

The Ethics of Pediatric Clinical Trials

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Abstract

Children are a unique population with developmental and anatomical differences from adults, so they require age-specific medical treatments. In order to develop these specialized medical treatments, clinical trials must be conducted on pediatric patients. However, the participation of children in research and clinical trials presents ethical concerns. This study explores the ethical issues and concerns that arise from pediatric clinical trials through a qualitative phenomenological study based on interviews of medical professionals and physicians. Interviews of guardians of children who have participated in a pediatric clinical trial were conducted as well, with a primary focus on gathering their first hand accounts of pediatric clinical trials. Through a thematic analysis of the two groups of interviews, ethical issues, concerns, and challenges did arise. Limitations and implications from this study suggest future directions for other researchers. Future researchers should continue to look into this topic as healthcare is constantly evolving and changing.

Introduction

Children are a unique population with developmental and anatomical differences than adults. Children's bodies work in different ways than adults and undergo changes as they grow from adolescence to adulthood. The participation of children in research and clinical trials presents ethical considerations, and these issues are particularly important for society. According to the NIH National Institute on Aging, "Clinical trials are research studies performed in people that are aimed at evaluating a medical, surgical, or behavioral intervention." This type of research studies new treatments in order to evaluate its effects on human health. Challenges and ethical concerns in pediatric clinical trials and research include "balancing risk and benefit, informed consent and assent, and clinical equipoise" (Laventhal et al., 2012). One of society's most vulnerable groups are children. They are at risk in the context of clinical drug research since they are not seen as capable or competent of giving "informed consent," which is a requirement of the current clinical trial process. They are not seen to be mentally mature enough to fully comprehend the complicated problems at hand, such as the risks they

must "voluntarily" accept in order to profit from taking part in pediatric clinical studies. Researchers Wim Pinxten, Nys Herman, and Kris Dierickx claim that nonetheless, "these issues need to be addressed to facilitate the ethical conduct of pediatric research and the practical implementation of the ethical and legal frameworks governing pediatric clinical research" (2010). Respecting and prioritizing young participants at all times should be key across child research and healthcare settings. Evaluation of the importance it places on the vulnerable members of society needs to be taken into consideration in these processes.

Until after the 1980s, the use of children as subjects in clinical research was rare or nonexistent and unregulated. Generally, children with diseases that also affected adults were treated with a dose lower than adults, since children were considered 'small adults'. However there are diseases, such as genetic diseases, which are unique and fatal in childhood. Simply lowering the dose based on the size of the patient is not always equally effective. Sometimes, this can be toxic to a child's healthcare system as children do not process drugs the same way as an adult's system. Therefore, evaluation in effective treatments in children is important and critical.

As reported by the World Health Organization, "clinical trials in children are essential to develop age-specific, empirically-verified therapies and interventions to determine and improve the best medical treatment available". Since the 1960s, when children were designated as "therapeutic or pharmaceutical orphans," there has been a worldwide increase to conduct trials of children to improve their health. Advances in children's healthcare have resulted from the conduct of pediatric clinical trials. Advances in recent multicentre trials in children have "increased childhood cancer 5 year survival from 28% in the late 1960s to 79% by 2005" (Joseph et al., 2015). However, these results can not be generalized to other childhood conditions and diseases. Their disease presentation may differ from that of adults, and children also suffer from diseases that do not affect adults. Children have features that vary from adults and differ across the newborn to adolescent age range, possessing unique complex "physiological, developmental, psychological, and pharmacological characteristics" (Joseph et al., 2015) at each stage. Children metabolize certain medicines differently than adults. Therefore, the main goal of clinical trials involving children is to develop medicines that are safe and effective for them. However, many ethical issues and concerns arise regarding pediatric clinical trials.

Ariella Binik, of University of Oxford, questioned: "What justifies children's research participation and exposure to research risks when they cannot provide informed consent?" When children can not provide informed consent, their participation in the clinical trial may not be permissible. According to Klaus Rose, consultant in pediatric drug development, and his colleague Hans Kummer, clinician and academic

researcher, even though this causes concerns, “never in the history of mankind has child health seen a higher place in public attention and clinical health care than today in developed western countries.” With healthcare advancing everyday, research on how to improve treatments has been on the rise. However, many drug prescriptions for children have not even been tested in children (Meadows 1). It is imperative to have an adequate participant group who are similar to the groups taking the drug. This is significant, as “an adult clinical trial protocol cannot be adapted to children by simply replacing the word ‘patient’ with ‘child’ or ‘pediatric patient’” (Rose et al.). As can be seen, action needs to be taken to address these ethical issues.

