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# Demographic Profile of Clinical Research Volunteers: Improving the Effectiveness of Promotional Recruitment

Amanda M. McAllister

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Demographic Profile of Clinical Research Volunteers: Improving the Effectiveness of  
Promotional Recruitment

by

Amanda M. McAllister

Thesis

Submitted to the College of Health and Human Services

Eastern Michigan University

in partial fulfillment of the requirements

for the degree of

MASTER OF SCIENCE

in

Clinical Research Administration

Thesis Committee:

Stephen A. Sonstein, PhD, Chair

Kenneth A. Getz, MBA

February 9, 2009

Ypsilanti, Michigan

## Acknowledgements

I would like to acknowledge the Center for Information and Study on Clinical Research Participants (CISCRP) for allowing the survey for this project to be sent to their database of clinical research volunteers.

I would like to extend my gratitude to Cari Krzyzaniak, a recent graduate of the Master of Science in Clinical Administration Program for her advice and support during this project.

I would also like to acknowledge the volunteers who agreed to participate in this study. This research project would not have been possible without the efforts of the study participants.

Last, I would like to recognize my thesis advisor, Dr. Stephen Sonstein, for his guidance during this project.

## Abstract

*Background:* Successfully recruiting participants for clinical trials is a challenge that crosses all medical disciplines. Slow enrollment to clinical trials delays the completion of clinical research studies.

*Objectives:* This study collected demographic data of current and past clinical trial volunteers. Furthermore, it examined similarities and differences between clinical trial volunteers, which provides deeper understandings of who volunteers are and which may allow for improved education and recruitment of subjects.

*Methods:* 87 adults who had participated in at least one clinical research study were surveyed.

*Findings:*

- Healthcare represented the most common career at 27.6%.
- 93.1% received education beyond high school.
- 0% met the Investigator's definition for low socioeconomic status.
- 4.6% had no healthcare coverage.
- 54% associate themselves with the Democratic Party.

*Conclusions:* There does not appear to be any strong commonalities among clinical research volunteers and the following demographics: career, education level, household income, religious affiliation, political affiliation, and musical affiliation.

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## Chapter 1: Introduction and Background

The majority (nearly 86%) of clinical trials conducted in the United States fail to enroll subjects within the contract period. This failure rate is up from 80% of trials in the late 1990s. These delays result in significant direct development costs for the study sponsor. Extended enrollment periods can also cause delays in new product introductions – a substantially higher cost that is due to missed market opportunity. Nearly two thirds of investigative sites argue that challenges of patient recruitment and retention are becoming more difficult (Woodin, 2004).

In a recent poll, 94% of people recognize the importance of participating in clinical research in order to assist in the advancement of medicinal science. Yet very few patients are even aware that they are eligible to participate in clinical trials. Seventy-five percent of the general public state that they have little to no knowledge about the clinical research enterprise and the anticipation process (CISCRP, 2008).

Where and how to recruit subjects for clinical trials depends on the demographics of the target populations and the condition under investigation (De Looze, 1999). Demographics are the characteristics of human populations and population segments. Psychographic information includes information regarding personality traits of individuals and/or groups. Accurate demographic data is the foundation of successful research, planning distribution and marketing strategies (Claritas, 2008)). Knowing exactly who your audience is provides critical data that is useful when developing educational and recruitment tools.

Recruitment methods can be for a population sample or patients. Population recruitment includes telephone, letter, household, advertising, and the Web. Patient



recruitment methods include clinics, hospitals, advertisements, referrals, and the Web. (Leupker, 2008).

The lack of understanding of clinical trials deters participation in research studies. Recruitment tools and educational materials developed specially for specific target populations may help increase the percentage of the eligible population that enrolls in clinical trials and thus decrease enrollment delays.

The National Institute of Health (NIH) requires that NIH-supported biomedical and behavioral research involving human subjects must report gender, race, and ethnicity information to ensure that all populations are offered the opportunity to participate (2001). Therefore, basic demographic data for clinical trial volunteers are well tracked.

#### *Statement of the Problem*

Despite well tracked basic demographics (gender, race, ethnicity), data representing the socioeconomic status and psychosocial characteristics of clinical research volunteers are lacking. It is suspected that the lack of data available for the following demographics –career, education level, household income, religious affiliation, political affiliation, and musical affiliation– is the result of a few factors:

1. Historically, study sponsors have viewed these data as competitively sensitive information; therefore, it has been difficult to find and to aggregate the data.

Sponsors have their own mechanism for gathering information and collected data that they consider proprietary. These individual methods for collection and collected data are not shared because it does not benefit their company to share. Benefiting another company actually causes damage to their own;

2. Most professionals tend to think about the patients that they need for their specific studies and not about study volunteers as a group.

### *Purpose of the Study*

This research study acquired the following demographic and psychographic data from current and past clinical subject volunteers: career, education level, household income, religious affiliation, political affiliation, and musical affiliation. Hopefully, the data collected will enable professionals to develop more effective educational and recruitment tools for untapped subpopulations, facilitating partnerships with lay people predisposed to considering participating in trials. These relationships and better educational and recruitment tools may help studies meet their enrollment goals in a timelier manner, which would decrease the amount of extra costs incurred due to enrollment delays and potentially speed the approval process of effective drugs, biologic, or devices.

### *Significance*

Acquiring the following demographic and psychographic data -career, education level, household income, religious affiliation, political affiliation, and musical affiliation of current and past clinical research volunteers- will inform research professionals, policymakers, politicians, and regulatory agencies with a deeper understanding of who (demographic and psychographic data) volunteers are. The data collected will hopefully enable professionals to improve the process of recruiting and retaining subjects for clinical trials.

## *Research Questions*

This study addressed the following research questions:

- Do clinical research volunteers who have participated in three or more trials have more socioeconomic and psychosocial characteristics in common than those who participated in two or fewer trials?
- Do clinical research volunteers have minimal education (high school education or less)?
- Are there are commonalities between certain careers and being a research volunteer?
- Do the majority of clinical research volunteers come from a low socioeconomic status (meet the following three criteria: highest level of education –high school education or less; healthcare coverage –none; and household income –below \$40,000)?
- Do the majority of clinical research volunteers have healthcare coverage?
- Which religious denominations are represented most among clinical research volunteers?
- Do Republicans (the conservative party) participate less often than Democrats (the liberal party) for clinical trials?
- Are there commonalities among research volunteers and the genres of music they prefer?

## Chapter 2: Review of Related Literature

A recent literature search failed to yield articles with data representing the following demographic and psychographic information of clinical trial volunteers: career (profession or occupation), education level (the highest level of training or schooling), household income (money received for work), religious affiliation (belief pursued with devotion), political affiliation (government political party favored), and musical affiliation (genre/category of music preferred).

## Chapter 3: Research Design and Methodology

### *Sample Selection*

The target population for this study consisted of adults who have participated in  $\geq 1$  clinical trial.

### *Human Subjects Protection*

Prior to initiating this research, the Investigator submitted a Request for Approval of Research Involving Human Subjects to the Eastern Michigan University College of Health and Human Services Human Subjects Review Committee (HSRC) for review and approval. The HSRC approved the study for initiation on October 22, 2008 (Appendix A).

