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Are clinical research professionals more inclined to participate in clinical trials?

Rania Mohammad Felemban

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Are Clinical Research Professionals
More Inclined to Participate in Clinical Trials?

By
Rania Mohammad Felemban

Thesis
Submitted to the Department of Health and Human Sciences
Eastern Michigan University
in partial fulfillment of the requirements for the degree of

MASTER OF SCIENCE
in
Clinical Research Administration

Thesis Committee:
Irwin Martin, PhD
Jean Rowan, MD, M.S.

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Ypsilanti, Michigan
Acknowledgments

This research would not have been possible without the support of the Clinical Research Administration Department at Eastern Michigan University. They allowed me to use the database of the program’s alumni for my thesis. I am especially indebted to Dr. Irwin Martin, my teacher and mentor, for the continuous support of my master’s thesis, for his motivation, and for his immense knowledge. He is the inspiration for my thesis. I would also like to thank Mr. Matthew Dick, in the Research and Statistical Support Department, for his statistical assistance. Also, I have a special appreciation to Zakery Northrop, a student in the Clinical Research Administration Master’s Program, for validating the database of program’s alumni. I am grateful to all of those who participated in the survey, and all members of my thesis committee for their insightful comments and encouragement: Dr. Martin, and Dr. Jean Rowan. I have sincere gratitude to Dr. Sonstein, my advisor, and the director of the Clinical Research Administration Program, who has been supportive of my academic milestones. Last but not least, I would like to thank my mother, brother, and sisters for supporting me spiritually throughout my study, writing this thesis, and my life in general.
Abstract

The objective of this study was to identify the impact of professional knowledge and education on a willingness to participate in clinical trials. It hypothesized that there is no statistical difference in the median rank score between clinical research professionals and other post-graduate educated participants. The research question asked whether the clinical research program graduates were more inclined to participate in clinical trials than other groups with a post-graduate education. A cross-sectional quantitative study of 83 clinical research professionals was conducted. All participants were invited to complete a shortened version of the Center for Information and Study on Clinical Research Participation (CISCRP) survey assessing their willingness to participate in clinical trials. This study showed that there is a significant difference between the two groups. Although some factors must be considered when determining their actual participation rate, these findings should not discourage recruiting clinical research professionals into clinical trials.
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I. Introduction

A large proportion of research on potential participants within the clinical research professionals remains incomplete. Patient recruitment targeted typical and more traditional populations. However, clinical research professionals and the post-graduate public with clinical knowledge are a considerable population to be studied. Knowledge of the clinical research professionals’ willingness to participate in clinical trials might enhance the diversity and effectiveness of recruitment. The objectives of this study were to identify the impact of professional knowledge in clinical research in the willingness to participate in clinical trials compared to other educated populations. This study aimed to better understand the barrier of recruiting different human subjects into clinical research.

There is a lack of knowledge of clinical research professionals’ willingness to participate in clinical trials. Observing the differences in willingness to participate in clinical trials between the post-graduate public and clinical research professionals is required. The assumption is that there is no statistical difference in the median rank score between clinical research professionals and the other post-graduate participants.
II. Review of Literature

Clinical trials are the application of exploring the updates of therapies and preventions in medical science. Although the objective of the clinical trial is to deliver a maximum expectation of care and to enrich science, a limited number of patients are enrolled in clinical trials (Sood et al., 2009). One of the factors of success of clinical trials is enrolling the target population of the intended treatment or prevention. According to Sood et al. (2009), the assessment of patients’ perspectives of clinical studies indicates that 68% responded positively to the idea of participating in clinical trials. However, 82% were unaware of how to access information about clinical trials for their disease. Therefore, recruitment of patients should be more efficient to update medical care and disease prevention through the application of clinical trials.

Recruitment of patients for clinical trials has been getting attention in the clinical research field recently. The processes of recruiting and retaining patients are becoming more complicated, which delays drug development (Findlay, 2009). According to English, Lebovitz and Giffin (2010), this delay is costing the clinical research industry money, time, and resources, depending on the type of trial, populations, and research setting. The overall estimate of the cost of delay is up to $300–$600 million to implement, conduct, and monitor a large, multicenter trial to completion (Institute of Medicine [US]) Forum on Drug Discovery, 2010). Speeding patients’ recruitment is attainable to enhance the overall clinical trial enterprise by recognizing the factors of participation.

Willingness to participate in clinical trials is one of the factors of participation. According to Gul and Ali (2010), most studies have focused on the willingness of patients and their families to participate in clinical trials. However, a recent survey from the
Center for Information and Study on Clinical Research Participation (CISCRP; 2015) found that approximately 80% of the general population had a positive predilection to be involved in clinical trials. These participants comprise a large part of the participants in potential therapies and protection trials. Therefore, the public perspective and willingness to participate are significant in the clinical trial enterprise.

Patients have various reasons for participating in clinical trials. According to Brintnall-Karabelas et al. (2011) and Getz (2014), even if the participants are qualified to enroll in the clinical trials, they have concerns about receiving placebo, adverse effects, medical exposure, confidentiality, and unexpected costs. Interestingly, the CISCRP (2015) revealed that 43% of the public perceived the side effects as a major risk of participating in clinical trials, while only 28% related their contribution to helping medical science and potential therapies. This result is similar to the Teschke et al. (2010) study, which showed that possible medical advantages to the person or community encourage participation in clinical trials. Respondents were highly concerned either their diseases or their relatives’ condition. Approximately 25% were unwilling to participate, while 29% were unsure about contributing to clinical trials (Teschke et al., 2010). The public seems to consider the benefits and risks before they join any clinical trials.

Willing and unwilling groups have different characteristics. According to Teschke et al. (2010), the characteristics of willing participants included having a sick family member, being elderly, prior involvement in clinical research, or having a positive inclination toward clinical trial participation. Research results were also a great motivator. However, the characteristics of unwilling respondents included post-graduate education and an attitude, depending on the objective of the trial, toward clinical trial participation.
CLINICAL RESEARCH PROFESSIONALS PARTICIPATE IN CLINICAL TRIALS

(Teschke et al., 2010). According to Nelson, Martin and Getz (2015), 18 - 34-year-olds were the least willing to participate in clinical trials compared with older generations. In addition, the younger generation had diverse concerns of health issues, such as weight control, healthy lifestyle, and prevention of diseases, which were different than the perception of the older generations (Nelson et al., 2015). The characteristics of willing and unwilling participants vary based on their clinical trial perspectives, which determine their willingness to participate.

In addition, willingness to participate in clinical trials differs from the public to specific patient groups. As explained earlier, the public might consider their participation as social contribution while patients might consider their health status before participation in clinical trials. According to English, Lebovitz and Giffin (2010), patients have different perceptions depending on their disease type and severity. Around 68% of patients were willing to participate in clinical trials, while 82% were unfamiliar with the clinical trials on their illness (Sood et al., 2009). Agoritsas, Deom and Perneger (2011) found that patients appreciated the contribution of clinical trials if these trials were safe and suitable and if they had adequate information from their physicians. Consequently, patients were willing to participate in clinical trials if they had sufficient knowledge about the trials.

