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

by

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Thesis

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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
Jean Rowan, MD, MS.

February 26, 2018
Ypsilanti, Michigan
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Abstract

Adolescents and young adults remain underrepresented in clinical trials. Knowledge and perceptions related to clinical research usually determine willingness to participate. During the spring of 2016, an in-class paper survey was conducted to determine whether providing a brief introduction to clinical research would affect the willingness of undergraduate students from the College of Arts and Sciences and the College of Technology at Eastern Michigan University to participate in clinical trials. Some participants received information on clinical research through a short paragraph, and some received no new information, which differentiated the “active” group from the “placebo” group. Overall, both groups provided similar responses to the questions related to understanding and willingness. The majority (>40%) of responders answered that they had little knowledge. However, only 37% of the active group and 11% of placebo group participants knew that the research was related to humans. Across both groups, nearly 60% of responders expressed willingness to participate in clinical trials. Monetary compensation was the most common motivator, and uncertainty about safety was the most common reason for non-participation in clinical trials.

Keywords: clinical trials, participation, willingness
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Chapter 1: Introduction

According to the World Health Organization, “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.” Clinical trials (CTs) play a significant role in the advancement of medicine by enhancing the approachability of various treatments. Along with a rising population, there is an equivalent increase in the incidence of various diseases. However, considering the uncertainty of the outcomes, people’s resistance to taking part in clinical studies has been growing. While a few participate, many others step back, being skeptical of the unexpected effects of a new molecular entity. Spreading awareness is the only way to improve participation (Bevan, Chee, McGhee, & McInnes, 1993).

According to the Pharmaceutical Research and Manufacturers of America (PhRMA) Annual Membership Survey (2016), approximately 48% of research and development expenditure is related to conducting Phase I–III clinical trials. Recruitment issues are critical, and a recently published whitepaper from Clinithink (2017) reported that 46% of trials fail because of poor recruitments. In addition, recruitment delays significantly increase the clinical trial budgets, currently about $1.3 million per delayed day. Nearly one-third of clinical trial expenses are related to patient recruitment. The cost of patient recruitment amounts to worldwide expenditures of $1.2 billion, $759 million in the US alone. During the last decade, there was an increase of approximately 150% in eligibility criteria. Thus, limitations in volunteer participation results in clinical trials getting costly and delayed, and failing to address the primary research question. The latest survey by the Center for Information and Study on Clinical Research (CISCRP, 2017), taken by 12,427 people across
the world, revealed that 87% of respondents were willing to participate in clinical trials. This survey also reported that young people are generally less knowledgeable and less likely to understand that clinical trials are safe. Perhaps for this reason they were also less willing to participate (CISCRP, 2017). Data from the 2013 CISCRP survey regarding age were analyzed by Nelson, Martin, and Getz, who observed that generational differences existed in the perceptions on clinical trials and that the then 18 to 34-year-olds were the least willing to participate in trials. These respondents were broadly referred to as Generation Y, and they were found to be significantly less willing to participate in a trial than those aged 35 years or older (Nelson et al., 2015).

Because adolescents and young people are underrepresented in several trials, this hampers the availability of these treatments for these populations (Kapogiannis, 2008; Roth et al., 2016; Brown et al., 2015). Reasons for participation and non-participation among adolescents and young people have been studied by a multitude of researchers. However, most of these studies were conducted in specific disease or racial groups (Ferrari, Montello, Budd, & Bleyer, 2008; Cavallo, 2016; Parsons, Harlan, Seibel, Stevens, & Keegan, 2011; Midgley, Isaacs, Weitkamp, & Target, 2016; Diaz, Mainous, McCall, & Geesey, 2008; Pearce et al., 2016). Such data are lacking from healthy volunteers, who constitute a potential pool of participants for future clinical trials.

