

Children in Research: Should They Be A Part of The Biomedical Research World?

Neuroethics

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*Children in Biomedical Research*

Our children are our future; if this is so, why should they be excluded from important scientific studies which could be aided by their participation? The role of children in society has spanned the full spectrum, ranging from helpless individuals to “little adults,” but what exactly should their role in research participation be? In the past, they have been taken advantage of, used in research that exposed them to unnecessary risks. Prior to 1966, children were frequently research subjects because they were convenient and cheap in the sense that they were non-valued or viewed as expendable commodities (Ross, 2006). The research of the time unfortunately reflected this devalued vision of children.

In the 1950s and 60s in Staten Island, New York researchers conducted the Willowbrook study. The Willowbrook State School was designated as a school for mentally defective persons (Burns, 2003). Researchers gave doses of hepatitis to children in order to learn the natural course of the infectious disease and to test the effects of gamma globulin in preventing or improving the disease (Burns, 2003). Henry Beecher, author of “Ethics and Clinical Research,” made note that although this research was important it was not ethically sound; the Willowbrook population should not have been at risk in order to benefit others (Ross, 2006). Despite the researchers proclamation that the study was sound, this is one example in which children were poorly treated for scientific progress.

Healthy newborns were involved in a study to determine whether ureteral reflux could occur in the normal bladder (Ross, 2006). The study included the infants undergoing radiology when their bladders were full and empty. However, the long-term effects of the imaging was not known, thus these infants may have been at an increased risk for complications as they

developed. As Kipnis (2003) explains, human research subjects should be treated with respect and dignity; this includes informing participants and/or their proxy of a study's potential risks.

Another study demonstrating the exploitation of a vulnerable population occurred at the University of Iowa in the 1930s. This vulnerable population consisted of orphans who were used as part of a study on stuttering. Participants were subjected to harassment, badgering and other negative verbal abuse as researchers tried to induce speech impediments (Associated Press, 2007). The study is now more commonly referred to as, "The Monster Study." Children were told they stuttered even if they did not while the researchers, viewed themselves as people who were saving these children from their own language impediments. The study which was conducted in 1939 was not discussed until 2001 when the University apologized for the experiment. As a result, orphans who participated in the study sued and were given \$925,000. However, this sum of money cannot account for the participants' lifelong psychological and emotional scars.

As described in the aforementioned studies, children have been involved in biomedical research, but they have been taken advantage of. Research has developed and changes have been made; however, children are still a debated population: should they be considered children, unable to think and make decisions or should they be given more respect and help to make their medical decisions? According to the National Institute of Health (NIH), children should have a role in scientific research. In fact, as a result of the 1998 policy issued by the NIH, the inclusion of children is a requirement of all human research which is conducted or supported by NIH (Caldwell, Murphy, Butow, & Craig, 2004). Children represent a significant part of the world's population and they should be involved in research, they deserve to be part of the scientific

progression. Golombeck, van den Anker, and Rose (2007) describe the primary moral question in research with children as how to secure the progression for children as a group, while protecting the individual research subject's rights and welfare; it is not a question of whether we should do this research, but how we should further this research according to ethical standards.

*Pediatric Research Should Not Occur*

Despite the scientific advancement due to pediatric research, there is a dispute on the negative aspects that this research population presents. First and foremost, specific risks for children during the research process may include, but are not limited to: discomfort, inconvenience, pain, fear, separation from parents or familiar surroundings, effects on growing or developing organs, and size or volume of biological samples (Caldwell et al., 2004). People feel it is not necessary for children to have to endure the emotions associated with the potential negative aspects of a study. Further, people feel that there is a lack of understanding regarding children's behavior and that there is also limited experience using child-sensitive measurement tools (Rice & Broome, 2004). Economically speaking, studies can be costly. A pediatric study can be more expensive especially because of the need for a specialized research team (e.g., pediatric investigators, child life specialist, third party to consider the child's and parent's perspective, recruitment support, etc.). There is a lack of infrastructure and support for research and a shortage of investigators with an interest and expertise in pediatrics and clinical research (Caldwell et al., 2004). As it may become apparent, pediatric research is less glorified than adult research and for this reason, doctors and researchers choose not to recruit children and conduct these kinds of studies. Recruitment for children is more difficult, with the exception of pediatric oncology trials (Caldwell et al., 2004). Beyond recruitment difficulty, pediatric studies are not

commonly conducted as a result of financial constraints, extra work involved for physicians, lack of resources, lack of rewards and recognition, difficulty with ethics requirements and informed consent, concerns about the effect on the doctor-patient relationship, discomfort with randomization and preference for a particular treatment (Caldwell et al., 2004). Although the reasons against pediatric research are many, overtime these uncertainties in experimental studies can and will be accounted for.

