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Factors influencing parental trust in medical researchers for child and adolescent patients' clinical trial participation

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Abstract

Parental trust in medical researchers is a commonly cited barrier to their child's participation in clinical research. Yet, there is little understanding of factors influencing parental trust to be implemented in interventions to address their concerns. This study seeks to identify psychosocial and modifying factors influencing parental trust in medical researchers to improve child and adolescent patients clinical trial participation, and potentially their health outcomes. We conducted a cross-sectional study with 307 parents. Multiple ordinary linear (OLS) regression was conducted to determine: (1) psychosocial and modifying factors associated with parental trust; and (2) perceived advantages and disadvantages associated with parental trust. Parent's race (White) ($\beta = .343, p < .001$), higher education level ($\beta = .409, p < .001$), higher perceived advantages of adolescent clinical trials ($\beta = .142, p < .001$), and lower perceived disadvantages of adolescent clinical trials ($\beta = -.337, p = .001$) were the most significant predictors of higher levels of parental trust in medical researchers. Parents who were African American and had lower education levels expressed lower levels of trust in medical researchers. Education on the benefits of clinical trials could reduce parents' apprehension towards their child's participation in clinical trials. Results support the

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Conflict of Interest

The authors declare that there is no conflict of interest.

Informed consent and patient details

"I confirm all patient/personal identifiers have been removed or disguised so the patient/person(s) described are not identifiable and cannot be identified through the details of the story."

Data Statement

The data is unavailable because it is confidential.

development of a clinical trial education program for parents to improve their trust in medical researchers.

Keywords

children and adolescents; clinical trials; parent trust; medical researchers; psychosocial; modifying factors

Introduction

Recruitment of children and adolescents is a relentless challenge for researchers seeking to include these populations in clinical trials (Caldwell, Murphy, Butow, & Craig, 2004; Johnson & Unguru, 2015). Low recruitment rates and lack of ethnic diversity in clinical trials contribute to insufficient or inadequate treatment options for underrepresented populations such as child and adolescent participant populations (Shaddy & Denne, 2010; Steinbeck, Baur, Cowell, & Pietrobelli, 2009). This delays improvements in prevention-related factors (i.e., vaccine use), and healthcare delivery (Steinbeck, Baur, Cowell, & Pietrobelli, 2009). Ultimately, this jeopardizes children and adolescents receipt of the best healthcare to promote positive clinical outcomes.

While children and adolescents can play a role in the decision to participate in clinical trials (Jonsen, 1978; Santelli et al., 2003), parents are the primary decision-makers (Jonsen, 1978; Stevens-Simon, 2006). This is due to legal, developmental, and ethical issues unique to this population (Bleyer et al., 1997; Freyer & Seibel, 2015; Kapogiannis & Mattison, 2008; Santelli et al., 2003; Stevens-Simon, 2006). Parents' knowledge, attitudes, and perceptions towards research are factors influencing their decision for their child's participation in clinical trials (Hoberman et al., 2013; Pasquali, Lam, Chiswell, Kemper, & Li, 2012; Rothmier, Lasley, & Shapiro, 2003; Tait, Voepel-Lewis, & Malviya, 2003; Woolfall et al., 2013). Additional factors include prior research experiences and external influences (e.g., adolescent health status, cultural beliefs) (Lynch, Hines, Theodore, & Mitchell, 2016). While these factors have been well-studied, less is known about the role of trust in medical researchers in a parent's decision to enroll their child in a clinical trial.

The relationship between medical researchers and participants is often predicated on trust. Trust in medical researchers is a key determinant in parental willingness to allow their child to participate in clinical trials (Hoberman et al., 2013; Shaw, Morrell, Corbie-Smith, & Goldsmith, 2009; Tait et al., 2003). Studies have demonstrated a relationship between trust and parents' race (Rajakumar, Thomas, Musa, Almario, & Garza, 2009; Shaw et al., 2009). Specifically, Rajakumar et al. (2009) found increased levels of distrust in medical research in minority parents when compared with Caucasian parents (Rajakumar et al., 2009). However, many studies neglect to identify the factors (i.e., psychosocial and modifying factors) influencing parental trust in medical researchers. Hence, to our knowledge, there are no strategies to improve and sustain parental trust in medical researchers, which promotes adequate representation of children and adolescents of diverse backgrounds in clinical trials.