All potential study participants were informed of the study purpose and procedures by means of an email bulletin (Appendix B). All potential participants had the right to refuse participation or withdraw from the study prior to completing the survey. Filling out the survey constituted the subject's agreement to participate in this study. Submission (completion) of the survey represented informed consent.

In addition, all data collected for this study were anonymous and confidential. Participants were instructed via bulletin email that their answers were confidential and could not be traced back to them.

### *Data Collection*

Following HSRC approval, the Manager of Outreach and Customer Service at the CISCRP sent an email bulletin (Appendix B) to a proprietary list of names housed in a database at the CISCRP. The bulletin asked the recipients to consider participating in the research study and included a web link to a short online survey (see Appendix C). After

completing eight multiple choice questions, the participant was directed to click the “submit” button, which submitted their anonymous survey answers to the Investigator.

## Chapter 4: Presentation and Analysis of Data

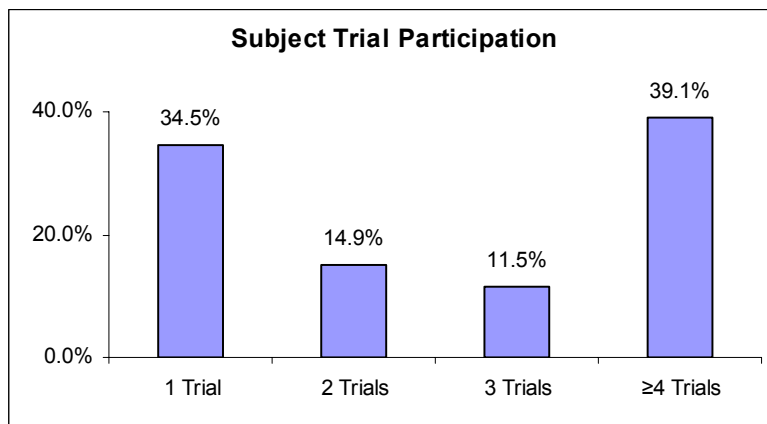
The Manager of Outreach and Customer Service at the CISCRP sent the email bulletin to 1061 potential participants. Three hundred and seventeen contacts opened the email. One hundred and thirty-seven participants submitted surveys to the Investigator, which equates to a 43.2% response rate. Fifty participants did not meet the eligibility criteria (participated in < 1 clinical trial); as a result, their data were excluded from analysis. Thus, a final sample of 87 volunteers participated in this study.

### *Question #1*

Number of clinical trials participated in?

Survey participants chose from the following four options: a.) 1, b.) 2, c.) 3, or d.)  $\geq$  4.

The objectives of this question were to: 1.) Ensure that participants had indeed participated in at least one clinical trial and 2.) To assist in the assessment if clinical research volunteers who have participated in three or more trials have more socioeconomic and psychosocial characteristics in common than those who participated in two or fewer trials.



*Figure 1:* Number of Trials Participated in

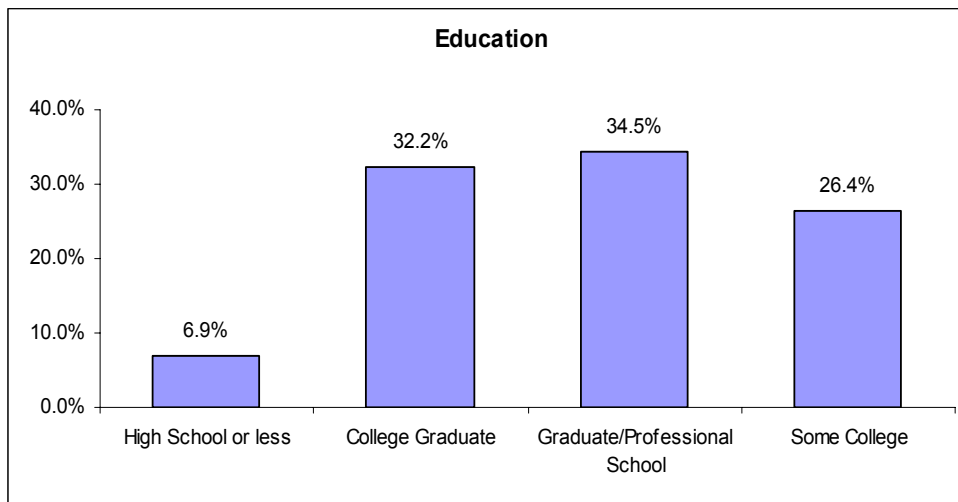
Of the 87 survey participants, 44 (50.6%) had participated in three or more clinical trials, while 43 (49.4%) had participated in two or fewer clinical trials.

*Question #2*

Highest level of education?

Survey participants chose from the following five options: a.) High School or less, b.) Technical/Trade School, c.) Some College, d.) College Graduate, or e.) Graduate/Professional School.

The objective of this question was to assess if the majority of clinical research volunteers have minimal education (high school education or less).



*Figure 2a:* Level of Education (all survey responses 1 -  $\geq 4$  trials participated in)

Six survey participants answered that their highest level of education was high school or less. Eighty-one survey participants answered that they had received education beyond high school. These data do not support the hypothesis that clinical research volunteers have minimal education (high school education or less).



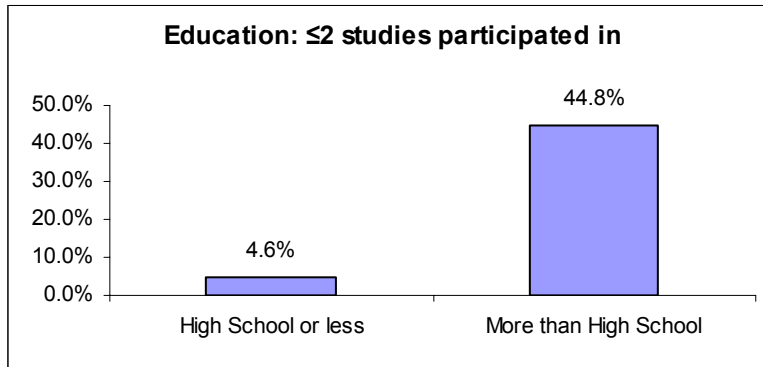


Figure 2b: Education: ≤2 studies participated in

Four of the six survey participants (66.7%) whose highest level of education was high school or less had participated in two or fewer clinical studies.

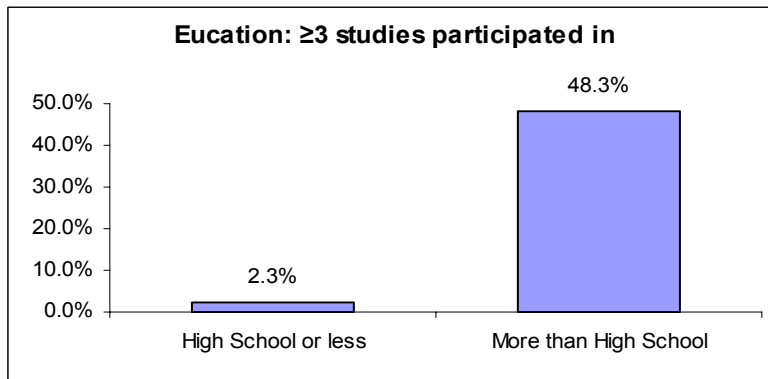


Figure 2c: Education: ≥3 studies participated in

Two of the six survey participants (33.3%) whose highest level of education was high school or less had participated in three or more clinical studies.