Research has shown that patients’ education about the research could enhance their participation in clinical trials, but there is limited research on the level of education as a factor associated with a willingness to participate in clinical trials. According to Fayed (2016), the clinical trial type and complexity affect decisions to participate in clinical trials. About 80% of healthcare providers surveyed were willing to participate in clinical trials. However, they were more willing to participate in surveys than trials with
intervention or new therapies for diseases. Also, a recent study by Bouida et al. (2016) stated that 89% of physicians were willing to participate in clinical trials. The main encouragement was enhancing science, while the largest reason for reluctance was the complications. Despite the willingness of professionals to participate in clinical trials, the level of education is a factor that distinguishes the public from professionals.

Similarly, the public, healthcare providers, or professionals were equally concerned about the complications of the clinical trials. According to Fayed (2016), 87.2% of healthcare providers were concerned about adverse events, and 79.5% had issues about the endpoints of clinical trials. Despite their background, they were hesitant about the significance behind these clinical trials. Although there is a lot of research on public perception, professional willingness to participate in clinical trials needs more attention.

According to the literature, there is a lack of knowledge about clinical research professionals’ willingness to participate in clinical trials. Earlier literature concentrated on patients, patients’ families, patients at risk, and the general public’s willingness to participate in clinical trials. However, only a limited number of studies reported how willing professionals are to participate in clinical trials. Therefore, there is a need to investigate the willingness of clinical research professionals to participate in clinical trials.

Studying clinicians or professionals and their willingness to participate in clinical trials will help researchers recognize if there is potential for new volunteers with new perceptions and experiences, or if a potential specialty could affect the willingness to participate in clinical trials. The assumption is that clinical research professionals would
be as willing to participate in clinical trials as the public. This study aims to observe the
differences, if they occur, in willingness to participate in clinical trials between
individuals with a post-graduate education and clinical research professionals. The post-
graduate population from the CISCRP (2015) was compared to alumni of the Clinical
Research Administration Graduate Program of Eastern Michigan University.
III. Research Design and Methodology

Research Question

Are clinical research administration program graduates more inclined to participate in clinical trials than other groups with a post-graduate education?

Research Objective

The objectives of this study were to identify the impact of professional knowledge and education on a willingness to participate in clinical trials.

Research Hypothesis

There is no statistical difference in the median rank score between clinical research professionals and other post-graduate educated participants.

Research Subjects

Respondents with a post-graduate education in the Center for Information and Study on Clinical Research Participation (CISCRP) study were compared to clinical research professionals who were 2000 to 2015 alumni of the clinical research administration graduate program at Eastern Michigan University. Differences in willingness to participate in clinical trials were evaluated. Current students who have not yet graduated from the CRA program were excluded. The CRA respondents were 97.59% USA residents; therefore, they were compared to the US post-graduate participants of the CISCRP survey.

Research Methods

CISCRP database. The CISCRP, an independent nonprofit organization, conducted an online international survey in 2015, titled “The 2015 CISCRP Perceptions
& Insights Study: Report on General Perceptions.” The study presents valued and substantive insights into actionable ways that stakeholders of the clinical trials can better comprehend and more adequately engage with the general population and study participants. The overall results and subgroup differences are presented by demographic data, education level, income, age, and severity of the disease.

The total number of survey respondents to the CISCRP survey was more than 12,000 people. The US residents and post-graduates (e.g. master’s or doctorate level degrees) of the CISCRP numbered 560 participants. The aggregated data of the subgroup was obtained from CISCRP and compared to the data of the CRA study focusing on one question of importance: How willing are you to participate in a clinical research study? There were five survey responses options: I am not sure, not at all willing, not very willing, somewhat willing, very willing, and I am not sure.

**CRA data.** A cross-sectional quantitative study of a purposive sample of 419 clinical research professionals derived from the clinical research administration department database was approved by the University Human Subjects Review Committee (UHSRC) of Eastern Michigan University. See Appendix A. The number of respondents totaled 83 participants or approximately 20% of the purposive sample. Of the respondents, 67.47% were employed in clinical research. All participants were invited to complete a shortened version of the CISCRP published survey after giving consent to participate in the study. The informed consent document is in Appendix B. The survey was open for two weeks. See Appendix C for the survey.
The first part of the electronic survey queried demographic data such as residency, age, race, gender, employment status, occupation, and income. The second part of the survey assessed willingness to participate in clinical trials. It involved a question about willingness to participate in clinical trials as a research subject. There were five survey responses options: I am not sure, not at all willing, not very willing, somewhat willing, very willing, and I am not sure. In addition, a question was posed regarding their efforts to join a clinical trial, and actual participation. This question was a direct yes or no question. Other detailed questions examined the reasons that most people participate in clinical trials, how these people perceive clinical research, and what kind of information they need to participate as a research subject. Participants were required to evaluate their level of agreement to some statements. In addition, one question determined the perception of the level of safety of clinical trials by asking participants to state one of the following answers: very safe, somewhat safe, not very safe, or not at all safe. Finally, participants were asked to specify possible benefits and risks of participating in clinical trials.

Data Management

Data were collected from Survey Monkey and exported to a secured Microsoft Excel file. The secured file was double locked, including passwords for the laptop and Microsoft Excel file. The survey instrument itself did not collect any personal identification information. Statistical analyses were conducted using IBM SPSS Statistics 24, and the data were exclusively aggregated. Several different statistical tests were also conducted on the data of this study: a set of Spearman’s correlations, several chi-square analyses, and odds ratio calculation.
The Spearman's rank-order correlation (often abbreviated to Spearman's correlation) calculates a coefficient, $r_s$ or $\rho$, which is a measure of the strength and direction of the association between two continuous or ordinal variables. It is also, a measure of the significance of the relationship between two measures, which can be ordinal, interval, or ratio. Spearman’s rho can vary from -1 to +1, with -1 indicating a perfect negative correlation, zero indicating no correlation, and +1 indicating a perfect positive correlation. This test was chosen to determine whether there is an association between safety, age, willingness to patriciate in clinical trials, and other ordinal variables among CRA participants.

Several one-sample chi-square analyses were conducted on these data. This test is used in order to determine whether there is a significant difference between responses given to some question; these responses are categorical, and some expected distribution. This test compares the actual responses provided by individuals with the expected distribution, which is specified by the researcher, in order to determine whether these two distributions are significantly different.

In addition, an odds ratio was calculated in the dataset question of CRA graduates or post-graduates CISCRP. It is a measure of association between an exposure and an outcome; the ratio of the probability that an event will occur to the probability that it will not occur, and it can be any number between zero and infinity. The odds ratio was calculated focusing upon the measure of willingness or unwillingness and its relationship with the dataset in the willingness question. Within the context of the current study, this odds ratio showed how much more likely respondents are to be willing to participate in clinical trials among those in the post-graduates CISCRP as compared with those in the
CRA graduates group. This odds ratio provided information about the association between these two measures over and above that obtained from a simple cross tabulation or chi-square test.