The purpose of this study is to identify factors that influence parental trust in medical researchers who conduct clinical trials involving child and adolescent participants. Our research questions were: (1) What demographic (parental race and education level), psychosocial (knowledge, perceived advantages and disadvantages of clinical trials for children and adolescents), and modifying (clinical trial experience, type of information heard on clinical trials, level of ease in understanding clinical trial information) factors are associated with parental trust in medical researchers?; (2) Which specific perceived advantages and disadvantages are associated with parental trust in medical researchers? This study will contribute to the literature by describing intervention targets that may be used to strengthen parental trust in medical researchers who conduct clinical trials involving children and adolescents. Ultimately, improving parental trust may increase child and adolescent participation in clinical trials, which will result in improved prevention strategies and treatment, healthcare delivery (e.g., diagnosis), and clinical outcomes across adolescent populations.

Materials and Methods

Study Design

A total of 307 parents participated in this cross-sectional study. Parents completed the *HPV Clinical Trial Survey for Parents with Children Aged 9 to 15* (CTSP-HPV) (Cunningham, Wallston, Wilkins, Hull, & Miller, 2015). The community (e.g., parents, community advisory boards) was engaged in the research process. Parents informed survey content and recruitment methods via Community Engagement Studio (Joosten et al., 2015). The researcher attended community meetings prior to survey implementation to gain more insight on how to recruit participants and the types of messages to promote parental study participation. The study was approved by the Meharry Medical College Institutional Review Board. Participants provided informed consent after reviewing the study purpose and procedures.

Sample and Recruitment

Participants were recruited from community, clinical, and online sites in Middle Tennessee. Specific recruitment sites were schools, churches, community centers, sports events, and [ResearchMatch.org](https://www.researchmatch.org). A convenience sampling method was used to recruit participants. Recruitment strategies included phone, emails, and flyers. Inclusion criteria were: (1) Age 18 or older, (2) English-speaking, and (3) Legal guardian or primary caregiver for an adolescent child aged 9 to 15 who has the potential to be selected for a clinical trial. Individuals who did not meet the inclusion criteria were excluded.

Data Collection Procedures

After providing informed consent, participants completed an anonymous online or paper-based survey. The Health Belief Model guided the development of the survey, in which items and scales with acceptable psychometric properties (Cronbach's α 0.70) were selected from the literature. Participants received a \$10 gift card for their time. Study procedures lasted up to 30 minutes. A brief description of the survey measures used in this

study is provided below. A full description of the survey and the developmental process is described in detail elsewhere (Cunningham et al., 2015).

Measures

Parental trust in medical researchers.—This 12-item mean score was the outcome variable. Response options were based on a 5-point Likert scale assessing level of agreement. Two items were reverse-coded, and then the mean score was calculated to measure trust. Examples of scale items are, “Medical researchers care more about doing their research than about the child’s medical needs.” and “Researchers who make mistakes try to cover them up.” Cronbach’s $\alpha = 0.88$.

Socio-demographic measures.—Self-reported parental demographics are gender, age, education level, marital status, household income, and race. Gender was coded as male, female, and other/prefer not to say. Age was reported as <30, 30–39, 40–49, and 50+. Marital status was coded as married, divorced, separated, single/never married, widowed, and other. Education level was originally coded as some high school, GED or high school diploma, some college, college, and post-graduate. This variable was recoded into some high school/GED or high school diploma, some college, and college/post-graduate. Household income was coded as less than \$20,000, \$20,001–\$40,000, \$40,001–\$60,000, \$60,001 – \$80,000, and more than \$80,000. Parental race was originally coded as White, Black, Hispanic, Native Hawaiian/Other Pacific Islander, American Indian, Asian, and Prefer not to answer, and other. This variable was recoded into Black, White, and Other.

Level of Ease in Understanding Clinical Trial Information.—This single question asked, “Has the information you heard about clinical trials for your child been easy to understand? Response options were “not at all”, “a little”, “some”, “a great deal”, “completely”, and “I haven’t received anything”.