### Question #3

Career/profession?

Survey participants chose from the following eight options: a.) Arts, b.) Business, c.) Education, d.) Health, e.) Technology, f.) Trade, g.) Unemployed or h.) Other.

The objective of this question was to assess if there were commonalities between certain careers and being a research volunteer.

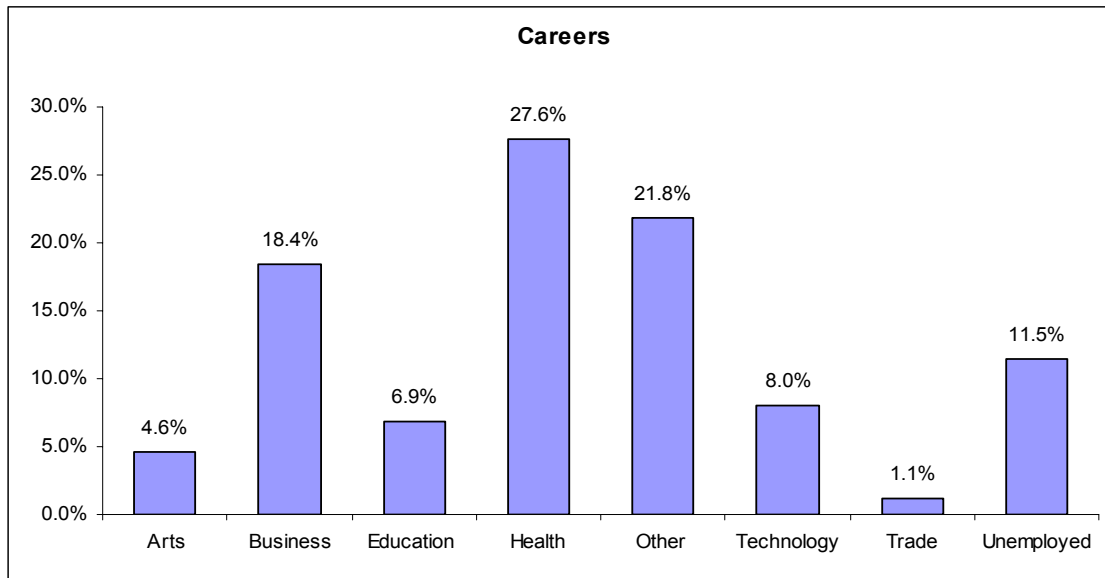


Figure 3a: Career (all survey responses 1 -  $\geq 4$  trials participated in)

The career with the highest representation was healthcare; 24 of the 87 survey participants selected that they worked in healthcare. It was interesting to find that the most underrepresented career was the trade's profession, 1 of 87 survey participants.

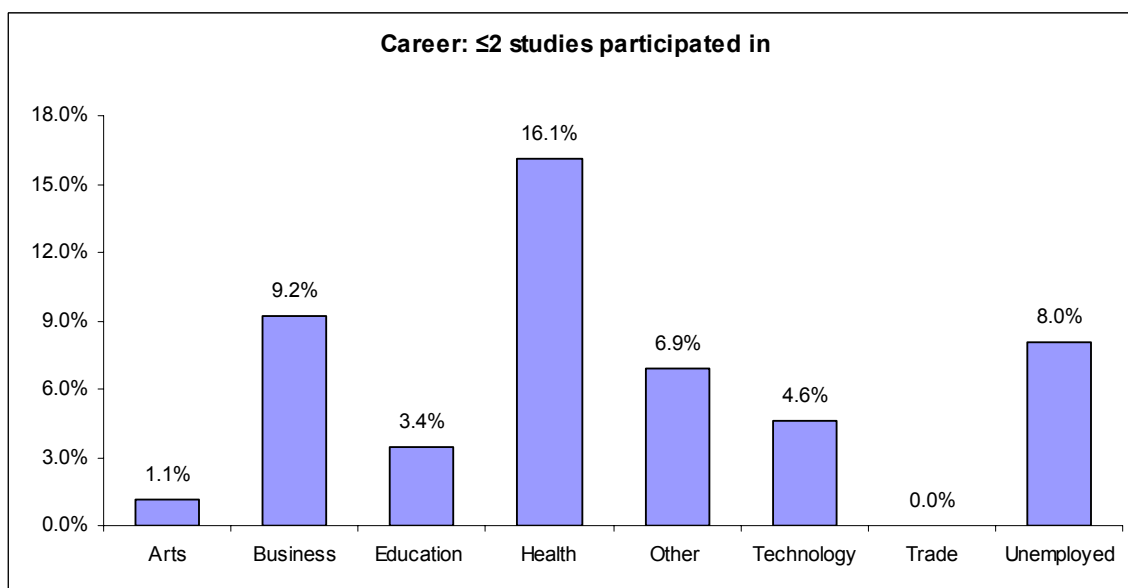


Figure 3b: Career:  $\leq 2$  studies participated in

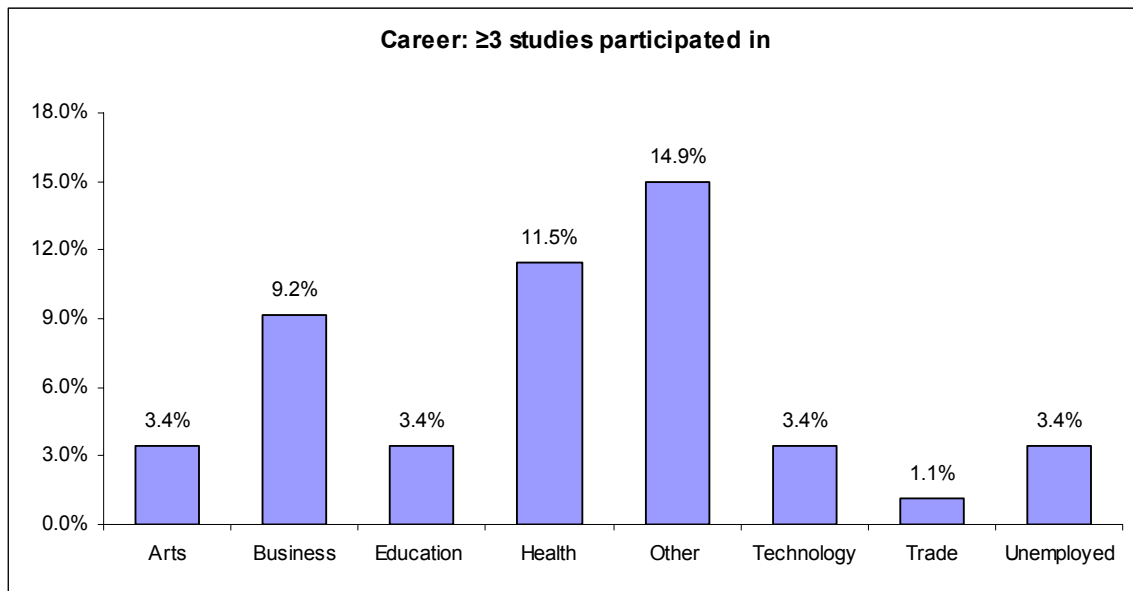


Figure 3c: Career:  $\geq 3$  studies participated in.