Participants’ Consent

Participants were introduced to the study survey through an invitation E-mail (Appendix D and E) which included the following: study title, study objectives, study procedure, voluntary rights, expected risks, expected benefits, dissemination of results, confidentiality, and contact information. See Appendix B for informed consent. Therefore, participants who were willing to participate followed the hyperlink to the survey in the E-mail. The introductory page of the survey covered the consent information of participating in the intended study and the voluntary rights to completing the survey.

Confidentiality

The survey was anonymous. The researcher and statistician involved in this study had access to the responses. Otherwise, information provided was compiled with other scores and turned into statistical data.

Ethical Aspects

The University Human Subjects Review Committee (UHSRC) of Eastern Michigan University reviewed and approved this study before the research was conducted. See Appendix A.
IV. Results

Spearman’s Correlation

Four hundred and eleven CRA graduates were invited to participate in the current study, among which 83 participants accepted to join the study; the response rate was 20%. The objective of the study was to identify the impact of professional knowledge and education on willingness to participate in clinical trials. Therefore, a series of Spearman rank order correlation were performed on the ordinal variables to assess the association between the perception of the safety of the clinical research and the willingness to participate in clinical trials among graduates of Eastern Michigan University clinical research administration program, and the other study variables. A summary of the results can be found in Table 1.
Table 1

Spearman’s Correlations

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Note. *p<.05, **p<.01, ***p<.001; 1: Safety of clinical trials, 2: willing to participate in clinical trials, 3: Age, 4: Spend a lot of time at the doctor's office, 5: Receive more time and attention from medical experts, 6: Potential risks and benefits, 7: Length of participation in the clinical research study (time commitment), 8: Types of medical procedures required, 9: Purpose of the clinical research study, 10: If I know there were no risks involved, 11: If my doctor recommended it, 12: If the treatment were free of charge to me, 13: If it were convenient for me to participate.

In the correlations conducted with the safety of clinical trials, three significant correlations were found in total. The correlation between the participant's perception of the safety of the clinical research and willingness to participate was a strong positive (Cohen, 1988): $rs(76) = .503$, $(p = .001)$. A weak positive correlation ($rs = .279$, $p = 0.013$, $df = 76$) was found between the participant's perception of the safety of the clinical research and their age. The correlation between the participant's perception of the safety of the clinical research and how much time is spent at doctor's office was a weak positive ($rs = .008$, $p = 0.947$, $df = 77$). A weak positive correlation ($rs = .137$, $p = 0.233$, $df = 76$) was found between the participant's perception of the safety of the clinical research and receiving more time and attention from medical experts. The correlation was
a weak positive ($rs = .105, p = 0.362, df = 76$) between the participant's perception of the safety of the clinical research and potential risks and benefits of the study. A weak negative correlation ($rs = -.087, p = 0.448, df = 76$) was found between the participant's perception of the safety of the clinical research and the length of research participation. Similarly, a weak negative correlation ($rs = -.054, p = 0.638, df = 76$) was found between the participant's perception of the safety of the clinical research and the types of medical procedures of the research. The correlation was a weak positive ($rs = .032, p = 0.748, df = 76$) between the participant's perception of the safety of the clinical research and potential risks and the purpose of the clinical research study. A weak positive correlation ($rs = .094, p = 0.416, df = 75$) was found between the participant's perception of the safety of the clinical research and no risks are involved in the research. The correlation was a weak positive ($rs = .074, p = 0.524, df = 75$) between the participant's perception of the safety of the clinical research and doctor’s recommendation. A weak positive correlation ($rs = .198, p = 0.085, df = 75$) was found between the participant's perception of the safety of the clinical research and free treatment. The correlation was moderate positive ($rs = .335, p = 0.003, df = 75$) between the participant's perception of the safety of the clinical research and the convenience of the participation.

In the correlations conducted with the willing to participate in clinical trials, four significant correlations were found. The correlation was a weak positive ($rs = .289, p = 0.011, df = 74$) between the participants’ willingness to participate in clinical trials and their age. The correlation between the participants’ willingness to participate in clinical trials and how much time is spent at doctor's office was a weak positive ($rs = .272, p = 0.016, df = 76$). A weak positive correlation ($rs = .146, p = 0.206, df = 75$) was
found between the participants’ willingness to participate in clinical trials and receiving more time and attention from medical experts. The correlation was a weak positive ($rs = .109 p = 0.343, df = 76$) between the participants’ willingness to participate in clinical trials and potential risks and benefits. A weak negative correlation ($rs = -.185, p = 0.105, df = 76$) was found between the participants’ willingness to participate in clinical trials and the length of research participation. Similarly, a weak negative correlation ($rs = -.051, p = 0.657, df = 76$) was found between the participants’ willingness to participate in clinical trials and the types of medical procedures of the research. The correlation was a weak positive ($rs = .101 p = 0.378, df = 76$) between the participants’ willingness to participate in clinical trials and the purpose of the clinical research study. A weak positive correlation ($rs = .138, p = 0.232, df = 75$) was found between the participants’ willingness to participate in clinical trials and no risks are involved in the research. The correlation was a weak positive ($rs = .200 p = 0.080, df = 75$) between the participants’ willingness to participate in clinical trials and doctor’s recommendation. A moderate positive correlation ($rs = .303, p = 0.007, df = 75$) was found between the participants’ willingness to participate in clinical trials and free treatment. The correlation was a weak positive ($rs = .245 p = 0.032, df = 75$) between the participants’ willingness to participate in clinical trials and the convenience of the participation.

In the correlations conducted with participants’ age, one significant correlation was found in total. A weak positive correlation ($rs = .106 p = 0.357, df = 75$) was found between the participant’s age and how much time is spent at doctor’s office. The correlation was a weak positive ($rs = .084 p = 0.472, df = 74$) between the participant’s
age and receiving more time and attention from medical experts. A weak positive correlation \((rs = .076, p = 0.512, df = 74)\) was found between the participant's age and potential risks and benefits. A weak negative correlation \((rs = -.040, p = 0.729, df = 74)\) was found between the participant's age and the length of research participation. The correlation was weak positive \((rs = .0954, p = 0.412, df = 74)\) between the participant's age and the types of medical procedures of the research. The correlation between the participant's age and the purpose of the clinical research study was a weak positive \((rs = .101, p = 0.378, df = 76)\). A weak positive correlation \((rs = .176, p = 0.132, df = 73)\) was found between the participant's age and no risks are involved in the research. The correlation was a weak positive \((rs = .013, p = 0.912, df = 73)\) between the participant's age and doctor's recommendation. A weak positive correlation \((rs = .074, p = 0.526, df = 73)\) was found between the participant's age and free treatment. The correlation between the participant's age and the convenience of the participation was a weak positive \((rs = .031, p = 0.793, df = 73)\).