Type of Information Received.—This single question asked, “Has the information you heard about clinical trials for your child been?” Response options were “mostly positive”, “both positive and negative”, “mostly negative”, and “haven’t heard anything”. Responses were recoded as “mostly positive”, “both positive and negative/mostly negative”, and haven’t heard anything.

Clinical Trial Experience—This single question asked parents, “Have you, or anyone close to you, ever participated in a clinical research trial?” Response options were “yes,” “no,” and “I don’t know.” These were recoded to “yes” and “no/I don’t know”.

Disadvantages of children and adolescent clinical trial participation.—This 9-item scale uses a 5-point Likert scale based level of agreement. Sample items include, “My child will be treated like a guinea pig.” and “My child will have to miss school.” To measure disadvantages of child clinical trial participation, the mean score was calculated. Cronbach’s $\alpha = 0.87$.

Advantages of children and adolescent clinical trial participation.—This 8-item scale uses a 5-point Likert scale based on level of agreement. “My child will receive the

newest treatment.” and “My child will do something to help others.” are example questions in this scale. The average score was taken to measure advantages of child clinical trial participation. Cronbach’s $\alpha = 0.90$.

Knowledge of children and adolescent clinical trials.—This scale consisted of 7-items based on a 5-point Likert scale on agreement. Example items include, “I am made aware of any possible complications or side effects of my child taking part in a clinical trial.” and “I can change my mind at any time and withdraw my child from a clinical trial.” Three items were reverse-coded and the mean score was computed. Cronbach’s $\alpha = 0.83$.

Data Analysis

Prior to analysis, 51 cases were removed due to a large portion of missing data in multiple variables. The analytical sample consisted of 256 individuals. Pearson correlation determined which psychosocial and modifying factors were associated with parental trust in medical researchers for inclusion in the regression analysis. Multiple ordinary linear (OLS) regression determined which factors were associated with parental trust in medical researchers for children and adolescent participation in clinical trials. To better inform intervention development, a second correlation analysis determined which specific perceived advantages and disadvantages were associated with parental trust in medical researchers. The second multiple OLS regression determined which specific perceived advantages and disadvantages found significant in the second correlation analysis were associated with parental trust in medical researchers. Analyses were conducted using a 0.05 alpha level.

Results

Parent Characteristics

Table 1 shows the demographic characteristics for the 256 parents. The mean age of participants was 41.03 ($SD = 8.5$). Many of the participants were African-American (58.6%), married (49.6%), and female (79.2%). Many completed college or a post-graduate degree (44.1%) and had an income less than \$40,000 (48.6%).

Correlation Analysis of Psychosocial and Modifying factors

A Pearson correlation analysis assessed the association between parental trust in medical researchers for children and adolescent participation in clinical trials and the psychosocial and modifying factors. *Parental Trust in Medical Researchers* was positively associated with *Knowledge of Children and Adolescent Clinical Trials* ($r = .360, p < .001$), *Advantages of Children and Adolescent Clinical Trials* ($r = .282, p < .001$), and *Level of Ease in Understanding Clinical Trial Information* ($r = .322, p < .001$). There was an inverse association between *Parental Trust* and *Type of Information Received* ($r = -.310, n = 256, p < .001$), *Disadvantages of Children and Adolescent Clinical Trials* ($r = -.464, n = 256, p < .001$), and *Clinical Trial Experience* ($r = -.329, n = 256, p < .001$) (See Table 2).

Association of Sociodemographic, Psychosocial and Modifying factors with Parental Trust

Multiple ordinary linear regression analysis tested demographic, psychosocial, and modifying factors significantly associated with parental trust in medical researchers. The