The data do not show any commonalities between a profession and the number of clinical trials participated in.

#### Question #4.

Household income?

Survey participants chose from the following four options: a.) Below \$40,000, b.) \$40,000 - \$75,000, c.) \$75,001 – \$100,000, d.) Over \$100,001.

The objective of this question was to assess if the majority of clinical research volunteers come from a low socioeconomic status (meet the following three criteria: highest level of education –high school education or less, healthcare coverage –none, and household income –below \$40,000.)

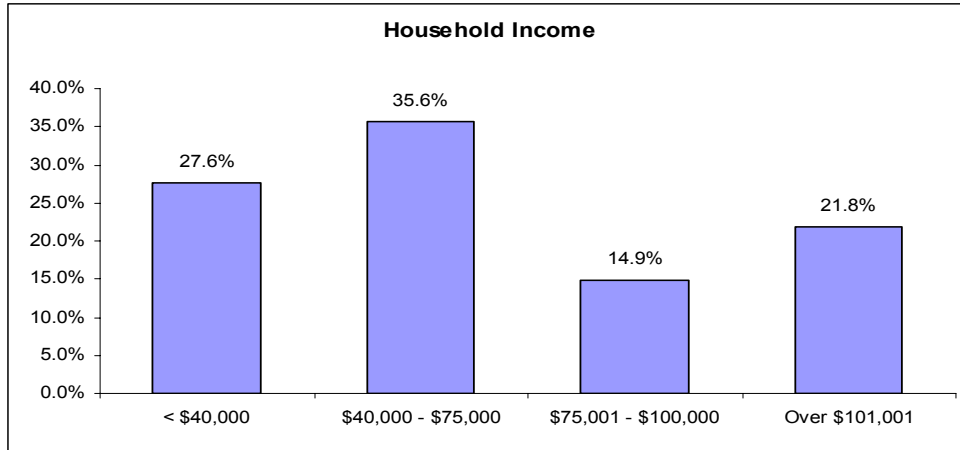


Figure 4a: Household Income (all survey responses 1 -  $\geq 4$  trials participated in)

Twenty-four of the survey participants answered that their household income was less than \$40,000.00. Of these 24 survey participants, one did not have health insurance but had education beyond high school, and four of the survey participants disclosed that the highest level of education they received was high school or less but they had health insurance. Therefore, of the subjects who participated in this study, none (0%) met all three criteria listed in the Investigator's definition for low socioeconomic status.

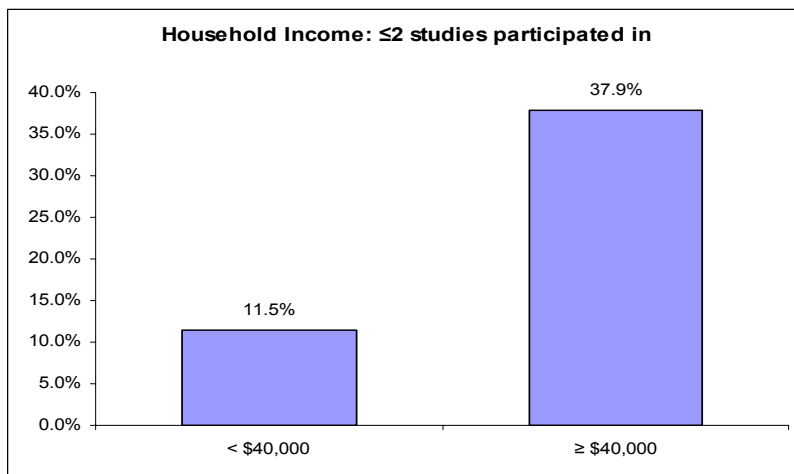


Figure 4b: Household Income:  $\leq 2$  studies participated in

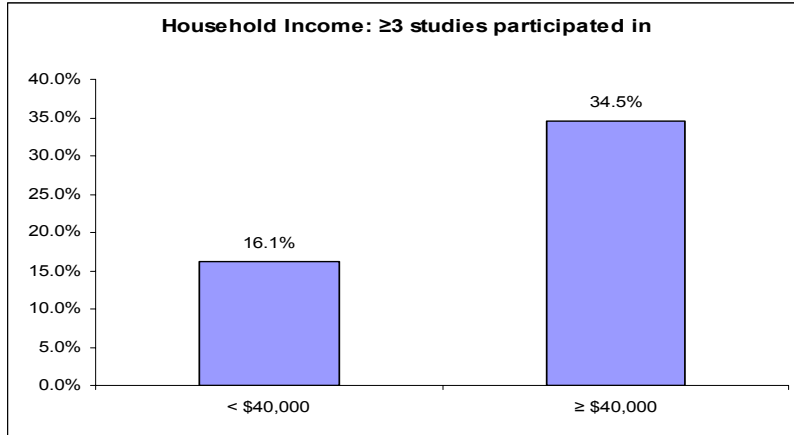


Figure 4c: Household Income: ≥3 studies participated in

The data do not show that the number of clinical trials participated in ( $\leq 2$  or  $\geq 3$ ) affected the < \$40,000 household income population.

*Question #5*

Healthcare coverage?

Survey participants chose from the following options: a.) yes or b.) no.

The objective of this question was to assess whether the majority of clinical research volunteers have healthcare coverage.

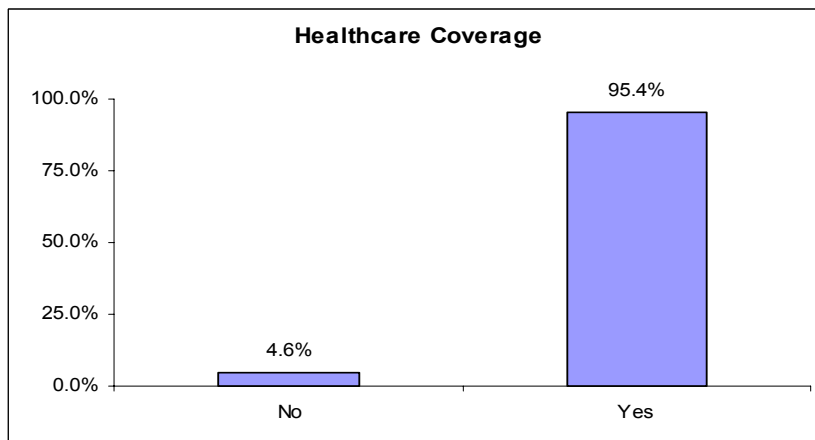


Figure 5a: Healthcare Coverage (all survey responses 1 - ≥4 trials participated in)