In the correlations conducted with the time spent in doctor's office, one significant correlation was found in total. A moderate positive correlation \((rs = .330, p = 0.003, df = 76)\) was found between how much time is spent at the doctor's office and receiving more time and attention from medical experts. The correlation between how much time is spent at doctor's office and potential risks and benefits was a weak positive \((rs = .004, p = 0.971, df = 76)\). The correlation was a weak positive \((rs = .043, p = 0.710, df = 76)\) between how much time is spent at doctor's office and the length of research participation. A weak positive correlation \((rs = .062, p = 0.592, df = 76)\) was found between how much time is spent at doctor's office and the types of medical procedures of the research. A
weak negative correlation ($rs = -0.105, p = 0.358, df = 76$) was found between how much time is spent at doctor's office and the purpose of the clinical research study. The correlation was a weak positive ($rs = 0.201, p = 0.079, df = 75$) between how much time is spent at doctor's office and no risks are involved in the research. A weak negative correlation ($rs = -0.048, p = 0.678, df = 75$) was found between how much time is spent at doctor's office and doctor’s recommendation. Similarly, a weak negative correlation ($rs = -0.006, p = 0.961, df = 75$) was found between how much time is spent at doctor's office and free treatment. The correlation between how much time is spent at doctor's office and the convenience of the participation was a weak positive ($rs = 0.090, p = 0.435, df = 75$).

In the correlations conducted with receiving more time and attention from medical experts, two significant correlations were found in total. The correlation was a weak positive ($rs = 0.158, p = 0.170, df = 75$) between receiving more time and attention from medical experts and potential risks and benefits. A weak positive correlation ($rs = 0.154, p = 0.182, df = 75$) was found between receiving more time and attention from medical experts and the length of research participation. Similarly, a weak positive correlation ($rs = 0.219, p = 0.056, df = 75$) was found between receiving more time and attention from medical experts and the types of medical procedures of the research. The correlation was a weak positive ($rs = 0.013, p = 0.914, df = 75$) between receiving more time and attention from medical experts and the purpose of the clinical research study. A weak positive correlation ($rs = 0.193, p = 0.096, df = 74$) was found between receiving more time and attention from medical experts and no risks are involved. The correlation between receiving more time and attention from medical experts and doctor’s recommendation
was a weak positive \( (rs = .013 \ p = 0.914, df = 75) \). A weak positive correlation \( (rs = .283 \ p = 0.013, df = 74) \) was found between receiving more time and attention from medical experts and free treatment. The correlation was a moderate positive \( (rs = .344 \ p = 0.002, df = 74) \) between receiving more time and attention from medical experts and the convenience of the participation.

In the correlations conducted with potential risks and benefits, seven significant correlations were found in total. A weak positive correlation \( (rs = .288, p = 0.011, df = 76) \) was found between potential risks and benefits and the length of research participation. The correlation was a moderate positive \( (rs = .408 p = 0.001, df = 76) \) between potential risks and benefits and the types of medical procedures of the research. A strong positive correlation \( (rs = .617, p = 0.001, df = 76) \) was found between potential risks and benefits and the purpose of the clinical research study. The correlation was a moderate positive \( (rs = .374 p = 0.001, df = 75) \) between potential risks and benefits and no risks are involved in the research. A weak positive correlation \( (rs = .267, p = 0.019, df = 75) \) was found between potential risks and benefits and doctor’s recommendation. Similarly, a weak positive correlation \( (rs = .245, p = 0.032, df = 75) \) was found between potential risks and benefits and free treatment. The correlation was a weak positive \( (rs = .255 p = 0.025, df = 75) \) between potential risks and benefits and the convenience of the participation.

In the correlations conducted with length of research participation, three significant correlations were found in total. A strong positive correlation \( (rs = .649, p = 0.001, df = 76) \) was found between the length of research participation and the types of medical procedures of the research. The correlation was a moderate positive \( (rs = .333, df = 76) \) between the length of research participation and the availability of medical experts.
$p = 0.003, df = 76$) between the length of research participation and the purpose of the clinical research study. A weak positive correlation ($rs = .094, p = 0.416, df = 75$) was found between the length of research participation and no risks are involved in the research. The correlation was a weak positive ($rs = .257, p = 0.024, df = 75$) between the length of research participation and doctor’s recommendation. Similarly, the correlation was a weak positive ($rs = .096, p = 0.406, df = 75$) between the length of research participation and free treatment. A weak positive correlation ($rs = .172, p = 0.135, df = 75$) was found between the length of research participation and the convenience of the participation.

In the correlations conducted with types of medical procedures of the research, two significant correlations were found in total. A moderate positive correlation ($rs = .324, p = 0.004, df = 76$) was found between the types of medical procedures of the research and the purpose of the clinical research study. The correlation was a weak positive ($rs = .196, p = 0.088, df = 75$) between the types of medical procedures of the research and no risks are involved in the research. Similarly, the correlation was a weak positive ($rs = .138, p = 0.231, df = 75$) between the types of medical procedures of the research and doctor’s recommendation. A weak positive correlation ($rs = .195, p = 0.008, df = 75$) was found between the types of medical procedures of the research and free treatment. The correlation between the types of medical procedures of the research and the convenience of the participation was a weak positive ($rs = .229, p = 0.045, df = 75$).

In the correlations conducted with the purpose of the clinical research study, four significant correlations were found in total. A moderate positive correlation ($rs = .334, p = 0.003, df = 75$) was found between the purpose of the clinical research study and no
risks are involved in the research. Similarly, a moderate positive correlation \((rs = .314, p = 0.005, df = 75)\) was found between the purpose of the clinical research study and doctor’s recommendation. Also, the correlation between the purpose of the clinical research study and free treatment was a moderate positive correlation \((rs = .320, p = 0.005, df = 75)\). The correlation was a weak positive \((rs = .264, p = 0.020, df = 75)\) between the purpose of the clinical research study and the convenience of the participation.

In the correlations conducted with no risks are involved in the research, three significant correlations were found in total. A weak positive correlation \((rs = .298, p = 0.008, df = 75)\) was found between no risk are involved in the research and doctor’s recommendation. The correlation was a weak positive \((rs = .290, p = 0.011, df = 75)\) between no risks are involved in the research and free treatment. However, a moderate positive correlation \((rs = .469, p = 0.001, df = 75)\) was found between no risks are involved in the research and the convenience of the participation.

The correlation was a moderate positive \((rs = .431, p = 0.001, df = 75)\) between doctor’s recommendation and free treatment. In addition, a moderate positive correlation \((rs = .300, p = 0.008, df = 75)\) was found between doctor’s recommendation and the convenience of the participation. However, the correlation was a moderate positive \((rs = .461, p = 0.001, df = 75)\) between free treatment and the convenience of the participation.
Chi-Square Goodness-of-Fit

The hypothesis of this study proposed that there is no statistical difference in the median rank score between CRA professionals and other post-graduate educated participants, and therefore an exact chi-square goodness-of-fit test was performed on the graduate sample of CRA to determine if this sample was representative of the post-graduates nationwide sample conducted by the CISCRP. There were significant differences in the distribution of responses to participants’ willingness to participate in clinical research $X^2(2) = 97.723, \ (p < .001)$. See Table 2 for a comparison of the clinical research administration (CRA) Program graduate sample and the post-graduate of the CISCRP sample data.