Denis Gill, professor at a children’s hospital, and Ronald Kurz, professor in the Division of General Pediatrics at the University Hospital of Graz, discussed the ethical principles and controversy regarding pediatric clinical trials. They claimed that good clinical practice (GCP) maintains balance by ensuring that participants are protected in research trials and studies. If good clinical practice isn’t followed, patient safety and treatment effectiveness could be compromised. Additionally, the authors provided explanations for the effects if good clinical practice is not followed. Many children, even those not directly involved in the clinical trial, can be put at risk, as the data can be unreliable or unusable.

A qualitative study was conducted by Wannes Van Hoof (Ph.D. Philosophy) and his colleagues at the Ghent University Hospital and the hospital of the Dutch-speaking university of Brussels on the ethical considerations prioritized by researchers when leading pediatric clinical trials. The researchers believed obtaining consent from the guardians of the pediatric participant was very important. According to Wannes Van Hoof and his colleagues, “Taking enough time for consent, involving the child whenever possible and verifying sufficient comprehension were all deemed important.”

Pathma D. Joseph and her colleagues of The Children’s Hospital at Westmead in Sydney, Australia published an article about the process and ethics of pediatric clinical trials. The authors used data from previously conducted trials as evidence for why improved clinical trial practices are needed, especially to increase children’s knowledge of their participation. Additionally, the authors mentioned how children can be given “ineffective medicines or medicines with unknown harmful side effects” (Joseph et al., 2015). The authors claimed that there are still insufficiencies that need to be addressed to accelerate equitable access to children’s medical therapies. They concluded that care for the future health of children hinges on the success of pediatric trials.

Researchers also face the fact that clinical trial research can involve risks to participants. The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) notes that the benefit to the individual must be balanced with the benefit to the

group. Thorough clinical practice can help maintain that balance by “ensuring that subjects are properly protected in research studies; studies are based on good science, well designed and properly analyzed; and study procedures are properly undertaken and documented” (Gill et al., 2002). If GCP is not followed, the study can be rejected by an ethics committee.

Several interviews have been conducted to learn about children’s experiences in clinical trials, and these interviews found that many children did not understand the basic aspects of the research they were participating in. Naomi Laventhal and her colleagues of the Department of Pediatrics and Communicable Diseases at University of Michigan School of Medicine interviewed children who had previously participated in pediatric clinical trials, and results suggested that children do not feel they play a significant role in decision-making during these trials (Turbitt et al., 2021). A recent qualitative study explored views about the ethical concerns involved in pediatric clinical trials by interviewing affected families of pediatric patients, along with two individuals who directly participated in trials. This study approach was effective as it allowed for first-hand accounts and experiences of the pediatric patients. Naomi Laventhal and her colleagues at the University of Michigan School of Medicine specifically discussed pediatric and neonatal research to provide evidence for challenges in pediatric research ethics. Additionally, the authors provided explanations for the effects of balancing risks and benefits in pediatric clinical trials. The authors claimed the challenge for medical professionals and researchers is to minimize risk, find an acceptable risk benefit ratio, and gain parental permission and child assent in order to determine which trials are morally acceptable. Furthermore, the authors recommended that these applications require extreme details of the study and flexibility for the comfort and safety of the vulnerable patient population.

When conducting research involving children, it can be difficult to determine issues of consent, as in who can consent. This can cause researchers to avoid enrolling pediatric patients when guardianship is unclear. Consequently, pediatric patients may be unrepresented in pediatric clinical trials and research.

Moreover, it is of interest to understand and analyze the ethical concerns regarding pediatric clinical trials. There is currently a gap in research that examines and analyzes the widespread and addressed ethics of pediatric clinical trials and how that process affects the final decisions of the guardians consenting to the trial. The future health of children hinges on the success of pediatric trials. Therefore, the ethical issues that arise need to be considered and evaluated. Therefore, the question guiding the researcher’s work was: To what extent are pediatric clinical trials ethical?