regression model accounts for 53% of the variance. Results indicated *Parental Race*, *Parental Education Level*, *Perceived Advantages of Children and Adolescent Clinical Trials*, and *Perceived Disadvantages of Children and Adolescent Clinical Trials* were significantly associated with *Parental Trust in Medical Researchers*. Caucasian parents were more likely to have higher levels of trust in medical researchers compared with African American parents ($\beta = .343, p < .001$). Parents with some college or a college/post graduate degree were more likely to have higher levels of trust compared to those who had some high school/GED or high school diploma ($\beta = .409, .465, p < .001$ respectively). *Perceived Advantages of Children and Adolescent Clinical Trials* had a statistically significant positive regression weight ($\beta = .142, p = .019$), indicating on average for each one unit increase in perceived advantages (i.e., agreement with the advantages of clinical trial participation), trust increases by .142. *Perceived Disadvantages of Children and Adolescent Clinical Trials* had a significant negative weight, indicating on average for each one unit increase in perceived disadvantages (i.e., agreement with the disadvantages of clinical trial participation), trust decreases by .337 ($\beta = -.337, p < .001$). *Knowledge of Children and Adolescent Clinical Trials*, *Clinical Trial Experience*, *Level of Ease in Understanding Clinical Trial Information*, and *Type of Information Heard on Clinical Trials* were not significantly associated with *Parental Trust in Medical Researchers* while adjusting for the other variables in the model (See Table 3).

To determine which specific *Perceived Advantages* (benefits) and *Perceived Disadvantages* (barriers) of Children and Adolescent Clinical Trials contributed to the significance of these variables on *Parental Trust*, a second correlation analysis was conducted to determine which specific advantages and disadvantages were used in the regression model (See Table 4 for results). Then, a second OLS regression was conducted using the significant variables from the second correlation analysis, adjusting for socio-demographic factors. Results indicated the only significant *Perceived Advantage* was, “My child will do something to help others. On average for each one unit increase in parents’ agreement with this statement, their level of trust increases by .11 ($\beta = 0.11, p = .049$). For disadvantages, “My child will be treated like a guinea pig.” had a significant negative weight. On average for each one unit increase in parents’ agreement with this statement, their level of trust decreases by .12 ($\beta = -0.12, p = .013$). Additionally, “My child’s daily routine will be disrupted.” had a significant negative weight. On average for each one unit increase in parents’ agreement with this statement, their trust decreases by .17 ($\beta = -0.17, p = .002$) (See Table 5).

Discussion

Trust in medical researchers has a long-standing history of negatively influencing adult participation in clinical trials (George, Duran, & Norris, 2014; Scharff et al., 2010). Similarly, prior work demonstrates trust in medical researchers is a key component influencing parents’ decision to allow their children and adolescents to participate in clinical trials (Hoberman et al., 2013; Shaw et al., 2009; Tait et al., 2003). Parental mistrust in medical researchers could lead to low participation rates in clinical trials among children and adolescents (Scharff et al., 2010), curtailing advancements in efficacious prophylactic treatments and therapies specific to these populations (Hoberman et al., 2013; Shaw et al., 2009; Tait et al., 2003). Therefore, it is critical to improve parental trust in medical

researchers to influence participation rates in clinical trials, subsequently improving health outcomes for conditions prevalent in children and adolescents. Despite acknowledgements of the value of trust in medical researchers, no studies, to our knowledge, have provided insight on factors influencing parental trust in medical researchers. The study fills this gap by providing preliminary data for intervention targets to improve parental trust in medical researchers that could increase child and adolescent participation in clinical trials.

The present study identified four factors that influence parental trust in medical researchers, *Parental Race*, *Parental Education Level*, *Perceived Advantages of Adolescent Clinical Trials*, and *Perceived Disadvantages of Adolescent Clinical Trials*. Similar to past studies identifying issues surrounding research participation (Rajakumar et al., 2009; Shaw et al., 2009), parents' race was positively associated with Caucasians having higher levels of trust in medical researchers compared to African Americans. This is unsurprising as African Americans have historically had higher levels of mistrust in medical researchers compared to Caucasians (Scharff et al. 2010; George, Duran, & Norris, 2014). Therefore, these parents could potentially instill their perspectives and possible "myths" surrounding medical research for adults and children in their offspring, extending the cycle of mistrust in medical researchers into the next generation. *Parental Education Level* was also an important factor positively associated with parental trust in medical researchers. These findings suggest that parents who have some college experience or a college/post graduate level degree, may have more knowledge on the role of researchers in the research process, potentially improving their trust in research.