Table 2

A Comparison of the Two Groups Regarding the Willingness to Participate in Clinical Trials

<table>
<thead>
<tr>
<th>Willingness</th>
<th>CRA Graduates’ N</th>
<th>%</th>
<th>CISCRP Post-graduates’ N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>I am not sure</td>
<td>6</td>
<td>7.6</td>
<td>6</td>
<td>1</td>
</tr>
<tr>
<td>Not at all willing</td>
<td>5</td>
<td>6.4</td>
<td>3</td>
<td>0.5</td>
</tr>
<tr>
<td>Not very willing</td>
<td>4</td>
<td>5.1</td>
<td>11</td>
<td>1.9</td>
</tr>
<tr>
<td>Somewhat willing</td>
<td>40</td>
<td>51.2</td>
<td>229</td>
<td>40.8</td>
</tr>
<tr>
<td>Very willing</td>
<td>23</td>
<td>29.4</td>
<td>311</td>
<td>55.5</td>
</tr>
</tbody>
</table>

Of the 78 CRA graduates that participated in this survey, six individuals were not sure to participate, five individuals were not at all willing, four were not very willing, 40
individuals were somewhat willing, and 23 individuals were very willing. In contrast, of 560 post-graduates of the CISCRP sample, six individuals were not sure to participate, three individuals were not at all willing, 11 were not very willing, 229 individuals were somewhat willing, and 311 individuals were very willing. Accordingly, the CISCRP post-graduates were more willing than CRA graduates while CRA graduates are somewhat more willing to participate in clinical trials.

In order to identify the impact of professional knowledge and education on a willingness to participate in clinical trials, several variables or factors should be considered. First, a comparison was conducted between the CRA graduates sample and the CISCRP sample with regard to their perception of clinical trials safety. See Table 3. There were significant differences in the distribution of responses to participants’ perception of clinical trials safety. Over 95% of the responses of both groups were characterized clinical trials as safe. Therefore, the perception of the safety of clinical trials in CRA graduates and CISCRP post-graduates are the same.
Table 3

Perception of Safety in Clinical Trials Among CRA and CISCRP

<table>
<thead>
<tr>
<th></th>
<th>CRA graduates’ perception of safety of clinical trials</th>
<th>CISCRP post-graduates’ perception of safety of clinical trials</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Count</td>
<td>%</td>
</tr>
<tr>
<td>Not safe</td>
<td>4</td>
<td>5.0%</td>
</tr>
<tr>
<td>Safe</td>
<td>76</td>
<td>95%</td>
</tr>
<tr>
<td>Total</td>
<td>80</td>
<td>100.0%</td>
</tr>
</tbody>
</table>

Second, a comparison was conducted between CRA graduates and the post-graduates CISCRP sample on regard to the greater risk associated with the clinical trials. See Table 4. Almost similar percentage of considering the possibility of side effects as the greatest risk associated with clinical trial participation; CISCRP responses were 59% while CRA graduates were 56%. However, the lowest percentages were not the same among both groups; the lowest percentage was 1.3% in CRA sample, which no risks are involved, and the lowest risk was 1% in CISCRP sample who thought that there was a possibility of stopping treatments that proved some benefits.
Table 4

The Greater Risk Associated with Clinical Trials Among CRA and CISCRP

<table>
<thead>
<tr>
<th></th>
<th>CRA graduates’ perception of the greater risk</th>
<th>CISCRP post-graduates’ perception of the greater risk</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>%</td>
</tr>
<tr>
<td>Possibility of side effects</td>
<td>45</td>
<td>56.3%</td>
</tr>
<tr>
<td>Possibility of receiving a placebo or inactive drug</td>
<td>8</td>
<td>10.0%</td>
</tr>
<tr>
<td>Possible risks to my overall health</td>
<td>16</td>
<td>20.0%</td>
</tr>
<tr>
<td>Possibility of stopping treatments that may be providing some benefit to me already</td>
<td>4</td>
<td>5.0%</td>
</tr>
<tr>
<td>I do not believe there are risks</td>
<td>1</td>
<td>1.3%</td>
</tr>
</tbody>
</table>

Another chi-square test was performed between the two groups. One-sample chi-square test was conducted on a willingness to participate, with a significant result being found, $\chi^2(4) = 97.723, p < .001$. The two groups were statistically different, which is not appropriate to compare between aggregated results of the CISCRP and individual responses of CRA results. This indicated a significant difference between the observed and expected frequencies, which are summarized in Table 5. These results indicate a substantially greater likelihood of the CRA responding with I am not sure, Not at all willing, Not very willing, and Somewhat willing as compared with the expected
frequencies with a substantially lower likelihood of the CISCRP responding with Very willing as compared with what was expected if the groups were equal. Therefore, if the CRA followed the same distribution of the CISCRP, they should have the expected frequencies of the CISCRP.

Table 5

One-Sample Chi-Square Analysis: Willingness to Participate in A Clinical Trial

<table>
<thead>
<tr>
<th>Response Category</th>
<th>CRA</th>
<th>CISCRP</th>
<th>Residual</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>“Observed” N</td>
<td>“Expected” N</td>
<td></td>
</tr>
<tr>
<td>I am not sure</td>
<td>6</td>
<td>.8</td>
<td>5.2</td>
</tr>
<tr>
<td>Not at all willing</td>
<td>5</td>
<td>4.4</td>
<td>4.6</td>
</tr>
<tr>
<td>Not very willing</td>
<td>4</td>
<td>1.5</td>
<td>2.5</td>
</tr>
<tr>
<td>Somewhat willing</td>
<td>40</td>
<td>31.9</td>
<td>8.1</td>
</tr>
<tr>
<td>Very willing</td>
<td>23</td>
<td>43.3</td>
<td>-20.3</td>
</tr>
<tr>
<td>Total</td>
<td>78</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

An additional chi-square test was conducted on a willingness to participate of the sample of CRA to determine if this sample was previously participated in clinical trials. As presented in Table 6, out of 78 participants, one graduate participated though he was unsure of his willingness, and seven participants, who were somewhat willing, participated in clinical trials. However, ten graduates were very willing to participate in clinical trials, and13 participants already enrolled in clinical trials. Accordingly, 57
participants had not participated previously in clinical trials regardless of their willingness.

Table 6

Chi-Square Analysis: Willingness to Participate and Previous Participation

<table>
<thead>
<tr>
<th>Willingness to Participate in Clinical Research Study</th>
<th>No</th>
<th>%</th>
<th>Yes</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>I am not sure</td>
<td>5</td>
<td>83.3%</td>
<td>1</td>
<td>16.7%</td>
</tr>
<tr>
<td>Not at all willing</td>
<td>5</td>
<td>100%</td>
<td>0</td>
<td>0.0%</td>
</tr>
<tr>
<td>Not very willing</td>
<td>4</td>
<td>100%</td>
<td>0</td>
<td>0.0%</td>
</tr>
<tr>
<td>Somewhat willing</td>
<td>33</td>
<td>82.5%</td>
<td>7</td>
<td>17.5%</td>
</tr>
<tr>
<td>Very willing</td>
<td>10</td>
<td>43.5%</td>
<td>13</td>
<td>56.5%</td>
</tr>
<tr>
<td>Total</td>
<td>57</td>
<td>73.1%</td>
<td>21</td>
<td>26.9%</td>
</tr>
</tbody>
</table>

Odds Ratio

Table 7 presents the results of the cross tabulation conducted between CRA graduates and post-graduate CISCRP measures. Seventy-two participants in the study of CRA graduates responded to willingness question. However, the majority were willing to participate in clinical trials ($n = 63$). A similar trend was found of the 554 participants of the post-graduates CISCRP study. Among those with post-graduate CISCRP participants, the majority were willing to participate ($n = 540$). The odds ratio of post-graduate CISCRP respondents indicating willingness to participate in clinical research versus
respondents from CRA graduates is 5.510 CI [2.292, 13.246], which was calculated as \((540/14)/(63/9)\). See Table 8. Post-graduate CISCRP were 5.51 times more likely to state that they were willing to participate in clinical research than CRA graduates.