Methodology

Study Design

This study explored the ethical issues and concerns that arise from pediatric clinical trials. The participation of children in research and clinical trials presents particular ethical considerations that need to be addressed in order to facilitate safe and effective pediatric clinical trials. By addressing these issues, the implementation of the ethical frameworks will be taken into consideration and improved for the pediatric patient.

A qualitative phenomenological study was conducted, consisting of qualitative data collected through interviews. This approach sought to comprehend the viewpoints and perceptions of social reality held by participants. A qualitative method served this study well as the approach allowed for the reflection of the data being collected. A phenomenological approach also served this study well as it explored multiple perspectives on the ethics of pediatric clinical trials. Analyses of current pediatric clinical trial guidelines and ethics of clinical trials performed on children were performed by conducting interviews of medical professionals and physicians as well as guardians of children who have participated in a pediatric clinical trial. Stacey Crane of Cizik School of Nursing of the University of Texas Health Science Center and her colleagues conducted a qualitative, empirical phenomenology study consisting of 11 parents' experiences with their child participating in a cancer clinical trial. A phenomenological approach was effective for this study as it allowed for an "Understanding [of] the experiences of children and their families in these clinical trials [ensuring] that participation supports the children's and parents' well-being" (Crane et al., 2021). Overall, parents had positive responses and experiences about their child's participation in a pediatric clinical trial. However, there were five aspects that were challenging to parents: "learning about clinical trials, being referred to another institution, research-only procedures, adhering to trial requirements, and oral medications" (Crane et al., 2021). Through a phenomenological approach, Crane and her colleagues were able to identify and analyze the challenges and issues faced by guardians of pediatric patients.

Participants

The study consisted of medical professionals and physicians and families who have personal experiences with pediatric clinical trials. There were no restrictions on age and gender. The process required experts in pediatric medical and research knowledge. It also required the first-hand accounts of families who went through a pediatric trial. These participants aided in gathering information by answering composed interview questions. For the medical professionals and physicians, the set of questions primarily focused on the ethical concerns and the process of pediatric clinical trials. For the guardians, the set of questions

primarily focused on their first hand accounts of pediatric clinical trials.

Procedure

Before data collection, informed consent forms were obtained (see Appendix A, B, and D). Participants involved in interviews were recruited through the researchers' expert advisor or found through children's medical research institutes. These participants were contacted through emails and through medical professionals. After the participants completed and returned consent forms, an open-ended question interview took place. The interviews provided the researcher with findings and conclusions that led to data collection. The researcher set up a date/time to conduct said interviews. Participants went through required consent and then proceeded to the meeting date. At the interview, a recording software was used in order to easily document what was asked and answered by the participant.

All participants began by filling out a consent form. They were informed that participants' interview responses would be kept confidential, and individually identifiable data would not be shared with anyone aside from the researcher. Their responses were recorded and presented with pseudonyms in the researcher's paper. After confirming their participation, they took part in an open-ended question interview that consisted of questions relating to their experiences and knowledge regarding pediatric clinical trials and its ethics. These interviews and first-hand accounts allowed the researcher to go beyond just surface-level knowledge of pediatric clinical trials and dig deeper into the topic.

Participants with pediatric medical knowledge were asked questions about the process of pediatric clinical trials and common ethical issues and concerns that arise with it. Participants with guardian relationships to the participants under the age of 18 were asked questions about their first-hand accounts with the process of pediatric clinical trials.

1. What is your occupation?
2. How long have you been practicing?
3. What is your speciality?
4. What is your experience with pediatrics?
5. What Is a Clinical Study?
6. Who Conducts Clinical Studies?
7. How Long Do Clinical Studies Last?
8. Where Are Clinical Studies Conducted?
9. Who Can Participate in a Clinical Study?
10. How Are Participants Protected?
11. What tests and procedures are involved?
12. What are common ethical concerns regarding pediatric clinical trials?

TABLE 1. Interview Questions for Medical Professionals and Physicians

1. Have you participated in a pediatric clinical trial?
2. What is your experience regarding pediatric clinical trials?
3. What is your medical background?
4. What was being studied?
5. What tests and procedures were involved?
6. How did the possible risks, side effects, and benefits of the trial compare to your current treatment?
7. How long did the study last?
8. What type of long-term follow-up care was part of the trial?
9. What were your ethical concerns regarding the clinical trial?