Not surprisingly, perceived advantages and disadvantages of adolescent clinical research were associated with parental trust. To better inform intervention development, we further explored the influence of specific perceived advantages and disadvantages on parental trust. We found that the most influential advantage was parents' belief that their child will do something to help others. This was unsurprising because altruism is a significant worldview that impacts research participation (Lang et al., 2013; Burchard, 2014). This indicates that to increase parental trust in medical researchers there may be a need to not only emphasize the benefits of clinical trial participation for their child, but also how their child's participation impacts other children and adolescents. In further exploring perceived disadvantages, parents' most influential disadvantage was that their child's daily routine would be disrupted. Parents need to feel that by participating in a clinical trial, their child's daily activities will not be negatively impacted. Another novel finding is the idea of their child being treated like a guinea pig. Parents need to feel reassured their child will not be treated as the subject of an experiment, but instead their child's participation will improve the health of adolescents in general.

Implications

This study contributes to the literature on the relationship between researchers and participants and beneficence in research by identifying the informational needs of parents, which if met, could increase trust in medical researchers. For parents who have mistrust in medical researchers, particularly African American parents, they should be provided the following information: (1) details on the medical researcher and their role in the research

process; (2) the benefits of their child participation in the clinical trial, (benefits to their child and other children); and (3) the risks of participation in medical research (including disruptions to their daily routine) and assurance that their child will not be treated as a guinea pig. Based on previous literature (Holzer, Ellis, & Merritt, 2014; Hurd et al. 2017; McDavitt et al., 2016), intervention strategies that could be used to provide this information include application of community engaged approaches, message tailoring, and use of testimonials. These communication strategies are key to building trust among underrepresented populations in research, and could assist in building trust between parents and researchers. Finally, since education level was significant, there is also a need to ensure this information meets the parents' literacy and health literacy levels. Thus, parents with a high school education or lower should be engaged to develop the content for materials used to meet these information needs.

Limitations and Strengths

Our study is not without limitations. Due to the small sample size, we may be limited in detecting factors (e.g., modifying factors) associated with parental trust in medical researchers that could be detected in a larger sample. These findings have limited generalizability outside of the study since data are based on a convenience sample across Tennessee. Last, we excluded individuals who did not speak English which restricted our study population. This study provides implications for future studies to improve parental trust in medical researchers, which could ultimately improve child and adolescent participation in clinical trials.

Conclusion

Our study found that *Parental Race*, *Parental Education Level*, *Perceived Advantages of Adolescent Clinical Trials*, and *Perceived Disadvantages of Adolescent Clinical Trials* were predictors of parental trust in medical researchers for child and adolescent participation in clinical trials. High priority must be placed on establishing trustworthy relationships among medical researchers and parents of adolescent children. Future studies should explore factors influencing child and adolescent trust in medical researchers since they have the opportunity to play a role in the decision-making. Studies should also explore physician's willingness and potential role to implement interventions to build trust between parents and medical researchers, particularly since they are a preferred information source for clinical trials (Greenberg et al., 2018).

Additional research should also determine if parents with higher levels of trust in medical researchers are more apt to allow their children to participate in clinical trials, and if this varies by race. Parents, children, adolescents, and other key stakeholders (e.g., physicians, child and adolescent medical researchers) should be engaged to develop interventions to address parental mistrust in medical researchers. Together, these steps may improve parent, child, and adolescent perceptions towards clinical research, ultimately improving the relationship between medical researchers and parents and improving clinical trial participation and health outcomes among children and adolescents.