Table 7

Cross Tabulation Between Willing or Unwilling and Dataset

<table>
<thead>
<tr>
<th>Dataset</th>
<th>Groups</th>
<th>CRA Graduates</th>
<th>Post-Graduates</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Willing</td>
<td>63</td>
<td>540</td>
<td>603</td>
<td></td>
</tr>
<tr>
<td>Unwilling</td>
<td>9</td>
<td>14</td>
<td>23</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>72</td>
<td>554</td>
<td>626</td>
<td></td>
</tr>
</tbody>
</table>

Table 8

Risk Estimate

<table>
<thead>
<tr>
<th></th>
<th>Value</th>
<th>95% Confidence Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odds Ratio for Willing or Unwilling</td>
<td>5.510</td>
<td>2.292 [2.292, 13.246]</td>
</tr>
<tr>
<td>CRA graduates Dataset</td>
<td>3.745</td>
<td>2.138 [2.138, 6.562]</td>
</tr>
<tr>
<td>CISCRP Post-Graduates Dataset</td>
<td>.680</td>
<td>.489 [.489, .944]</td>
</tr>
<tr>
<td>N of Valid Cases</td>
<td>626</td>
<td></td>
</tr>
</tbody>
</table>
Themes

CRA graduate results showed a strong theme regarding a medical or scientific contribution. Out of 80 responses to the greatest benefit of participating in clinical trials, 49 responses were advancing the science, which was around 61.25%. See Figure 1. In addition, about 65.82% strongly agreed on the scientific contribution as a perception of how some people feel about clinical trials. See Figure 2.

Figure 1. Greatest Benefit of Participating in Clinical Trials.
Figure 2. CRA Professionals’ Perception on How Some People are Contributing to Science by Clinical Trials.
V. Discussion

Discussion

The exact chi-square goodness-of-fit rejected the null hypothesis of this study. The willingness to participate in clinical trials was compared between the clinical research administration (CRA) study sample and the post-graduate Center for Information and Study on Clinical Research Participation (CISCRP) sample. The CRA graduates, who were 67.47% of the study’s participants employed in clinical research, were somewhat more willing to participate in clinical trials than the sample of the post-graduate CISCRP. Although there was a significant difference between the two groups, it is difficult to state which group was more willing due to the residual value were missing between the CRA observed frequencies and the CISCRP expected frequencies. However, if we grouped the responses of those who were willing and somewhat willing, 80.7% of the CRA graduates were willing to participate in clinical trials, while the post-graduate CISCRP respondents were 93% more willing. Therefore, there is a difference between the two groups.

In addition, the odds ratio test demonstrated that CRA graduates were 7 times more likely to say that they were willing to participate in clinical trials, while CISCRP post-graduates were 38.57 times more likely to say that they were willing to participate in clinical trials. Accordingly, CISCRP post-graduates were 5.51 times more likely to state that they were willing to participate in clinical trials than CRA graduates. The odds ratio which is 5.51, supported the difference between the two groups as CRA graduates were less willing to participate in clinical trials.

However, the study sample of CRA graduates showed that the potential willingness to participate in clinical trials is highly associated with certain factors. These
factors consisted of the following: age, time allocated to the doctor’s office, free treatment and convenience of research participation, unavailability of other medical options, the treatment’s assisting other patients, and the reasonability of the time commitment. Interestingly, the influence of the time commitment and the convenience of the clinical research could be due to demand jobs; 67.47% of the study’s participants were employed in clinical research, which positively reflected on their behavior in and interpretations of clinical trials. In addition, the effect of personal advantages on participation in clinical trials was acceptable, as the study’s sample was more willing to participate if the treatment was free of charge. Moreover, there was a positive correlation between trusting physicians’ recommendations and the potential willingness to participate in clinical trials if there were scientific or social benefits without minimal side effects associated with the treatment, as well as sharing of a summary of research trial results with participants. Accordingly, there were as potential willingness to participate in clinical trials in CRA graduates regardless of their actual participation.

The results of the CRA graduates study acknowledged that the willingness to participate in clinical trials affected the behavior of participants. About 17.5% of those who were somewhat willing to participate and 56.5% who were very willing previously participated in clinical trials. Thus, participants who were involved in clinical trials were more willing to enroll in clinical studies. However, 73.1% of the total participants had not participated previously in clinical trials regardless of their willingness. This result indicated that their specialty and education affected their behavior of participation by being more skeptical and more aware of the effect of some variables such as time
commitment, side effects and adverse events. Therefore, potential participants with less serious health conditions tend to be highly skeptical of participating.

Being skeptical has not always had a negative impact. The CRA graduates' skepticism could be justified according to the importance of research objectives. In addition, sometimes there is a need to be skeptical of science especially in clinical research field due to the frequencies of errors or a large amount of expected and unexpected adverse events in clinical trials. Thus, having scientific doubts implies prioritizing evidence.

To support the skeptical of clinical research, a comparison of the CRA graduates and CISCRP post-graduates indicated that the professional knowledge and education had not impacted the overall perception of the safety profile of clinical trials. Both groups were aware of the careful conduction of clinical trials as they are the fastest and safest way to find treatments that work in people and to improve health. In addition, CRA graduates and post-graduates CISCRP had the same level of risk involvement in clinical trials. Both groups considered the possibility of side effects the greater risk. Due to their education level, they were knowledgeable of the medical consequences and unpleasant side effects that might occur during the participation in a clinical trial. Although both groups had post-graduate degrees, one of the CRA graduates and 18 of the CISCRP post-graduates selected no risks are involved in clinical trials. Yet, the safety of clinical trials and risks involvement in clinical trials are acknowledged.

In addition, CRA graduates’ results showed a strong theme, which is participation in clinical trials was considered a medical or scientific contribution. First, according to
CRA responses, the greatest benefit of participating in clinical trials is advancing the science. Second, CRA graduates’ perceptions of how some people feel about clinical trials strongly agreed that clinical trials considered a scientific contribution. This result interpreted the reason of that CRA graduates were less willing to participate in clinical trials as they were interested in the field as scientists more than clinical research participants.

Research Limitations

All participants were invited to complete a shortened version of the CISCRP published survey. Consequently, the language and items of the survey were not customized to the appropriate knowledge of CRA graduates to ensure the exposure to the same survey content of the two groups.