TABLE 2. Interview Questions for Parents and Children Involved in Pediatric Clinical Trials

Consent Procedure

Participants that were medical professionals were sent a Medical Professional and Physician Consent Form (see Appendix A) in order for them to participate in interviews. A Parent Consent Form (see Appendix B) was sent to the guardians of pediatric patients in order for the guardians to participate in interviews and share their first hand accounts in dealing with pediatric clinical trials. Interview participants were asked to answer as honestly as possible while answering open-ended questions. At the interview, a recording software was used in order to easily document what was asked and answered by the participant. Therefore, all of the participants were also sent a Recording Consent Form (Appendix D), granting permission to the researcher to record the answers of the participants. When the participant consented to both items, the researcher scheduled an interview date with the participant, and the participant and the researcher met via Zoom. During the interview process, the researchers asked a series of open-ended questions, and participants then proceeded to answer the questions with their knowledge and experience with pediatric clinical trials. They were informed that participants' interview responses would be kept confidential, and individually identifiable data would not be shared with anyone aside from the researcher.

Qualitative Interviews

The interviews (see Appendix E for questions) were conducted over Zoom meetings. The interviews were transcribed and then coded in an open-coding format for each emerging theme. Qualitative coding of interview transcripts was conducted using Transcribe (2017) iterative coding process. After multiple iterations of open-coding, 5 final themes about ethical issues in pediatric clinical trials emerged: 1) consent; 2) assent; 3) safety of pediatric participants 4) only treatment option and; 5) focus on guardians' struggles.

Findings

Before moving on to discuss the importance of coding the data into such a table, the meaning of each theme needs to be clarified. From all nine interviews, a total of five themes emerged. These themes and their definitions have been coded into the table below. Themes were assigned off of verbatim reference in the interviews, which were analyzed by the researcher. After analyzing the interviews, the researcher was then able to make descriptions of recurring themes.

Theme	Definitions	Number of interviews with this theme
Consent	Involves providing adequate information to allow for informed decisions about participation in the clinical trial	6
Assent	Involves informing the pediatric patient of the clinical trial	3
Safety of Pediatric Participant	Health care discipline aimed to prevent and reduce risks, errors and harm that may occur to patients	5

TABLE 3. Definitions of Themes Occurring from Medical Professional Interviews

Theme	Definitions	Number of interviews with this theme
Only Treatment Option	Clinical trial was only option due to severity of the pediatric patient's condition	3
Focus on Guardian Struggles	Lack of knowledge of day to day life occurring due to pediatric clinical trials	2
Safety of Pediatric Participant	Health care discipline aimed to prevent and reduce risks, errors and harm that may occur to patients	2

TABLE 4. Definitions of Themes Occurring from Pediatric Patient Guardian Interviews

As stated before, 6 medical professionals and 3 pediatric patient guardians were interviewed on their knowledge and experience regarding pediatric clinical trials. Their names and the organizations they represent have not been included in this study.

Quotes from Medical Professionals Interviews
<p>“Well... the biggest ethical issue is pediatrics... can't legally give consent, because in order to give consent, you have to either be emancipated or 18 and above. So is it ethical to do a study on a child that they can't consent for?”</p>
<p>“the biggest concern is safety. So if my child participates in this clinical trial, will they be safe? Is the drug or device that we're go going to use on them, is it safe? ...and I think that's the most common concern families have.”</p>
<p>“The children can provide assent. And so assent is mandated for clinical trials depending upon the age of the individual, the state at which the clinical trial is being done in the country.”</p>
<p>“There's a much stronger safeguard regarding any risk harm the children given that they're not able to consent in their own right in many cases. There is also the concern of the child's own ability to understand the context of the study, which puts a significant burden on, on parents or, or guardians to ensure that they're fully understanding and that they can hopefully help the child also understand.”</p>
Quotes from Guardians Interviews
<p>“We were wildly fortunate of having the convenience to home and an opportunity to participate for a rare disease. We had a very positive experience and just felt very fortunate. I mean, it was stressful, and the diagnostic journey was very stressful. The first month of the clinical trial was, was pretty stressful. As well as like trying to see if he qualified for it.”</p>
<p>“There's no, there was no other treatment. So there's no other option. And I mean, shortly thereafter, the clinical trial actually ended from a funding purpose. So, even after the clinical trial closed because of funding, all kids diagnosed ... would've no option. There's nothing out there. So it was really our, it was really our only opportunity to help stabilize.”</p>

“There's always concern when you're dealing with the brain and... something could go wrong, but I knew that in my heart and in my gut, this was the right thing to do.”