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References

- Bleyer WA, Tejeda H, Murphy SB, Robison LL, Ross JA, Pollock BH, ... Ungerleider RS (1997). National cancer clinical trials: children have equal access; adolescents do not. *J Adolesc Health*, 21(6), 366–373. doi:10.1016/s1054-139x(97)00110-9 [PubMed: 9401854]
- Burchard EG (2014). Missing patients. *Nature*, 513(7518), 301–302. [PubMed: 25230631]
- Caldwell PH, Murphy SB, Butow PN, & Craig JC (2004). Clinical trials in children. *Lancet*, 364(9436), 803–811. doi:10.1016/s0140-6736(04)16942-0 [PubMed: 15337409]
- Cunningham J, Wallston KA, Wilkins CH, Hull PC, & Miller ST (2015). Development and Psychometric Evaluation of the HPV Clinical Trial Survey for Parents (CTSP-HPV) Using Traditional Survey Development Methods and Community Engagement Principles. *Clin Transl Sci*, 8(6), 702–709. doi:10.1111/cts.12347 [PubMed: 26530324]
- Freyer DR, & Seibel NL (2015). The Clinical Trials Gap for Adolescents and Young Adults with Cancer: Recent Progress and Conceptual Framework for Continued Research. *Curr Pediatr Rep*, 3(2), 137–145. [PubMed: 30613438]
- George S, Duran N, & Norris K (2014). A systematic review of barriers and facilitators to minority research participation among African Americans, Latinos, Asian Americans, and Pacific Islanders. *Am J Public Health*, 104, e16–31.
- Greenberg RG, Gamel B, Bloom D, Bradley J, Jafri HS, Hinton D, ... Benjamin DK Jr. (2018). Parents' perceived obstacles to pediatric clinical trial participation: Findings from the clinical transformation initiative. *Contemporary clinical trials communications*, 9, 33–39. [PubMed: 29696222]
- Hoberman A, Shaikh N, Bhatnagar S, Haralam MA, Kearney DH, Colborn DK, ... Chesney RW (2013). Factors that influence parental decisions to participate in clinical research: consenters vs nonconsenters. *JAMA Pediatr*, 167(6), 561–566. doi:10.1001/jamapediatrics.2013.1050 [PubMed: 23546617]
- Holzer JK, Ellis L, & Merritt MW (2014). Why we need community engagement in medical research. *J Investig Med*, 62(6), 851–855.
- Hurd TC, Kaplan CD, Cook ED, Chilton JA, Lytton JS, Hawk ET, Jones LA (2017). Building trust and diversity in patient-centered oncology trials: An integrated model. *Clin Trials*, 14(2), 170–179. [PubMed: 28166647]
- Johnson LM, & Unguru Y (2015). Recruiting Children for Clinical Trials: Lessons From Pediatric Oncology. *Am J Bioeth*, 15(11), 24–26. doi:10.1080/15265161.2015.1088980
- Jonsen AR (1978). Research involving children: Recommendations of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. *Pediatrics*, 62(2), 131–136. [PubMed: 693150]
- Joosten YA, Israel TL, Williams NA, Boone LR, Schlundt DG, Mouton CP, ... Wilkins CH (2015). Community Engagement Studios: A Structured Approach to Obtaining Meaningful Input From Stakeholders to Inform Research. *Acad Med*, 90(12), 1646–1650. doi:10.1097/acm.0000000000000794 [PubMed: 26107879]
- Lang R, Kelkar VA, Byrd JR, Edwards CL, Pericak-Vance M, & Byrd GS (2013). African American participation in health-related research studies: indicators for effective recruitment. *J Public Health Manag Pract*, 19(2), 110–118. [PubMed: 23358288]