Attitude and knowledge about clinical trials are the key factors that influence willingness to participate. Early adulthood is a key phase of attitude formation. A positive attitude inculcated towards clinical trial participation during this period is more likely to promote participation in eligible trials (Visser, & Krosnick, 1998; Fishbein, & Ajzen, 1975).
adolescents towards clinical trials, only 33% of adolescents indicated that they had ever heard of a clinical trial. Only a median of 46% of answers were correct, thus highlighting the poor knowledge levels of this group on this topic. Educational interventions are therefore of utmost importance to overcome the knowledge-related participation barriers among adolescents (Brown et al., 2015).

During the winter of 2015, an email survey was conducted among the students enrolled at Eastern Michigan University (EMU) to assess their knowledge on the most commonly used terminology in an informed consent form. Of the approximately 20,000 recipients, only 1,869 responded, and only 45.1% of the respondents correctly identified the definition for the term clinical research. For the question Where do you think clinical research studies are conducted? 47.2% indicated that they thought it was conducted in hospitals, 70.9% in medical centers, 34.8% in clinics, 15.9% in a private physician’s office, and 4.6% were not sure (Garapati, 2015). The present study attempted to further investigate students’ understanding and willingness to participate in clinical research through an in-class paper survey.

**Purpose of the Study**

Several previous studies in cancer populations reported that educational interventions using 15-minute to 18-minute video presentations substantially changed patients’ attitudes towards clinical trials and increased trial enrolment rates (Banda, Libin, Wang, & Swain, 2012; Du, Mood, Gadgeel, & Simon, 2008). But no such research was conducted among healthy adolescents and young adults to examine the effect of educational interventions. Hence, the purpose of the present study was to assess whether providing basic awareness of clinical research via an introductory reading influenced the willingness of Generation Y
students (age 18–34 years) to participate in clinical trials. Specific research questions of the study follow.

**Research Questions**

- Does a short description of clinical research improve participant knowledge and willingness to participate in a clinical trial?
- Is there an influence of age, gender, class year, or college major on an individual’s willingness to participate in clinical trials?
Chapter 2: Methods

Undergraduate students from the College of Arts and Sciences and the College of Technology at EMU were asked to participate in this in-class paper survey during the spring 2016 semester. Approval was obtained from the University Human Subjects Review Committee (UHSRC) of EMU (Appendices A and B) before conducting the study. After getting permission from the two colleges, students were verbally informed of this survey. Two different kinds of survey sheets were provided randomly: one with a short description of clinical research, termed the “active” survey sheet (Appendix C), and another containing a short description of standard scientific method definition, not specific to clinical research, termed the “placebo” survey sheet (Appendix D). Respondents to the former sheet composed the active group, and those who responded to the latter were the placebo group. Both sheets included 12 questions. Some questions were related to demographics (such as age, sex, class year, and college major), and others were aimed at understanding and attitudes towards participation in clinical research. Students were asked to return the surveys; doing so was considered consent for participation (Appendix E).

All the data collected were entered into Microsoft Excel and later analyzed using Statistical Package for the Social Sciences (SPSS). Since the study variables were categorical, they were presented as counts and percentages in the results tables. Data related to each question were compared between the active and placebo groups to understand the effect of this intervention on knowledge and perception of clinical trials. Chi-square tests were performed to assess whether significant differences existed between the study groups and to explore any possible impact of demographic variables on knowledge- or perception-related responses.
Chapter 3: Results

In total, 220 undergraduate students responded to this survey, of whom 106 were in the active group and 114 were in the placebo group. Descriptive characteristics of the survey participants are presented in Table 1.