Results

The narratives collected through interviews outlined the ethical concerns regarding pediatric clinical trials. The knowledge and experiences regarding pediatric clinical trials were categorized by theme, then examined through a thematic analysis. Through thematic analysis, the research examined the data presented in the transcriptions by analyzing the data qualitatively. The research examined the data to identify common themes: topics, ideas, or patterns of meaning that came up repeatedly. The corresponding themes, for reference, can be found on Table 1 and Table 2. Table 1 presents the definitions of themes occurring from medical professional interviews. Table 2 presents the definitions of themes occurring from pediatric patient guardians interviews. Firstly, it is important to see which themes are repeated amongst all nine interviews. By identifying recurring themes, it was possible to observe the common ethical concerns and issues regarding pediatric trials and how that affects the guardians final decision to admit their child into the clinical trial. There were three recurring themes appearing in the medical professionals narratives, and four recurring themes appearing in the pediatric patient guardian interviews. These recurring themes, therefore, shed light on the most common ethical issues in pediatric clinical trials, and how these issues influence a guardians final decision to admit their child into a pediatric clinical trial.

Recurring Theme 1: Consent

Out of all five of the themes, the one which was most prevalent in each of the nine interviews was consent. All six medical professional interviews explained the issue and concern of guardians giving consent for the pediatric patient to participate in a clinical trial, falling under this theme as being a significant ethical concern. As defined by Table 1 and Table 2, consent involves providing adequate information to allow for informed decisions about participation in the clinical trial. Children are not able to give true consent until they turn 18, legally. All medical professional participants mentioned and explained how the most common ethical concern and issue regarding pediatric clinical trials was consent. Individual 5 (medical professional) questioned whether the parent or the guardian has the child's best interest at heart. Children cannot consent to participate in the clinical trials for themselves, therefore a guardian as to do it. The issue with pediatrics is that it is a vulnerable population. Individual 1 (medical professional) raised the question if it is ethical to do a trial or study on a child that can't consent. Therefore, you have to be

extremely cautious with pediatric studies. In certain situations, the permission of the child is required, as the child is explained the trial and the process; however, the consent must be given by the parent or guardian. Parents are reluctant to enroll their children when there are no guaranteed immediate benefits. Adults must provide "informed consent" before being accepted into a typical clinical trial. In the case of children, the legal guardian(s) obtains the "informed consent" factor, and the children give their assent to take part in the clinical investigation.

Recurring Theme 2: Assent

The theme of assent came up frequently among medical professional interview participants. As defined by Table 1 and Table 2, assent involves informing the pediatric patient of the clinical trial. When a child is under the age of 18, a parent or legal guardian signs for them. Four out of the six medical professionals explained how the child can provide assent depending upon local regulations. Individual 5 (medical professional) explained how children are provided the opportunity to understand what they are participating in. Therefore, assent is obtained, if the pediatric patient is of appropriate age. Individual 3 (medical professional) elaborated on the issue regarding assent, and the pediatric patient's ability to understand the context of the study. They explained how this puts a significant burden on parents and guardians to ensure that they fully understand, and can hopefully help the child also understand. Individual 4 (medical professional) believed the biggest ethical concern is the child's ability to understand the context of the study, and to be in a position to assent to their own participation. Children might be able to give their assent, as they are unable to provide true informed consent. Since children can lack the ability to understand the risks involved, they depend upon the adults in their lives to make decisions. Many parents and guardians are hesitant to give assent as they are uncomfortable making a decision for their child. Families of the child worry about dignity, privacy, and confidentiality. Informed consent and assent is an ethical issue that arises, and with that guardianship issues can become legally complex.

Recurring Theme 3: Safety of Pediatric Participant

The theme of the safety of the pediatric participants came up frequently among medical professional interview participants. As defined in Table 1 and Table 2, safety of pediatric participants refers to health care discipline aimed to prevent and reduce risks, errors and harm that may occur to patients. Three out of the six medical professionals explained how another common concern is the safety of the pediatric patient. Individual 4 (medical professional) mentioned how study subjects have been exploited or misused before in clinical trials. Safety of the pediatric patients plays a big role in the admission of that patient due to the risks involved. Individual 6 (medical professional) raised the question if the drug or

device being used on the pediatric patient is safe. Due to these clinical trials having a vulnerable population, the safety of the trial comes into play. The medical health of a pediatric patient can be more fragile, and therefore the clinical trial can be riskier to perform on the patient. The theme of the safety of the pediatric patient surfaced in both categories of interviews. However, in the guardian interviews, the pediatric patients' concern of safety was more personal. While the medical professionals did show concern for the safety of the patient, the patient was seen more as a subject, while the guardians were more concerned for the safety of their child.