- Steinbeck K, Baur L, Cowell C, & Pietrobelli A (2009). Clinical research in adolescents: challenges and opportunities using obesity as a model. *International Journal of Obesity*, 33, 2–7. [PubMed: 19065147]
- Kapogiannis BG, & Mattison DR (2008). Adolescents in clinical trials. *Clin Pharmacol Ther*, 84(6), 655–659. doi:10.1038/clpt.2008.191 [PubMed: 19008903]
- Lynch J, Hines J, Theodore S, & Mitchell M (2016). Lay Attitudes Toward Trust, Uncertainty, and the Return of Pediatric Research Results in Biobanking. *AJOB Empir Bioeth*, 7(3), 160–166. doi: 10.1080/23294515.2015.1053008 [PubMed: 28050575]
- McDavitt B, Bogart LM, Mutchler MG, Wagner GJ, Green HD Jr., Lawrence SJ, ... Nogg KA (2016). Dissemination as Dialogue: Building Trust and Sharing Research Findings through Community Engagement. *Prev Chronic Dis*, 13, 150473.
- Pasquali SK, Lam WK, Chiswell K, Kemper AR, & Li JS (2012). Status of the pediatric clinical trials enterprise: an analysis of the US [ClinicalTrials.gov](https://clinicaltrials.gov) registry. *Pediatrics*, 130(5), e1269–1277. doi: 10.1542/peds.2011-3565 [PubMed: 23027172]
- Rajakumar K, Thomas SB, Musa D, Almario D, & Garza MA (2009). Racial differences in parents' distrust of medicine and research. *Arch Pediatr Adolesc Med*, 163(2), 108–114. doi:10.1001/archpediatrics.2008.521 [PubMed: 19188641]
- Rothmier JD, Lasley MV, & Shapiro GG (2003). Factors influencing parental consent in pediatric clinical research. *Pediatrics*, 111(5 Pt 1), 1037–1041. [PubMed: 12728085]
- Santelli JS, Smith Rogers A., Rosenfeld WD, DuRant RH, Dubler N, Morreale M, ... Schissel A (2003). Guidelines for adolescent health research. A position paper of the Society for Adolescent Medicine. *J Adolesc Health*, 33(5), 396–409. [PubMed: 14596961]
- Scharff DP, Mathews KJ, Jackson P, Hoffsuemmer J, Martin E, & Edwards D (2010). More than Tuskegee: understanding mistrust about research participation. *J Health Care Poor Underserved*, 21(3), 879–897. doi:10.1353/hpu.0.0323 [PubMed: 20693733]
- Shaddy RE, & Denne SC (2010). Clinical report--guidelines for the ethical conduct of studies to evaluate drugs in pediatric populations. *Pediatrics*, 125(4), 850–860. doi:10.1542/peds.2010-0082 [PubMed: 20351010]
- Shaw MG, Morrell DS, Corbie-Smith GM, & Goldsmith LA (2009). Perceptions of pediatric clinical research among African American and Caucasian parents. *J Natl Med Assoc*, 101(9), 900–907. [PubMed: 19806847]
- Steinbeck K, Baur L, Cowell C, & Pietrobelli A (2009). Clinical research in adolescents: challenges and opportunities using obesity as a model. *Int J Obes (Lond)*, 33(1), 2–7. doi:10.1038/ijo.2008.263 [PubMed: 19065147]
- Stevens-Simon C (2006). Assent in pediatric research. *Pediatrics*, 118(4), 1800–1801; 10.1542/peds.2006-1577 [PubMed: 17015581]
- Tait AR, Voepel-Lewis T, & Malviya S (2003). Participation of children in clinical research: factors that influence a parent's decision to consent. *Anesthesiology*, 99(4), 819–825. [PubMed: 14508312]
- Woolfall K, Shilling V, Hickey H, Smyth RL, Sowden E, Williamson PR, & Young B (2013). Parents' agendas in paediatric clinical trial recruitment are different from researchers' and often remain unvoiced: a qualitative study. *PLoS One*, 8(7), e67352. doi:10.1371/journal.pone.0067352 [PubMed: 23844006]

Table 1:**Participant Characteristics**

	N	%
Gender		
Male	49	19.2
Female	202	79.2
Other/Prefer not to say	4	1.6
Age		
<30	22	8.8
30–39	95	37.8
40–49	88	35.1
50+	46	18.3
Education		
Some High School/ GED or High School diploma	62	24.2
Some College	81	31.6
College/Post-Graduate	113	44.1
Marital Status		
Married	126	49.6
Divorced	26	10.2
Separated	15	5.9
Single/Never Married	76	29.9
Widowed	8	3.1
Other	3	1.2
Household Income		
Less than \$20,000	63	25.1
\$20,001-\$40,000	59	23.5
\$40,001-\$60,000	37	14.7
\$60,000-\$80,000	32	12.7
More than \$80,000	60	23.9
Race		
African American	150	58.6
Caucasian	89	34.8
Other	17	6.6

Table 2:

Pearson Correlations of the Relationship in Parental Trust and Factors associated with Parental Trust in Medical Researchers Conducting Children and Adolescent Clinical Trials

Characteristic	Pearson Correlation	P-Value
Parents Education Level	.207	.001
Parents Race	.258	<.001
Type of Information Received	-.310	<.001
Knowledge of Children and Adolescent Clinical Trials	.360	<.001
Advantages of Children and Adolescent Clinical Trials	.282	<.001
Disadvantages of Children and Adolescent Clinical Trials	-.464	<.001
Level of Ease in Understanding Clinical Trial Information	.322	<.001
Clinical Trial Experience	-.329	<.001

Table 3.