The research question could be answered, and the results could be accurately interpreted if we could extract the individual responses from the CISCRP survey. Due to the need of subgroup analysis of nationwide post-graduate in the CISCRP survey, it was difficult to apply a new research question to their data. Therefore, the aggregated responses were interpreted in a comparison of this research data.

This study has surveyed the alumni of the clinical research administration graduate program at Eastern Michigan University, these respondents might not reflect all clinical research professionals due to the low responses rate. Thus, the results could decrease the possibility of the generalizability of the findings. In addition, the comprehension of the nature of the clinical trials of this sample of the population may affect their perception of participation in clinical trials positively or negatively.
Suggestions for Further Research

More quantitative research on potential participants of those who are post-graduate or have a clinical specialty, such as clinical research professionals, should be conducted. Researchers should identify the barriers and motivations of professionals’ participation. In addition, quantitative research should be conducted to test the time commitment of clinical research professionals as a factor that influences their participation due to the high percentage of the CRA sample who had not previously participate in clinical trials.
VI. Conclusion

Overall, this study found that there is a significant difference between the clinical research administration program graduates and the post-graduate Center for Information and Study on Clinical Research Participation (CISCRP) in terms of their willingness to participate in clinical trials. The CRA professionals were less willing to participate in clinical trials than the post-graduate CISCRP. Although some factors must be considered when attempting actual participation, knowledge and professional background affected the willingness to participate in clinical trials. These results are justifiable, as the studied sample is more knowledgeable about clinical research and have more concerns about their participation. This conclusion must not affect the decision of recruiting clinical research professionals in clinical trials. Rather, this work is intended to indicate some of the differences between the two groups.
References


Appendix
Appendix A: IRB Exempt Approval

RESEARCH @ EMU

UHSRC Determination: EXEMPT

DATE: December 26, 2016

TO: Rania Felemban
Department of Health Sciences
Eastern Michigan University

Re: UHSRC: # [SSS910-1]
Category: Exempt category
Approval Date: December 26, 2016

Title: Are Clinical Research Professionals More Inclined to Participate in Clinical Trials?

Your research project, entitled Are Clinical Research Professionals More Inclined to Participate in Clinical Trials?, has been determined Exempt in accordance with federal regulation 45 CFR 46.102. UHSRC policy states that you, as the Principal Investigator, are responsible for protecting the rights and welfare of your research subjects and conducting your research as described in your protocol.

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

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

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

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

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

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

Sincerely,

Terry Mortier
Chair
College of Health and Human Services Human Subjects Review Committee
Appendix B: Informed Consent for Participation in Clinical Research

Dear Participant,

You are invited to participate in this research as one of the alumni of the Clinical Research Administration Graduate Program at Eastern Michigan University.

Research Objective: To identify your willingness to participate in clinical trials.

Voluntary Participation: You are completely free to choose whether to join the study or not. You have the right of withdrawal from the study at any time. However, we would appreciate your full participation.

Study Procedures: If you decide to participate in this study, you will fill out the survey about your willingness to participate in clinical trials. It should take about 7-12 minutes of your time.

Expected Risks: There are no anticipated risks to participation.

Expected Benefits: You will not directly benefit from participating in this study.

Revision and Approval: The University Human Subjects Review Committee (UHSRC) of Eastern Michigan University revised and approved this study.

Dissemination of Results: Results of this study may be presented publicly and/or published in a scientific journal. A copy of the study results will be sent to all alumni via E-mail.
Confidentiality: This is an anonymous survey. The researcher and statistician involved in this study will only have access to your responses. Otherwise, the information you provide will be compiled with other data and reported statistically.

Contact Information: This study is graduate research for a Masters’ degree. If you have any questions or concerns, you can contact the researcher, Rania Felemban, at rfelemba@emich.edu. You can also contact the advisor, Dr. Irwin Martin, at imartin2@emich.edu.

Statement of Consent: As a respondent, I understand my rights as a participant in the above-described study and voluntarily consent to participate and follow the requirements. Additionally, I understand the purpose, intent, and necessity of the study I will be participating in, and I understand that if I do not, I may ask questions.
Appendix C: Survey Form

1) Where do you currently reside?

☐ USA

☐ India

☐ Canada

☐ Europe

☐ Other (please specify) ……………….

2) Which race/ethnicity best describes you? (Please choose one only)

☐ Asian

☐ African

☐ Hispanic/Latino

☐ White/Caucasian

☐ Other (please specify) ……………….

3) What is your gender?

☐ Male

☐ Female

4) What is your age? (type age in box below)

………………………….
5) **How would you describe your employment status?**

☐ Employed full-time

☐ Employed part-time

☐ Unemployed/looking for work

☐ Student

☐ Homemaker

☐ Retired

☐ Other (please specify) ……………….

6) **Are you employed in clinical research now?**

☐ Yes

☐ No

7) **If no, what is your position?**

…………………

8) **What was your total household income before taxes during the past 12 months in US dollars?**

☐ Less than $25,000 USD

☐ $25,000 USD to $34,999 USD

☐ $35,000 USD to $49,999 USD

☐ $50,000 USD to $74,999 USD

☐ $75,000 USD to $99,999 USD
9) In your opinion, how safe are clinical research studies?

☐ Very safe
☐ Somewhat safe
☐ Not very safe
☐ Not at all safe

10) Which one of the following do you consider to be the greatest risk of participating in a clinical research study? (select one)

☐ Possibility of side effects
☐ Possibility of receiving a placebo or inactive drug (sugar pill)
☐ Possibility of making my private medical information public
☐ Possible risks to my overall health
☐ Possibility of stopping treatments that may be providing some benefit to me already
☐ None - I do not believe there are risks
☐ Other (please specify) ..................
11) Which one of the following do you consider to be the greatest benefit of participating in a clinical research study? (select one)

☐ May help advance science and the treatment of my disease/condition
☐ May help save or improve the lives of other patients with my disease/condition
☐ May help improve my disease/condition
☐ May provide monetary compensation (money) for participation
☐ May guide understanding of how available medications compare with a new treatment
☐ May provide free medication (if applicable in your country)
☐ May provide free medical procedures and care (if applicable in your country)
☐ May receive more care and attention from medical doctors and staff
☐ May help my family understand an inherited disease/condition
☐ None - I do not believe there are benefits
☐ Other (please specify) ……………….

12) Which TWO of the following reasons do you feel best describe why most people participate in clinical research studies? (select up to TWO)

☐ To help others who may suffer from my disease/condition
☐ To follow-through on a doctor's recommendation to participate in a research study
☐ To receive monetary compensation (money)
☐ To help scientists understand more about how to treat my disease/condition
☐ To receive free medication (if applicable in your country)
Clinical Research Professionals Participate in Clinical Trials

☐ To receive free medical procedures and care (if applicable in your country)

☐ To follow-through on a recommendation from my family or friends

☐ To find a cure or better treatment for my illness

☐ To help family members who may have this disease or condition in the future

☐ To receive more care and attention from medical doctors and staff

☐ Other (please specify) ……………….

13) The following statements describe how some people feel about clinical research studies. Please indicate how strongly you agree or disagree with these statements.