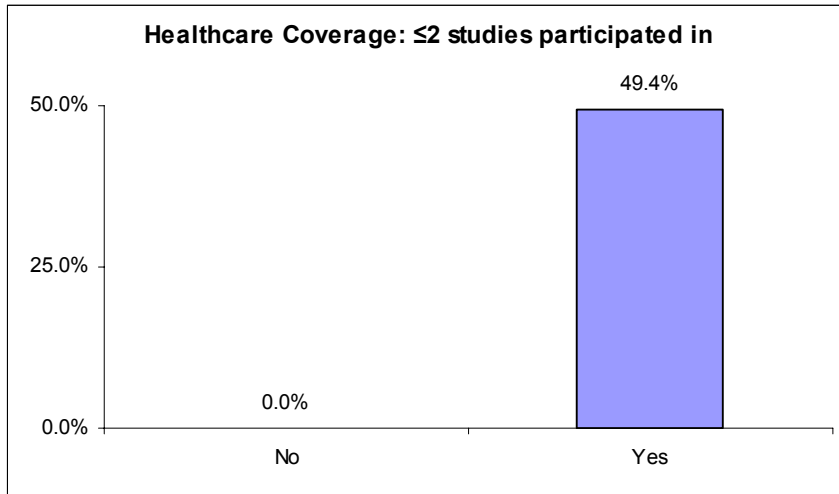


Figure 5b: Healthcare Coverage:  $\leq 2$  studies participated in

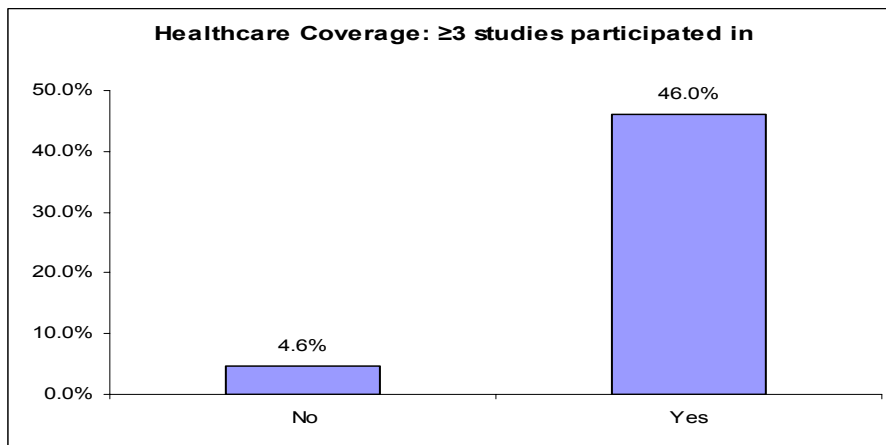


Figure 5c: Healthcare Coverage:  $\geq 3$  studies participated in

Only four of the study participants had no healthcare coverage. It was interesting to find that 100% of these four participants had participated in three or more clinical trials. These data coincide with current beliefs that people without insurance volunteer for clinical research studies for access to healthcare and/or to assist with healthcare costs; however, the Investigator does not feel that she can support these beliefs with data from four subjects (4.6% of the survey population).

*Question #6*

Religious affiliation?

Survey participants chose from the following 13 options: a.) Baptist, b.) Buddhist, c.) Catholic, d.) Episcopal, e.) Evangelical, f.) Hindu, g.) Jehovah's Witness, h.) Jewish, i.) Lutheran, j.) Methodist, k.) non-denominational, l.) none, or m.) other.

The objective of this question was to assess which religious denominations are represented most among clinical research volunteers.

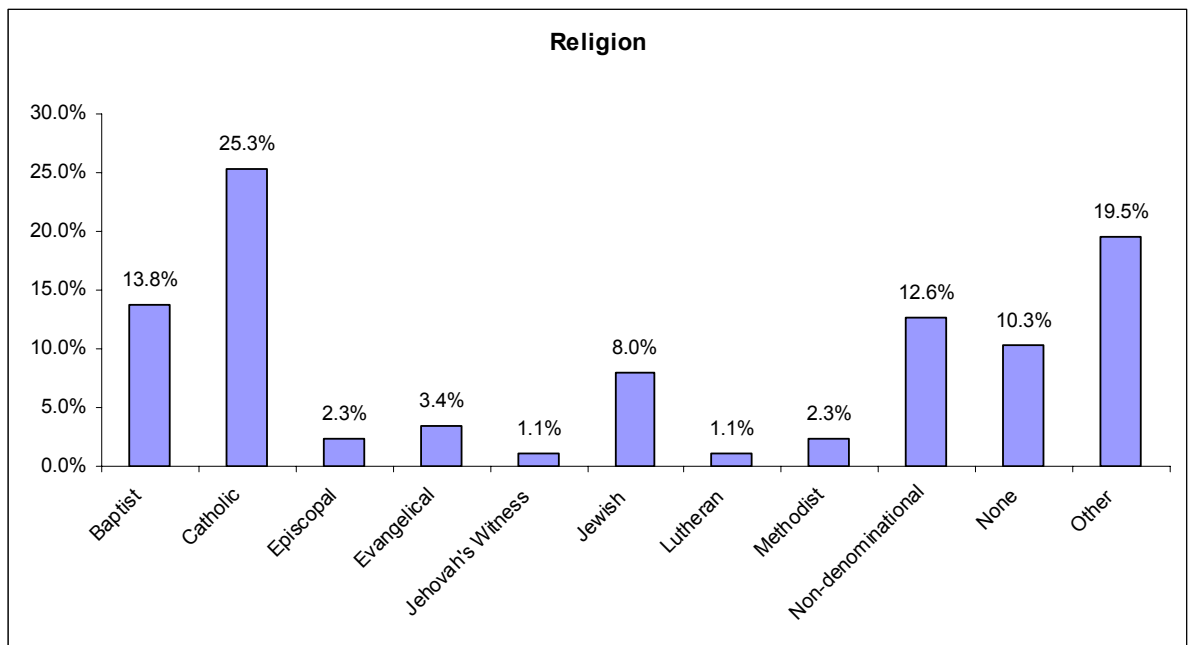


Figure 6a: Religion (all survey responses 1 -  $\geq 4$  trials participated in)