Recurring Theme 4: Only Treatment Option

The theme of it being the only treatment option came up during all three pediatric patient guardian interviews. As defined in Table 2, only treatment option refers to how a clinical trial was the only option due to severity of the pediatric patient's condition. Individual 7 (guardian of a pediatric patient) explained how there was no cure for the condition of their child, therefore this was the only and best treatment option for their child. Individual 8 (guardian of a pediatric patient) explained how there was no treatment for their child's condition. Individual 9 (guardian of a pediatric patient) explained how there was no other treatment and no other option for their child and their child's condition. Due to the severity of the pediatric patients conditions, a pediatric clinical trial is their option of treatment. It is essential to develop age-specific medical treatments. Medical professionals may not know the best treatments, therefore researchers have to conduct and test new treatments.

Recurring Theme 5: Focus on Guardian Struggles

The theme of it being a struggle for the guardian of the pediatric patient came up in two of three of the pediatric patient guardian interviews. As defined in Table 2, the focus on guardian struggles refers to the lack of knowledge of day to day life occurring due to pediatric clinical trials. Individual 7 (guardian of a pediatric patient) explained how there was a lack of knowledge of day to day life possessed by the trial coordinators and doctors. Some of the requests, expectations, and logistics of the trial were unrealistic for patients. Individual 8 (guardian of a pediatric patient) explained how a struggle for them was having to go back and forth to the site of the clinical trial for five years. They explained how recently it's been harder due to the Coronavirus, and have had to do a lot of virtual meetings.

Discussion

The purpose of this study was to explore common ethical issues and concerns regarding pediatric clinical trials, and how these issues and concerns impact a guardians final decision to admit their child into the

pediatric clinical trial. Prior to analysis, it was expected that ethical concerns would arise due to the association of pediatric patients in healthcare. This investigation's findings, for the most part, correlate those of earlier publications. For one, many concerns *did* arise when admitting a child (pediatric patient) into an invasive source of treatment to treat their rare conditions and/or diseases. However, no conclusion can be confirmed as to what causes ALL guardians to admit their child into a pediatric clinical trial.

Implications

Regardless of limitations, this study still makes *several* contributions to the discussion of the future of pediatric health care. Foremost, the findings analyzed were from different medical positions and roles in pediatric healthcare, as well as the guardians of the pediatric patients. Additionally, when considered with those of previous publications, this study's conclusions imply steps and action needs to be taken to improve healthcare for pediatric patients. The findings analyzed correlate with the need to develop age-specific, empirically-verified medical treatments. As clinical trials contribute to medical research, clinical trials offer more care options for rare health conditions.

Future Studies

There are a *few* directions for future research emerging from this study. A qualitative analysis of the mental and physical health of previous pediatric patients, years after their participation and treatment in a pediatric clinical trial is highly necessary. For the protection of the rights and safety of the participants of clinical trials monitoring is extremely critical. This will build the foundation for future collection and high-quality data allowing new treatments to be based. This will further the improvements and advancements of pediatric healthcare and medicine. Additionally, variables such as interviewing pediatric patients (those who have participated in a pediatric clinical trial) would be incorporated. Pediatric patients are, of course, not the only patients in healthcare. However, this is a need to advance and better pediatric healthcare. Children need additional monitoring and mediations with caregivers with special needs, as their healthcare needs are regularly changing.

Limitations

There were limitations to this study that required recognition. For one, the number of guardian participants interviewed was relatively small. Small sample sizes can skew data by making limited occurrences seem more common than they actually are. The 3 guardian participants reported their concerns with admitting their child into a pediatric clinical trial. All the responses were similar to each other, and correlated with one another. As a

result, this may have prevented the findings from being extrapolated. All guardian participants gained concerns due to the severity of their child's condition. This could indicate higher levels of concerns and worries.