Table 1

Demographics of Survey Respondents

<table>
<thead>
<tr>
<th>Demographics</th>
<th>All Respondents n (%)</th>
<th>Active Group n (%)</th>
<th>Placebo Group n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age range</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18–24 yrs</td>
<td>155 (70.5%)</td>
<td>73 (68.9%)</td>
<td>82 (71.9%)</td>
</tr>
<tr>
<td>25–34 yrs</td>
<td>44 (20.0%)</td>
<td>22 (20.8%)</td>
<td>22 (19.3%)</td>
</tr>
<tr>
<td>35 or older</td>
<td>20 (9.1%)</td>
<td>10 (9.4%)</td>
<td>10 (8.8%)</td>
</tr>
<tr>
<td>Unspecified</td>
<td>1 (0.5%)</td>
<td>1 (0.9%)</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>78 (35.5%)</td>
<td>36 (34.0%)</td>
<td>42 (36.8%)</td>
</tr>
<tr>
<td>Male</td>
<td>140 (63.6%)</td>
<td>69 (65.1%)</td>
<td>71 (62.3%)</td>
</tr>
<tr>
<td>Unspecified</td>
<td>2 (0.9%)</td>
<td>1 (0.9%)</td>
<td>1 (0.9%)</td>
</tr>
<tr>
<td>College Year</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>First</td>
<td>29 (13.2%)</td>
<td>16 (15.1%)</td>
<td>13 (11.4%)</td>
</tr>
<tr>
<td>Second</td>
<td>40 (18.2%)</td>
<td>19 (17.9%)</td>
<td>21 (18.4%)</td>
</tr>
<tr>
<td>Third</td>
<td>46 (20.9%)</td>
<td>24 (22.6%)</td>
<td>22 (19.3%)</td>
</tr>
<tr>
<td>Fourth</td>
<td>103 (46.8%)</td>
<td>47 (44.3%)</td>
<td>56 (49.1%)</td>
</tr>
<tr>
<td>Graduate</td>
<td>2 (0.9%)</td>
<td>0 (0.0%)</td>
<td>2 (1.8%)</td>
</tr>
<tr>
<td>College Major</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Arts &amp; Sciences</td>
<td>111 (50.5%)</td>
<td>53 (50.0%)</td>
<td>58 (50.9%)</td>
</tr>
<tr>
<td>Technology</td>
<td>109 (49.5%)</td>
<td>53 (50.0%)</td>
<td>56 (49.1%)</td>
</tr>
</tbody>
</table>

Survey Response Results by Intervention

The survey response results among the active and placebo respondents are presented in Table 2. A similar percentage of active and placebo group respondents were found to have complete, somewhat, little knowledge, and no knowledge at all on clinical trials with no significant difference between the groups. Only 1% of active group and 4% of placebo group
participants appeared to have complete knowledge on clinical trials. More than 40% of respondents across both groups answered that they had little knowledge.

As an answer to the multiple-choice question on clinical trial/research definition, only 37% of the active group and 11% of placebo group participants knew that the research is related to humans. Nearly half of the placebo group students thought clinical research related to laboratory investigations. Although a slightly higher percentage of respondents in the active group than in the placebo group answered the clinical trial definition question correctly, the difference was not significant.

Across both study groups, 60% of participants expressed willingness to participate in clinical trials, and there was no significant difference between the groups. Only 14% of the active group and 15% of the placebo group respondents said yes to participation in clinical trials with a novel treatment untested in animals or humans, indicating no difference between the groups.
Table 2

*Difference in Survey Responses Between Active and Placebo Groups*

<table>
<thead>
<tr>
<th>Knowledge Levels</th>
<th>Active group, n (%)</th>
<th>Placebo Group, n (%)</th>
<th>$\chi^2$, $p$ value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete</td>
<td>1 (0.9%)</td>
<td>4 (3.5%)</td>
<td>2.067, 0.559</td>
</tr>
<tr>
<td>Somewhat</td>
<td>20 (18.9%)</td>
<td>25 (21.9%)</td>
<td></td>
</tr>
<tr>
<td>Little</td>
<td>49 (46.2%)</td>
<td>49 (43.0%)</td>
<td></td>
</tr>
<tr>
<td>No knowledge at all</td>
<td>36 (34.0%)</td>
<td>36 (31.6%)</td>
<td></td>
</tr>
</tbody>
</table>