Multiple Linear Regression of Associations with Parental Trust in Medical Researchers for Children and Adolescent Participation in Clinical Trials, R^2 (.49)

Variable	B	SE	P-value
<i>Socio-Demographics</i>			
Parental Race			
Other	-.057	.162	.723
Caucasian	.343	.089	<.001
African American	Ref		
Parent Education Level			
College/Post Graduate	.409	.111	<.001
Some College	.465	.109	<.001
Some High School/GED or high school diploma	Ref		
<i>Psychosocial Factors</i>			
Knowledge of Children and Adolescent Clinical Trials	.043	.068	.527
Perceived Advantages of Children and Adolescent Clinical Trials	.142	.060	.019
Perceived Disadvantages of Children and Adolescent Clinical Trials	-.337	.056	<.001
<i>Modifying Factors</i>			
Clinical Trial Experience	-.016	.092	.863
Level of Ease in Understanding Clinical Trial Information			
A great deal/ Completely	.048	.100	.632
None/A Little/ Some	-.149	.104	.153
Haven't heard anything	Ref		
Type of Information Heard about Clinical Trials			
Positive Information	.201	.132	.130
Negative information/positive and negative Information	-.034	.124	.784
Haven't heard anything	Ref		

Table 4:

Pearson Correlation Analysis of Advantages and Disadvantages with Parental Trust in Medical Researchers for Children and Adolescent Participation in Clinical Trials

Characteristic	Pearson Correlation	P-value
<i>Perceived Advantages</i>		
My child will receive the newest treatment.	.300	<.001
My child will do something to help others.	.353	<.001
My child will get free medications.	.130	.038
My child will help to prevent a disease.	.276	<.001
My child will do something positive for self.	.266	<.001
My child will get a cash stipend or gift card.	.091	.146
My child will get better care and follow-up.	.159	.011
<i>Perceived Disadvantages</i>		
My child will be treated like a guinea pig.	-.457	<.001
My child will have to miss school.	-.257	<.001
My child will lose his/her privacy.	-.394	<.001
My child will experience side effects of the treatment.	-.245	<.001
My child's daily routine will be disrupted.	-.401	<.001
I will have to find/pay for my child's transportation.	-.207	<.001
My child does not have health insurance or my child's health insurance will not cover his/her participation in a clinical research trial.	-.317	<.001
My child is too young to participate in a clinical research trial.	-.431	<.001

Table 5.

Linear Regression of Advantages/Disadvantages Associated with Parental Trust in Medical Researchers for Children and Adolescent Clinical Trial Participation

Predictor	β	SE	P-Value
Parent Race			
African American	ref		
Other	-.036	0.13	0.787
Caucasian	.462	0.08	<.001**
Parents Education Level			
Some High School/GED or high school diplomas	ref		
Some College	.269	0.09	0.003**
College/Post-Graduate	.293	0.08	0.001**
<i>Benefits</i>			
My child will receive the newest treatment.	0.08	0.05	0.106
My child will do something to help others.	0.11	0.05	0.049*
My child will get free medications.	-0.06	0.05	0.188
My child will help to prevent a disease.	0.05	0.06	0.362
My child will do something positive for self.	-0.02	0.06	0.362
My child will get better care and follow-up.	0.02	0.05	0.748
<i>Barriers</i>			
My child will be treated like a guinea pig.	-0.12	0.05	0.013*
My child will have to miss school.	0.00	0.43	0.956
My child will lose his/her privacy.	-0.03	0.05	0.495
My child will experience side effects of the treatment.	0.03	0.05	0.552
My child's daily routine will be disrupted.	-0.17	0.05	0.002**
I will have to find/pay for my child's transportation.	-0.02	0.04	0.655
My child does have health insurance or my child's health insurance will not cover his/her participation in a clinical research trial.	-0.04	0.04	0.248
My child is too young to participate in a clinical research trial.	-0.02	0.39	0.635