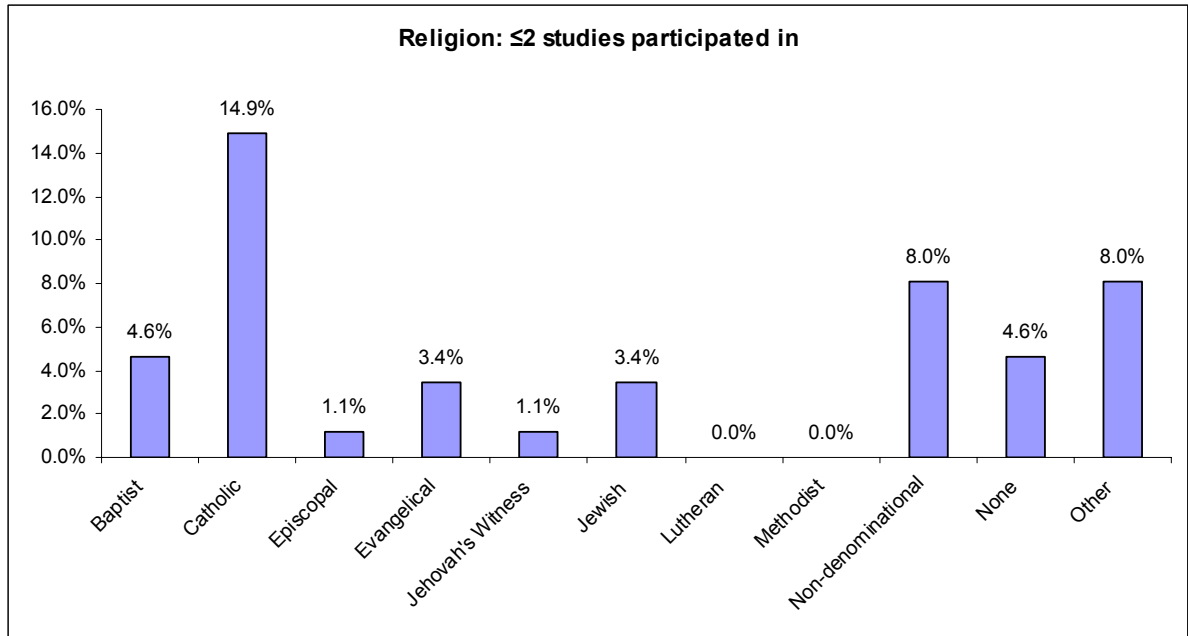


Figure 6b: Religion:  $\leq 2$  studies participated in

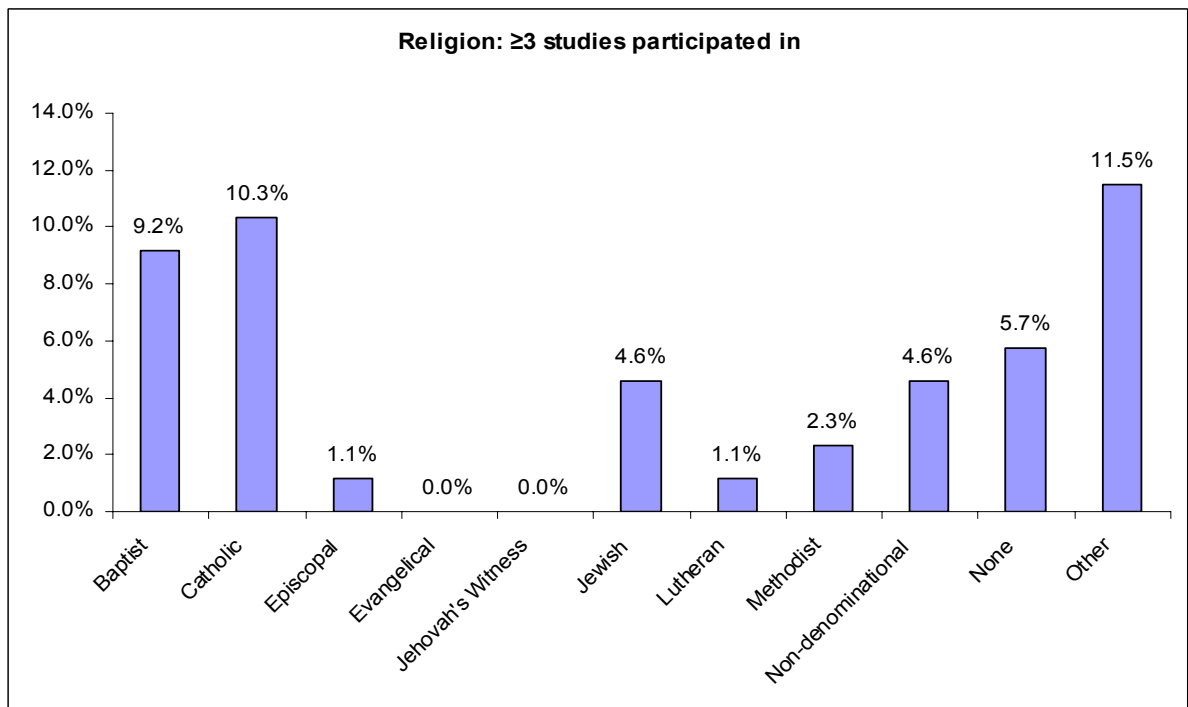


Figure 6c: Religion:  $\geq 3$  studies participated in



The data collected do not show any commonalities between religious affiliation and the number of clinical trials participated in.

*Question #7*

Political affiliation?

Survey participants chose from the following three options: a.) Democrat, b.) Republican, or c.) other.

The objective of this question was to assess whether Republicans (the conservative party) participate less often than Democrats (the liberal party) for clinical trials.

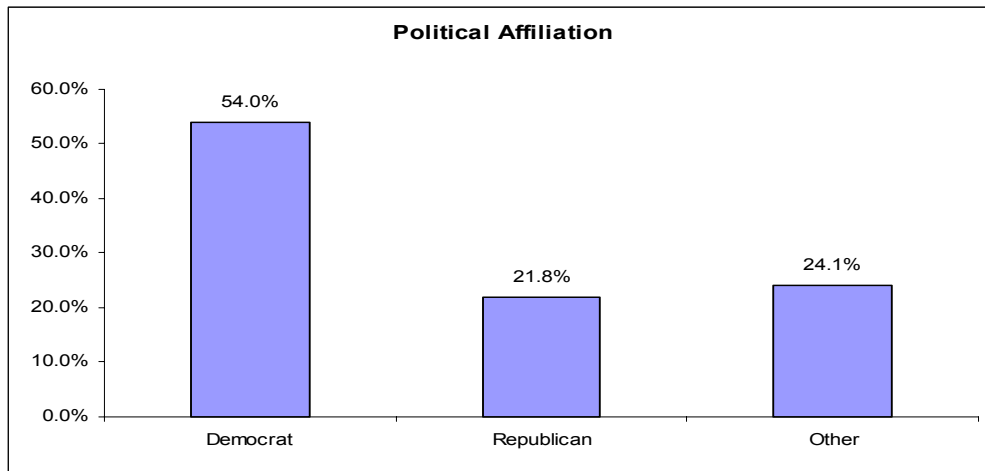


Figure 7a: Political Affiliation (all survey responses 1 -  $\geq 4$  trials participated in)

