form**. These forms are 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 Expedited research project is not completed and closed after **three years**, the UHSRC office requires a new **Human Subjects Approval Request Form** prior to approving a continuation beyond three years.

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,

April Nelson, MS
Research Compliance Administrator
University Human Subjects Review Committee

Appendix C: Active Survey Sheet

SCHOOL of HEALTH SCIENCES



Please read this paragraph before you answer

Drug development is the process of bringing a new pharmaceutical or medicine to the market. For pharmaceuticals/medicines to enter the market they have to be first tested in animals and humans. Clinical research is research done with patients to determine the safety and effectiveness of a new medicine. **Please select the answer(s) that best represents your understanding. Check or circle all that apply:**

- Q1. How knowledgeable are you about clinical research?
- a) Not at all knowledgeable
 - b) A little knowledgeable
 - c) Somewhat knowledgeable
 - d) Completely knowledgeable
- Q2. Clinical research or clinical trials are:
- a) Scientific investigations using humans to study treatment of human disease
 - b) Scientific investigations using animals to study treatment of human disease
 - c) Scientific investigations using laboratory studies to study treatment of human disease
 - d) Not sure
- Q3. If given a chance, would you consider participating in a clinical research study?
- a) Yes
 - b) No
- Q4. I might agree to be in a clinical research study:
- a) If I get paid
 - b) To help future generations
 - c) Because it might be an interesting thing to do
 - d) To get help with my illness
- Q5. I might not agree to participate in a research study:
- a) Because I do not want to be used as a guinea pig in research
 - b) Because I do not know if it would be safe
 - c) As I simply prefer not to
 - d) Because I am concerned about taking an experimental drug
- Q6. Would you take a drug which was not tested in animal or humans?
- a) Yes
 - b) No
- Q7. How would you like to be informed of a clinical research study you might be appropriate for?
- a) From my physician
 - b) By reading an advertisement
 - c) From a government list
 - d) From an on campus posting
 - e) Through Facebook or other social media
- Q8. Where do you think clinical research is conducted? **(Check or circle all that apply)**
- a) Hospitals
 - b) University Medical Centers
 - c) Clinics
 - d) Private Physician's Office
 - e) Not sure
- Q9. I am currently:
- a) 18-24 years old
 - b) 25-34 years old
 - c) 35 or older
- Q10. Female Male Prefer not to answer
-
- Q11. My class year is:
- a) First
 - b) Second
 - c) Third
 - d) Fourth
 - e) Graduate
- Q12. My major is or likely will be in the College of:
- a) Arts & Sciences
 - b) Technology
 - c) Health & Human Services
 - d) Business
 - e) Education

Appendix D: Placebo Survey Sheet

SCHOOL of HEALTH SCIENCES



Please read this paragraph before you answer

The scientific method is a body of techniques for investigating phenomena, acquiring new knowledge, or correcting and integrating previous knowledge. To be termed scientific, a method of inquiry is commonly based on empirical or measurable evidence subject to specific principles of reasoning. **Please select the answer(s) that best represents your understanding. Check or circle all that apply:**

- Q1. How knowledgeable are you about clinical research?
- a) Not at all knowledgeable
 - b) A little knowledgeable
 - c) Somewhat knowledgeable
 - d) Completely knowledgeable
- Q2. Clinical research or clinical trials are:
- a) Scientific investigations using humans to study treatment of human disease
 - b) Scientific investigations using animals to study treatment of human disease
 - c) Scientific investigations using laboratory studies to study treatment of human disease
 - d) Not sure
- Q3. If given a chance, would you consider participating in a clinical research study?
- a) Yes
 - b) No
- Q4. I might agree to be in a clinical research study:
- a) If I get paid
 - b) To help future generations
 - c) Because it might be an interesting thing to do
 - d) To get help with my illness
- Q5. I might not agree to participate in a research study:
- a) Because I do not want to be used as a guinea pig in research
 - b) Because I do not know if it would be safe
 - c) As I simply prefer not to
 - d) Because I am concerned about taking an experimental drug
- Q6. Would you take a drug which was not tested in animal or humans?
- a) Yes
 - b) No
- Q7. How would you like to be informed of a clinical research study you might be appropriate for?
- a) From my physician
 - b) By reading an advertisement
 - c) From a government list
 - d) From an on campus posting
 - e) Through Facebook or other social media
- Q8. Where do you think clinical research is conducted? **(Check or circle all that apply)**
- a) Hospitals
 - b) University Medical Centers
 - c) Clinics
 - d) Private Physician's Office
 - e) Not sure
- Q9. I am currently:
- a) 18-24 years old
 - b) 25-34 years old
 - c) 35 or older
- Q10. Female Male Prefer not to answer
-
- Q11. My class year is:
- a) First
 - b) Second
 - c) Third
 - d) Fourth
 - e) Graduate
- Q12. My major is or likely will be in the College of:
- a) Arts & Sciences
 - b) Technology
 - c) Health & Human Services
 - d) Business
 - e) Education

Appendix E: Verbal Consent Form

RESEARCH @ EMU

Informed Consent Form

The personnel in charge of this study are Divya Pandiri, the Principal Investigator and Shashikiran Pathakamudi, the Co-Principal Investigator. They are graduate students at Eastern Michigan University. Their faculty adviser is Irwin G. Martin. Throughout this form, this person will be referred to as the "investigator."

Purpose of the study

The purpose of this research study is to determine students understanding about health research.

What will happen if I participate in this study?

Participation in this study involves answering questions related to research, which will help us to determine college aged students understanding and their attitude towards research.

What are the anticipated risks for participation?

There are no anticipated physical or psychological risks to participation.

The primary and the only risk of participation in this study is that the student sitting beside or students among themselves might know they have participated in the study. Since no names will be collected on the survey sheets there are no identifiers.

Are there any benefits to participating?

You will not directly benefit from participating in this research. You may tend to learn more about Research.

What are the alternatives to participation?

The alternative is not to participate.

How will my information be kept confidential?

As we are not collecting student names on the survey sheets, your information will therefore be confidential.

The investigators will also ask you not to tell anyone outside of the class about anything that was said during the survey. However, we cannot guarantee that everyone will keep the discussions private.

Approved by the Eastern Michigan University Human Subjects Review Committee
UHSRC Protocol Number: 871645-1
Study Approval Dates: 03/07/16 – 03/06/17