*People who participate in clinical research studies...*

<table>
<thead>
<tr>
<th>Statement</th>
<th>Strongly disagree</th>
<th>Somewhat disagree</th>
<th>Neutral</th>
<th>Somewhat Agree</th>
<th>Strongly agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>Have access to the best doctors</td>
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<td>Get the best possible treatment</td>
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<td>Are like experimental test subjects as opposed to a patient/person</td>
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<tr>
<td>Are making a contribution to science</td>
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<tr>
<td>Have a chance to receive free medicine and care</td>
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<tr>
<td>Strongly disagree</td>
<td>Somewhat disagree</td>
<td>Neutral</td>
<td>Somewhat agree</td>
<td>Strongly agree</td>
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<tr>
<td>Are taking a gamble with their health</td>
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<tr>
<td>Learn more about their condition and health</td>
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<td>Spend a lot of time at the doctor's office</td>
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<tr>
<td>Are part of an experiment to test medications/treatments already available to the public</td>
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<tr>
<td>Are part of an experiment to test medications/treatments not already available to the public</td>
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<tr>
<td>Receive more time and attention from medical experts</td>
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</tbody>
</table>

14) In general, how willing would you be to participate in a clinical research study?

☐ Very willing

☐ Somewhat willing

☐ Not very willing

☐ Not at all willing

☐ I am not sure
15) Before deciding to participate in a clinical research study, how important is knowing each of the following types of information to you?

<table>
<thead>
<tr>
<th>Information</th>
<th>Not at all important</th>
<th>Not very important</th>
<th>Somewhat important</th>
<th>Very important</th>
</tr>
</thead>
<tbody>
<tr>
<td>Potential risks and benefits</td>
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<tr>
<td>Physical location of the research center (distance from home or work)</td>
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<tr>
<td>Length of participation in the clinical research study (time commitment)</td>
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<tr>
<td>Number of study visits and types of medical procedures required</td>
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<tr>
<td>Purpose of the clinical research study</td>
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<tr>
<td>If I would have access to the study drug after my participation ended</td>
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<tr>
<td>If my confidentiality would be protected</td>
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<tr>
<td>If I would receive a summary of the study results after my participation ended</td>
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<tr>
<td>Potential costs and reimbursements</td>
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<tr>
<td>Hearing about the experiences of previous research participants</td>
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</tbody>
</table>
16) Have you ever tried to join (i.e., tried to participate in) a clinical research study?

☐ Yes

☐ No

17) Which of the following are reasons why you would not be willing to participate in clinical research studies? (select all that apply)

☐ I do not want to risk getting an inactive drug (also known as sugar pill or placebo)

☐ I don't want to be treated like an experimental test subject as opposed to a patient/person

☐ I am concerned about protecting my privacy

☐ I have concerns about the risks associated with clinical research studies

☐ Too much time is required to participate

☐ I am not interested in clinical research

☐ I do not know enough about clinical research

☐ It costs too much money to participate

☐ My health insurance does not cover the costs

☐ My family/caregiver did not want me to participate

☐ Online information convinced me not to participate

☐ I could not afford the time away from my job

☐ I have heard too many negative stories in the media and by word-of-mouth

☐ I do not think clinical research studies are ethical
☐ I do not want to take a chance with my health

☐ It is too difficult for me to get to the research center

☐ I do not have any reason to participate

☐ There are no reasons in particular

☐ Other (please specify) ……………….

18) Please rate each of the factors below on their likelihood of influencing your decision to participate in a clinical research study.

<table>
<thead>
<tr>
<th>Factor</th>
<th>Not at all likely</th>
<th>Not very likely</th>
<th>Neutral</th>
<th>Somewhat likely</th>
<th>Very likely</th>
</tr>
</thead>
<tbody>
<tr>
<td>If I had a terminal illness (incurable or fatal)</td>
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<tr>
<td>If I thought a study drug might cure me</td>
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<tr>
<td>If I knew that I would receive an active drug and not an inactive substance or sugar pill (placebo)</td>
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<td>If I received money for participating</td>
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<td>If I knew the risks associated with the treatment</td>
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<td>If I knew that it would not cost me anything to participate</td>
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<tr>
<td>If I knew there were no risks involved</td>
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<td><strong>If</strong></td>
<td><strong>Not at all likely</strong></td>
<td><strong>Not very likely</strong></td>
<td><strong>Neutral</strong></td>
<td><strong>Somewhat likely</strong></td>
<td><strong>Very likely</strong></td>
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<td>If my doctor recommended it</td>
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<td>If the treatment were free of charge to me</td>
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<td>If I thought the drug/treatment would help me</td>
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<td>If it were convenient for me to participate (e.g., convenient appointment times, the research center was not too far away)</td>
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<td>If I had a condition other than a terminal illness</td>
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<td>If there were no other medical options available to me</td>
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<td>If there were minimal side effects associated with the treatment</td>
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<td>If I thought the drug/treatment would help someone else in the future</td>
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<tr>
<td>If I already take a drug/treatment manufactured by the pharmaceutical company sponsoring the study</td>
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<tr>
<td>If I knew someone else with my condition was participating in the study</td>
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<td></td>
<td>Not at all likely</td>
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<td>If my family recommended it</td>
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<td>If it were recommended via an online social network or disease forum</td>
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<td>If the time commitment was reasonable</td>
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<tr>
<td>If I knew a summary of the research study results would be shared with me</td>
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</tbody>
</table>

19) Have you ever participated in (i.e., joined or enrolled) a clinical research study?

☐ Yes

☐ No
Good morning,

You have been identified as one of the alumni of the Clinical Research Administration Graduate Program at Eastern Michigan University. You are invited to participate in a study for a graduate research project. The purpose of this study is to assess your willingness to participate in clinical trials.

I would appreciate your willingness to participate in the study, and I value your feedback. This study consists of an on-line survey, and it should take about 7-12 minutes of your time. Your feedback is highly appreciated.

If you have any questions or concerns, you can contact the researcher, Rania Felemban, at rfelemba@emich.edu. You can also contact the advisor, Dr. Irwin Martin, at imartin2@emich.edu.

To begin, please click the survey URL below:

https://www.surveymonkey.com/r/Felemban
Thank you for taking the time to participate in the survey. We truly value the information you have provided. By participating in this survey, you contributed to enhancing subject enrollment in clinical trials and better understanding the barrier to recruiting human subjects into clinical research.

Regards,

Rania Felemban
A graduate student
Clinical Research Master’s Program
To: Clinical Research Administration Program Alumni

Subject: Clinical Research Survey

Date: Tue, Jan 17, 2017 at 10:40 AM

Good morning,

This is a friendly reminder to participate in a study for a graduate research project. If you are already participated, please disregard this E-mail.

You have been identified as one of the alumni of the Clinical Research Administration Graduate Program at Eastern Michigan University. You are invited to participate in a study for a graduate research project. The purpose of this study is to assess your willingness to participate in clinical trials.

I would appreciate your willingness to participate in the study, and I value your feedback. This study consists of an on-line survey, and it should take about 7-12 minutes of your time. Your feedback is highly appreciated.

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Rania Felemban
A graduate student
Clinical Research Master’s Program