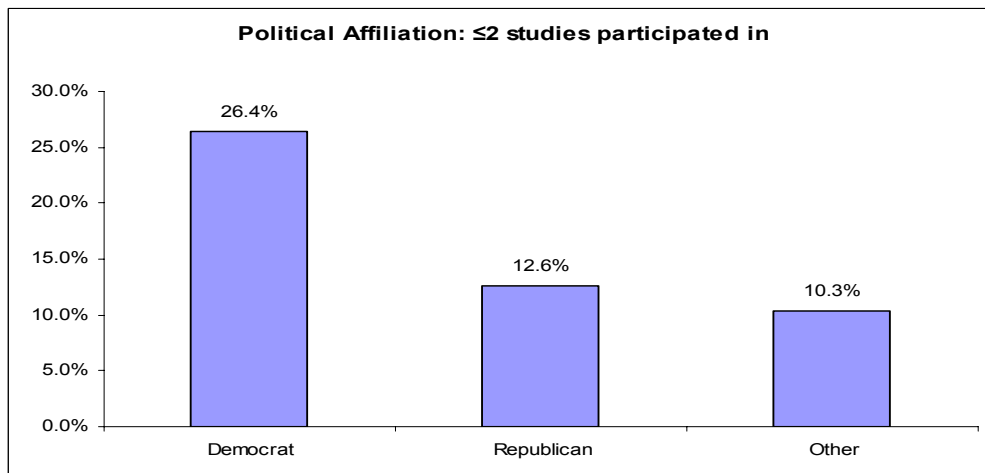


Figure 7b: Political Affiliation:  $\leq 2$  studies participated in

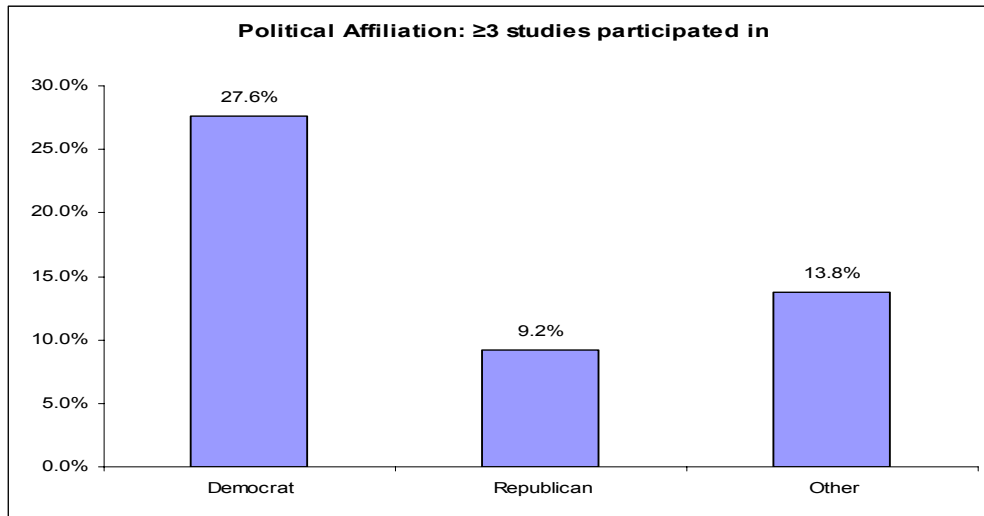


Figure 7c: Political Affiliation:  $\geq 3$  studies participated in

Even though the majority of the survey participants disclosed that they associate themselves with the Democratic Party, the data collected does not show any commonalities between political affiliation and the number of clinical trials they participated in.

#### Question #8

Type/genre of music?

Survey participants chose from the following five options: a.) Country & Folk, b.) Hip-Hop & R&B, c.) Jazz & Blues, d.) Pop & Hits, or e.) Rock.

The objective of this question was to assess whether there are commonalities among research volunteers and preference of genres in music.

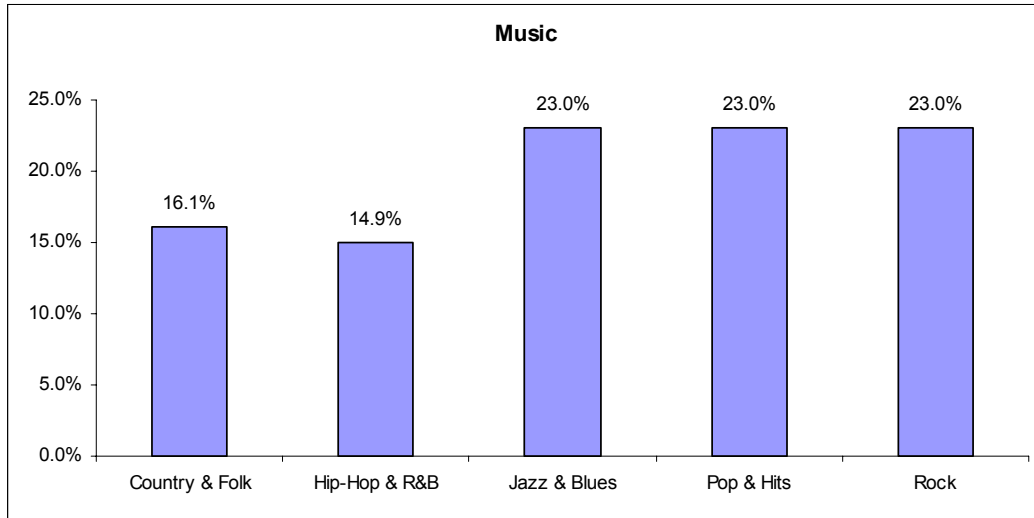


Figure 8a: Music (all survey responses 1 -  $\geq 4$  trials participated in)