Another limitation is that pediatric patients were not interviewed. The researcher was not able to interview the children of the guardians interviewed, due to the severity of the child's condition. The researcher had reached out to pediatric patient organizations, but did not receive many responses. The three family responses the researcher did receive were interviewed. Due to the lack of pediatric patient interviews, their personal experiences and concerns were not found and analyzed. Since pediatric patients were not interviewed, the Parental Consent Form (see Appendix C) was not used by the researcher. The Parental Consent Form asked for a pediatric patient's first-hand accounts and experiences regarding pediatric clinical trials.

Conclusion

To conclude: providing guidance is extremely necessary through a child's development (personally and medically). This is because children are a vulnerable population. Clinical trials are to better not only a patient's condition, but to advanced healthcare. However, the patient's rights need to always be taken into consideration. Therefore, healthcare workers and researchers must continue to evaluate the correlation between clinical trial practices (tests and procedures) and the rights and needs of the pediatric patient.

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Appendix A

Consent Form

Note: This form was used for all participants.

Title of the Study: The Ethics of Pediatric Clinical Trials

Researcher Name(s): [REDACTED]

The general purpose of this research is to examine and analyze the ethical issues and concerns that arise from pediatric clinical trials. Participants in this study will be asked to share their experience and knowledge regarding pediatric clinical trials. Data from this study will be used in a student thesis that presents the findings of the research, as well as an oral defense presentation to the instructor of Advanced Placement Capstone Research, as well as a board that is created in response to the content of the study. Findings of the research have the potential to be published in a scholarly journal.

I hereby give my consent to participate in this research study. I acknowledge that the researcher has provided me with:

- A. An explanation of the study's general purpose and procedure.
- B. Answers to any questions I have asked about the study procedure.

I understand that:

- A. My participation in this study will take approximately 15 - 60 minutes.
- B. The probability and magnitude of harm/discomfort anticipated as a result of participating in this study are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
- C. The potential benefits of this study include educational benefits as participation in the study could potentially lead to a new outlook on the ethics of pediatric clinical trials.
- D. I will not be compensated for participating in this study.
- E. My participation is voluntary, and I may withdraw my

consent and discontinue participation in the study at any time. My refusal to participate will not result in any penalty or disadvantage.

F. My responses will be confidential. My responses will be recorded with pseudonyms. The data will be stored in a secure location on a password protected computer in the researcher's personal room located in the researcher's residence, will be available to the researcher will have access to the data, and research reports will only present findings on a group basis, without any personally identifying information.

Name (printed): _____

Signature: _____

Date: _____

Appendix B

Consent Form

This form was used for all participants.

Title of the Study: The Ethics of Pediatric Clinical Trials

Researcher Name(s): _____

The general purpose of this research is to examine and analyze the ethical issues and concerns that arise from pediatric clinical trials. Participants in this study will be asked to share their experience and knowledge regarding pediatric clinical trials. Data from this study will be used in a student thesis that presents the findings of the research, as well as an oral defense presentation to the instructor of Advanced Placement Capstone Research, as well as a board that is created in response to the content of the study. Findings of the research have the potential to be published in a scholarly journal.

I hereby give my consent to participate in this research study. I acknowledge that the researcher has provided me with:

A. An explanation of the study's general purpose and procedure.

B. Answers to any questions I have asked about the study procedure.

I understand that:

A. My participation in this study will take approximately 15 - 60 minutes.

B. Participating in this research may result in emotional distress, psychological stress, or in feeling overwhelmed due to stress that may be caused by the worry of participants' confidentiality and protection.

C. The potential benefits of this study include educational benefits as participation in the study could potentially lead to a new outlook on the ethics of pediatric clinical trials.

D. I will not be compensated for participating in this study.

E. My participation is voluntary, and I may withdraw my consent and discontinue participation in study at any time. My refusal to participate will not result in any penalty or disadvantage.

F. My responses in this study will be kept confidential, to the extent permitted by law. The data will be stored in a secure location on a password protected computer in the researcher's personal room located in the researcher's residence, will be available to the researcher and will have access to the data, and research reports will only present findings on a group basis, without any personally identifying information.