| Definition of Clinical Research   |                     |                      | 8.767, 0.187        |
| Humans                            | 39 (36.8%)          | 12 (11.3%)           |                     |
| Animals                           | 31 (27.2%)          | 7 (6.1%)             |                     |
| Laboratory Studies                | 31 (29.2%)          | 52 (45.6%)           |                     |
| Humans and Animals                | 2 (1.9%)            | 1 (0.9%)             |                     |
| Humans and Lab Studies            | 1 (0.9%)            | 0 (0.0%)             |                     |
| Humans, Animals, and Lab Studies  | 3 (2.8%)            | 4 (3.5%)             |                     |
| Not Sure                          | 18 (17.0%)          | 19 (16.7%)           |                     |

| Correctness of Clinical Trial Definition |                     |                      | 2.333, 0.127        |
| Correct Response                   | 39 (36.8%)          | 31 (27.2%)           |                     |
| Incorrect Response                  | 67 (63.2%)          | 83 (72.8%)           |                     |

| Willingness to Participate         |                     |                      | 0.231, 0.631        |
| Yes                               | 63 (60.0%)          | 72 (63.2%)           |                     |
| No                                | 42 (40.0%)          | 42 (36.8%)           |                     |

| Willingness to Administer a Novel Treatment |                     |                      | 0.010, 0.919        |
| Yes                                            | 15 (14.2%)          | 17 (14.9%)           |                     |
| No                                             | 89 (84.0%)          | 97 (85.1%)           |                     |

| Preferred Mode of Communication regarding a Clinical Trial |                     |                      | 12.160, 0.515       |
| From my Physician                              | 80 (75.5%)          | 78 (68.4%)           |                     |
| Reading an advertisement                       | 3 (2.8%)            | 4 (3.5%)             |                     |
| Government List                                | 6 (5.7%)            | 10 (8.8%)            |                     |
| Campus Posting                                 | 6 (5.7%)            | 9 (7.9%)             |                     |
| Facebook or Other Social Media                 | 1 (0.9%)            | 2 (1.8%)             |                     |
Figure 1 presents the distribution of reasons for willingness or unwillingness to participate in any clinical trial. Monetary compensation was the most common motivator for clinical trial participation, and uncertainty of safety was the most common reason for non-participation in clinical trials.

Figure 1. Reasons for Acceptance/Refusal to Participate in Clinical Trials

About 68% of participants in both active and placebo groups thought that clinical trials were performed at university medical centers. Similar percentage distributions were noted in participants who felt that clinical trials were conducted in hospitals (41% vs. 53%), clinics (38% vs. 39%), and private physicians’ offices (18% vs. 21%).

The majority of students (75% in active and 68% in placebo groups) preferred learning from a physician regarding a clinical trial. In contrast, only 1% of active group
respondents and 2% of placebo group respondents chose to learn from Facebook or other social media (Table 2).

**Impact of Demographics on Survey Response Results**

Across all demographic comparisons, more than 75% of participants claimed to have little or no knowledge at all, irrespective of age, gender, academic year, and college major. However, with each increasing year of academic standing, there was a significant increase in the number of participants who said they had some or little knowledge and a decrease in the number of participants who said they had no knowledge of clinical research ($p = .003$). Also, there was no statistical influence of age, gender, college year, or academic major on the correctness of their answer to the definition of *clinical trials*. Across all subgroups, nearly 60% or more participants answered incorrectly.

Similarly, there was no statistically significant difference for readiness in clinical trial participation among the demographic subgroups by age, gender, academic year, or college major. However, with age, a slightly decreasing trend of those who might be willing to participate was observed. Full information using separate tables for each survey question are presented in Appendix F.