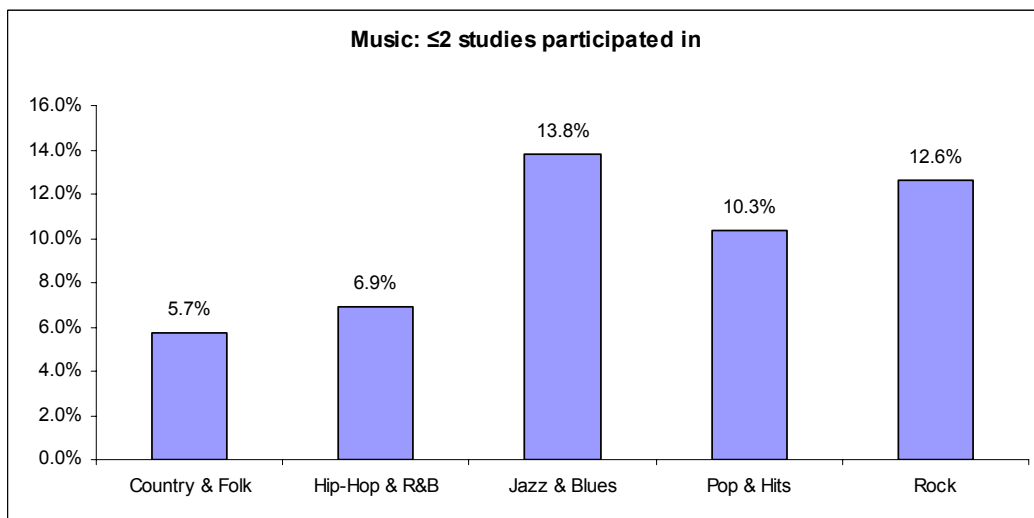


Figure 8b: Music:  $\leq 2$  studies participated in

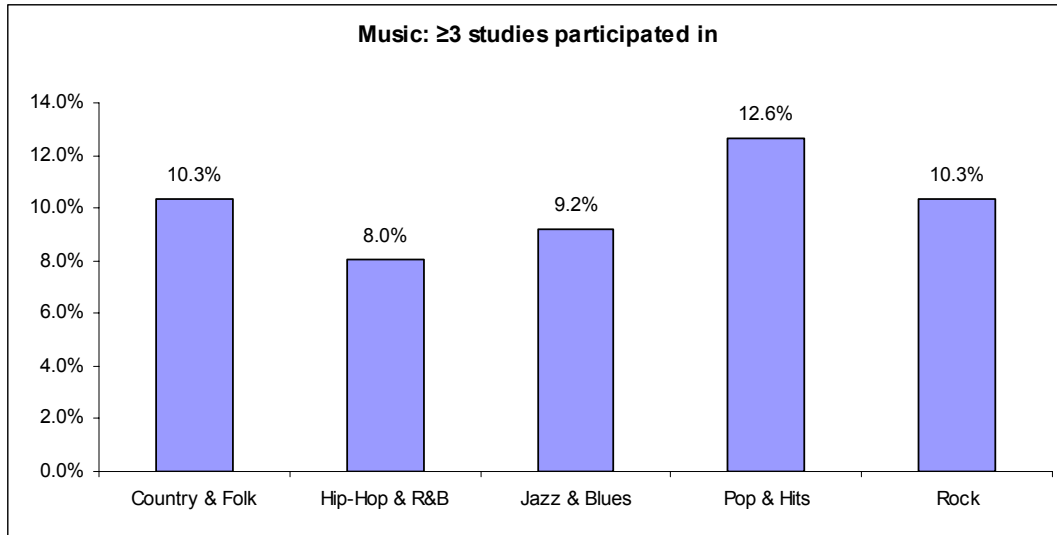


Figure 8c: Music:  $\geq 3$  studies participated in

The data do not show any significant commonalities between a musical preference and the number of clinical trials participated in.

## Chapter 5 Summary, Conclusions and Inferences

The Investigator was hoping to find psychographic commonalities among the survey participants and even more commonalities among those participants who had participated in three or more clinical trials. The data collected did not provide this as the number of trials that a subject had participated in did not appear to indicate any other similarities.

The Investigator was able to disprove the common belief that clinical research volunteers have minimal education (high school education or less). However, the population this survey was sent to may have played a factor in these results (see Recommendations for Further Research below).

The career that represented the study population most was healthcare. This was not a surprising result as healthcare workers would be more likely to be volunteers for a group like the Center for Information and Study on Clinical Research Participation and are exposed to clinical trials and the true intention of these studies.

The Investigator hypothesized that household income does not correlate with volunteering for clinical studies. The study data collected support this theory. The Investigator also hypothesized that the current belief that volunteers come from low socioeconomic lifestyles would be disproved. The data collected did disprove this current belief; however, please see Recommendations for Further Research below.

Many people believe that people who volunteer for clinic trials do so because they do not have any form of healthcare coverage and volunteering for a clinical study is a way to have part of their medical care and/or medication covered by research funds. The data collected in this study disproved this current belief.

The Investigator was surprised to learn that certain religious denominations were not represented more than others among the study participants. Catholicism was expected to be the most prevalent selection; however, no other religion was represented by more than 13.8 %, and every religion was represented in this study, through the “other” category.

The Investigator hypothesized that Republicans (the conservative party) participate less often than Democrats (the liberal party) for clinical trials. The data collected in this study supported the Investigator’s theory. There could be some bias, though, because this survey was completed approximately one month following an election that placed a Democrat in office.

The Investigator was surprised to learn that a specific genre of music was not represented more than any other. There weren’t any commonalities among research volunteers as the data collected showed almost even representation for each genre.

#### *Recommendations for Further Research*

To confirm the results of this study, future investigators should replicate this research in a larger population. Since this study used an online survey, participants required access to the internet. The assessment of low socioeconomic may be skewed since this population may not have internet access. In addition this survey was sent to volunteers for the Center for Information and Study on Clinical Research Participation. This is a select population. A more broad population would most likely provide a wider spectrum of answers.

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Appendix A: College of Health and Human Services Human Subjects Review Committee  
Approval Letter



EASTERN MICHIGAN UNIVERSITY

October 22, 2008

Amanda McAllister  
c/o Stephen Sonstein  
Eastern Michigan University  
School of Health Sciences  
Ypsilanti, Michigan 48197

Dear Amanda,

The CHHS Human Subjects Review Committee has reviewed the revisions to your proposal entitled: "Demographic Profile of Clinical Research Volunteers: Utilizing Demographic Characteristics to Improve the Effectiveness of Promotional Recruitment" (CHHS 09-008).

The committee reviewed your proposal and concluded that the risk to participants is minimal. Your study is approved by the committee.

Good luck in your research endeavors.

Sincerely,

A handwritten signature in cursive script that reads "Gretchen D. Reeves".

Gretchen Dahl Reeves, Ph.D.  
Interim Chair, CHHS Human Subjects Review Committee



## Appendix B: Survey Completion Request



Have you ever participated in a clinical research study?

December 2, 2008

Dear Clinical Research Volunteer:

A graduate student at Eastern Michigan University is currently working on her master's thesis exploring demographic information of current and past clinical research volunteers.

She would greatly appreciate your willingness to participate in her survey. All that is required is that you complete a brief online survey (eight multiple choice questions) by clicking on the link below. Your answers to the survey will be confidential, and cannot be tracked back to you.

Click on the following link to access the survey:

[http://www.surveymonkey.com/s.aspx?sm=wKsFCryKYfqkizT37nOcfA\\_3d\\_3d](http://www.surveymonkey.com/s.aspx?sm=wKsFCryKYfqkizT37nOcfA_3d_3d)

This survey will be posted online for approximately two weeks to allow for your participation. Thank you.

Warm Regards,

Meaghan Dunn  
Manager of Outreach & Customer Service  
CISCRP

✉ **SafeUnsubscribe®**

This email was sent to akingsle@med.umich.edu by [mdunn@ciscrp.org](mailto:mdunn@ciscrp.org).

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CISCRP | 990 Washington St. | Suite 101 | Dedham | MA | 02026

## Appendix C: Survey

### SURVEY for PAST AND CURRENT CLINICAL TRIAL PARTICIPANTS

1. HOW MANY CLINICAL TRIALS HAVE YOU PARTICIPATED IN?

- 0
- 1
- 2
- 3
- 4 or more

2. WHAT IS YOUR HIGHEST LEVEL OF EDUCATION?

- High School or less
- Technical/Trade School
- Some college
- College Graduate
- Graduate/Professional School

3. WHAT IS YOUR CAREER/PROFESSION?

- Arts
- Business
- Education
- Health
- Technology
- Trade
- Unemployed
- Other

4. WHAT IS YOUR HOUSEHOLD INCOME?

- Below \$40,000
- \$40,000 - \$75,000
- \$75,001 – \$100,000
- Over \$100,001

5. DO YOU HAVE ANY KIND OF HEALTHCARE COVERAGE?

- Yes
- No

6. WHAT IS YOUR RELIGIOUS AFFILIATION?

- Baptist
- Buddhist
- Catholic
- Episcopal
- Evangelical
- Hindu
- Jehovah's Witness
- Jewish
- Lutheran
- Methodist
- Non-denominational
- None
- Other

7. WHAT IS YOUR POLITICAL AFFILIATION?

- Democrat
- Republican
- Other

8. WHAT TYPE OF MUSIC DO YOU LIKE BEST?

- Country & Folk
- Hip-Hop & R&B
- Jazz & Blues
- Pop & Hits
- Rock