Name (printed): _____

Signature: _____

Date: _____

Appendix C

Parental Consent Form

Title of the Study: The Ethics of Pediatric Clinical Trials

Researcher Name(s): [REDACTED]

The purpose of this research is to examine and analyze the ethical issues and concerns that arise from pediatric clinical trials. Participants in this study will be asked to share their experience and knowledge regarding pediatric clinical trials. Data from this study will be used in a student thesis that presents the findings of the research, as well as an oral defense presentation to the instructor of Advanced Placement Capstone Research, as well as a board that is created in response to the content of the study. Findings of the research have the potential to be published in a scholarly journal. The project/story explores the ethical issues and concerns regarding pediatric clinical trials. The study will answer the question of how these issues impact doctors, researchers, parents and their children, and how we can better and assure the process of pediatric clinical trials. While participating in this study, your child will be asked to share their first-hand accounts and experiences regarding pediatric clinical trials. The researcher will ask the child open-ended interview questions that consist of the process of pediatric clinical trials. Your child will be asked about their ethical concerns and issues regarding pediatric clinical trials. The researcher will collect the responses from the child.

Data from this study will be used in a student thesis that presents the findings of the research, as well as an oral defense presentation to the

instructor of Advanced Placement Capstone Research, as well as a board that is created in response to the content of the study. Findings of the research have the potential to be published in a scholarly journal.

I hereby give my consent for my child to participate in this research study. I acknowledge that the researcher has provided me with:

A. An explanation of the study's purpose and procedure.

B. Answers to any questions I have asked about the study procedure.

I understand that:

A. My child's participation in this study will take approximately 15-60 minutes.

B. Participating in this research may result in emotional distress, psychological stress, or in feeling overwhelmed due to stress that may be caused by the worry of participants' confidentiality and protection.

C. Research sessions will not be held when important academic material is being covered.

D. The potential benefits of this study include educational benefits as participation in the study could potentially lead to a new outlook on the ethics of pediatric clinical trials.

E. My child will not be compensated for participating in this study.

F. My decision to allow my child to participate is voluntary, and I may withdraw my consent and discontinue my child's participation in the study at any time. My refusal to participate will not result in any penalty or disadvantage for me or my child.

G. In addition to my written consent, my child will give verbal agreement to participate in the research. My child will be able to discontinue their participation at any time, without penalty, and this will be explained to them before they agree.

H. My child's responses in this study will be kept confidential, to the extent permitted by law. The data will be stored in a secure location on a password protected computer in the researcher's personal room located in the researcher's residence, will be available to the researcher and will have access to the data, and research reports will only present findings on a group basis, without any personally identifying information.

Name of child (printed): _____

Name of parent (printed): _____

Parent signature: _____

Date: _____

Appendix D

This form was used for all participants.

Additional Consent Form for Recordings of Interviews

Title of the Study: The Ethics of Pediatric Clinical Trials

In addition to agreeing to participate, I consent to having the interview audio recorded. I understand that the recording of my interview will be transcribed by the researcher(s) and erased once the transcriptions are checked for accuracy. Transcripts of my interview may be reproduced in whole or in part for use in presentations or written products that result from this study, but will not be linked to my name. Neither my name nor any other identifying information (such as my voice or picture) will be used in presentations or in written products resulting from the study, unless I give my explicit permission.

A. I consent to having the interview audio recorded.

Name (printed): _____

Signature _____

Date _____

B. I consent to having my name associated with my responses. (If I do not sign, my name will not be used.)

Signature _____

Date _____

C. Lastly, I consent to use of my voice in presentations or in written products resulting from the study. (If I do not sign, my voice will not be used.)

Signature _____

Date _____

Appendix E

Interview Questions

Medical Professionals and Physicians:

1. What is your occupation?
2. How long have you been practicing?
3. What is your speciality?
4. What is your experience with pediatrics?
5. What Is a Clinical Study?
6. Who Conducts Clinical Studies?
7. How Long Do Clinical Studies Last?
8. Where Are Clinical Studies Conducted?
9. Who Can Participate in a Clinical Study?
10. How Are Participants Protected?
11. What tests and procedures are involved?
12. What are common ethical concerns regarding pediatric clinical trials?

Parents and Children Involved in Pediatric Clinical Trials:

1. Have you participated in a pediatric clinical trial?

2. What is your experience regarding pediatric clinical trials?
3. What is your medical background?
4. What was being studied?
5. What tests and procedures were involved?
6. How did the possible risks, side effects, and benefits of the trial compare to your current treatment?
7. How long did the study last?
8. What type of long-term follow-up care was part of the trial?
9. What were your ethical concerns regarding the clinical trial?