**Responses Among Generation Y Participants**

Within the pool of Generation Y participants, responses were compared between active and placebo groups, and these results are presented in Table 3. The responses followed a broadly similar trend, as the results of the whole population show no notable differences between the active and placebo groups.
Also, Generation Y participant responses were separately compared with those of the older participants (> 35-year-olds). These results are presented in the Figure 2. As compared to older respondents, a higher percent of Generation Y respondents rated themselves as having no knowledge of clinical research (34% vs. 18%), while fewer rated themselves as having some (20% vs. 24%) or little knowledge (43% vs. 59%). More Generation Y participants marked the definition of clinical trials or research incorrectly (70%) than older participants (59%). However, 63% of Generation Y versus 47% of older participants expressed interest in clinical trial participation, and 16% vs. 0% showed willingness to take a novel medication. As the total number of older respondents is too low (n = 17), tests of significance were not performed for the above comparisons.
Figure 2. Generation Y Participant Responses (n = 199) vs. Older Participant (n = 17) Responses.
Chapter 4: Discussion

This cross-sectional survey assessed knowledge and perceptions of clinical research among students from the College of Arts and Sciences and the College of Technology at Eastern Michigan University. Another researcher had conducted a similar survey in the College of Business and College of Health and Human Services. These survey results were published and available online (Pandiri, 2017). In both surveys, the same 12 questions were posed, four related to demographics and eight assessing the participants’ understanding of clinical trials and their willingness to participate in clinical trials. Except for the brief explanation of clinical trials in the active intervention group and general paragraph in the placebo group, there is no other difference between the survey sheets of the two groups.

In this study, it was observed that the active group (n = 106) provided no significantly different answers with respect to knowledge or acceptance for participation in clinical trials than the placebo group (n = 114). Although 66% of active and 69% of placebo participants had rated themselves as having little to complete knowledge on clinical trials, 63% and 73%, respectively, chose incorrect answers for clinical trial definition. This finding was similar to those in the Pandiri (2017) study, which had 82.4% participants claiming little to complete knowledge, of whom 61%–62% had given an incorrect definition. In our study, the majority of active group respondents were aware that the definition of clinical research referred to investigations performed in humans, but 46% of placebo group participants thought that it related to laboratory studies, similar to the findings of Garapati (2015). These results indicate that the intervention had a slight, although insignificant, impact on improving the understanding of students. Had the intervention been more intense, coupled with detailed description and perhaps a relevant exercise or an audio/video presentation on clinical trials
before the survey, the difference likely would have reached significance in this study.

Consistent with this finding, the study by Pandiri (2017) also showed no significant
difference between the percentage of participants in active and placebo groups providing
correct answers.

In the subgroup analysis assessing the impact of demographics, participants in higher
grades showed a significantly higher level of knowledge ($p = .003$). But the percentages of
participants giving correct definitions did not increase with grade, similar to the study by
Garapati (2015). This clearly implies that participants overrated their knowledge levels.
Participants from the two colleges—Arts and Sciences, and Technology—indicated a similar
distribution of their level of knowledge. In the parallel study by Pandiri, significantly more
participants majoring in health and human services claimed to have more knowledge than
those majoring in business. In both studies, age did not significantly impact the students’
level of knowledge (Pandiri, 2017). In the present study, when age criteria were collapsed to
compare Generation Y ($n = 199, 91\%$) to older participants ($n = 17, 9\%$), more of the older
participants selected the correct definition of clinical trial.

Attitudes towards acceptance or reluctance to participate in a clinical trial were also
assessed. Sixty percent of active and 63\% of placebo respondents stated willingness to
participate in a clinical trial; the difference between these groups was not significant. An
earlier study conducted in Maryland, which included more than 5,000 adults, found that
knowledge of clinical trials was a key factor that significantly increased the likelihood of
participation (Baquet, Commiskey, Daniel, & Mishra, 2006). However, knowledge acquired
during the period of illness or trial enrolment may not favor clinical trial participation
(Hoffner et al., 2012). Educating people much ahead of the decision-making point is
necessary for enhancing participation rates (Profit, 2014). Thus, an insignificant difference between active and placebo groups highlights the ineffectiveness of the brief description provided in the active survey sheet in influencing the student’s decision for participation. A similar finding was observed in the survey by Pandiri (2017), which showed that 53% of active group participants vs. 59% of placebo group respondents might agree to participate in clinical trials. This is well within the range of 29%–80% reported by other studies assessing the willingness across varied non-patient populations (Ise, Takechi, Miyamoto, Ishizawa, & Yanagawa, 2017; Fayed, 2016; Bruce et al., 2014; Bouida et al., 2016).

None of the demographics showed a significant impact on willingness to participate in clinical trials. More Generation Y participants than older participants expressed this willingness, but the survey included very few older participants. So extrapolation of these results may not present a true picture. This was also a trend seen in the study by Pandiri (2017) across the Colleges of Health and Human Services, and of Business at EMU.

More than half of the respondents in this survey indicated that the primary motivational factor for trial participation was financial compensation. This was also highlighted in a survey of healthcare professionals, 70% of whom considered financial incentives as the key factor to encourage clinical trial participation (Fayed, 2016). Concerns about safety were cited as the primary reason for non-participation, consistent with several other studies (Fayed, 2016; Bouida et al., 2016; Dunlop et al., 2011; Profit, 2014).

A majority of survey participants chose to be informed of new clinical trials by their physicians, and university medical centers were the most common clinical trial location. Similar findings were observed in the research by Pandiri (2017) and Garapati (2015).
Overall the research results suggest that the intervention failed to demonstrate a positive impact on knowledge and perceptions among the university students. There exists a strong need for educational interventions that address knowledge and inculcate positive attitudes towards clinical research (Brown et al., 2015). Future researchers may consider investigating the effectiveness of intensive interventions, such as audio/video sessions or more detailed description and a relevant exercise, among students.
Chapter 5: Conclusion

The findings from this predominantly Generation Y participant sample revealed that university students are generally unaware of clinical research. Also, providing a short description of clinical research did not improve their knowledge or willingness to participate in a clinical trial any more than those who were not given such information. In the future, the effectiveness of intensive educational sessions involving audio/visual presentations or exercises that ensure participants’ attention should be tested.
References


http://dx.doi.org/10.1111/ecc.12476


APPENDICES
Appendix A: UHSRC Approval Letter

RESEARCH @ EMU

UHSRC Determination: EXPEDITED INITIAL APPROVAL

DATE: March 7, 2016

TO: Divya Pandiril, 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.

Sincerely,

Jennifer Keilman Fritz, PhD
Chair
University Human Subjects Review Committee
Appendix B: UHSRC 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

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 illnesses

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
   f) 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

**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
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 advisor 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.
Appendix F: Supplementary Tables

Supplementary Table 1

**Impact of Demographics on the Knowledge on Clinical Trials**

<table>
<thead>
<tr>
<th>Factor</th>
<th>Complete Knowledge</th>
<th>Somewhat Knowledge</th>
<th>A little Knowledge</th>
<th>No Knowledge at All</th>
<th>$\chi^2$, $p$ value</th>
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<td>18-24 yrs</td>
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<td>32 (20.6%)</td>
<td>69 (44.5%)</td>
<td>51 (32.9%)</td>
<td>6.054, 0.734</td>
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<td>8 (18.2%)</td>
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<td>35 or older</td>
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<td>4 (23.5%)</td>
<td>10 (58.8%)</td>
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<td>34 (43.6%)</td>
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<td>4 (2.9%)</td>
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<td>22 (20.2%)</td>
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Supplementary Table 2

*Impact of Demographics on the Correctness of Clinical Trials Definition*

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<th>( \chi^2 ), ( p ) value</th>
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Supplementary Table 3

*Impact of Demographics on the Willingness to Participate in Clinical Trials*

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