*Pediatric Research Should Occur*

Despite the difficulties in conducting ethically sound and economically efficient pediatric research the need for medical research on children is evident. Admittedly, medical research has not been without its flaws and terrible decisions have been made against children, yet, it is also documented that there has not been enough medical research on children (Golombeck et al., 2007; Burns, 2003). It is important to consider that pediatric clinical trials have often only dealt with small case numbers (due to reasons described above, difficulty with recruitment, financially, etc.) and have been conducted with limited resources. If children are not to be included in research, it may deny children of the benefits that may come from these studies such as potential treatment, and it is in opposition to the previously described 1998 NIH inclusion of children policy. Even if research in children is difficult, clinical trials have resulted in significant improvements in their health care and should continue (Caldwell et al., 2004).

Pediatric medical research is beneficial, it is this altruistic aspect that acts as an important determining factor for child research participation. In fact, 76% of subjects participated in research as a way to help others (Tait, Voepel-Lewis & Malviya, 2004). As mentioned, pediatric oncology is the most prominent childhood research studied, Bleyer, Tejada, Murphy, Robison,

Ross, Pollock, Severson, Brawley, Smith, and Ungerleider (1997) describe the benefits of pediatric research specific to oncology:

First there is immediate access to the collective wisdom of experts in the treatment of pediatric cancer. Second, there is access to state-of-the-art therapies and technologies. Third, expertise in translational research is unparalleled; virtually any laboratory advance which may assist in understanding the disease afflicting the patient is present within the groups and available to the patient and family. Also, the survival rates of children and adolescents with cancer are significantly enhanced by participation in cooperative group clinical trials.

The benefits of pediatric oncology research will parallel pediatric research in general providing access to experts, therapies and technologies and the hopeful improvement in other childhood disorders. Although there appear to be many reasons for not participating and conducting child research, many of the difficulties mentioned can be diminished if pediatric research is acknowledged and more people are aware of the importance of the research of this population.

#### *Generalizability*

Pediatric research cannot simply be extrapolated and generalized from adult research of the same medical conditions for several reasons. For one, the existence of developmental differences result in the differences in the progression of diseases in children. It is not justifiable to use the same results from adults as a rationale for pediatric medications or treatments.

Generalizing findings across age groups is dangerous (Burns, 2003). Children have different ranges of diseases and metabolize medications differently, resulting in responses to treatment that are unpredictably different from adults (Caldwell et al., 2004). Understanding this distinction is essential when considering pediatric pharmacology.

#### *Pediatric Pharmacology*

In the early 1960s many drugs released did not follow the guidelines, “*Not to be used in*

*children...is not recommended for use in infants and young children since few studies have been conducted in this age group...clinical studies have been insufficient to establish any recommendations for use in infants and children...should not be given to children”* (Shirkey, 1999). For instance, many physicians had ignored the warnings and prescribed restricted drugs (Shirkey, 1999). As such, many medications given to children were off-label, unlicensed for use in children, and without adequate pharmacokinetic or safety data regarding use in children (Caldwell et al., 2004; Burns, 2003).

In response, guidelines were provided to promote and entice pediatric pharmaceuticals. *The Pediatric Rule of 1998* gave the Food and Drug Administration (FDA) the authority to direct pediatric clinical trials in drugs with an unmet medical need to research in children (Golombek et al., 2007). However, there is a clause that mandates age-appropriate dose formulation (e.g., liquid formulation, chewable tablet, preferential flavors, etc.). Beyond the initial response to pharmaceutical provisions, the United States Government sought to provide financial incentive for pharmaceutical drug development by introducing the *FDA Modernization Act* (Caldwell et al., 2004).

Pediatric medications should be both developmental and age-appropriate. By not investigating medications for children it is possible that practices such as adult extrapolation result in either toxic doses or underdosing, both of which are detrimental for the health of children (Field & Behrman, 2004). Pharmacokinetic studies focus on the way medications are absorbed, the way in which they are distributed among organs in the body and the relationship between the dose and the concentration of medicine in the blood; these studies are vital for pediatric pharmacology (Field & Behrman, 2004). As discussed above, age-appropriate

formulations are in effect because of the necessary needs of children. It is important to consider that some drugs may simply not work in children because a receptor that permits the activity of the drug is not present or has not yet developed (Field & Behrman, 2004). It is frightening to think children are given medications that their body is not only not used to, but something that their bodies cannot break down because of their physical stage of development.

Although there is a need for pediatric pharmaceuticals, medicine for children is not as profitable as adult medications. For example, the commercial value of various preventative, diagnostic, and therapeutic options for children, especially for rare diseases, may not be enough to offset the costs of developing them (Field & Behrman, 2004). Beyond commercial value, development costs may also be increase because more time is often required per patient to complete study procedures and because more expensive, specialized laboratory studies may be required for small-volume biological samples (Field & Behrman, 2004). As Caldwell and colleagues (2004) explain, drug development priorities tend to be driven by political and economical rationale and the needs of children (the supposed reason for the drug development) receive secondary consideration. However, possible profitability of drugs should play a secondary role, while the obligation to assess interventions in children should be of primary importance. It is discouraging that it is so difficult to bring the collaborative efforts of the people who can help, pharmaceutical companies, doctors, clinicians and researchers, together in order to find ways to optimize the benefit that children can gain from medical and pharmaceutical progress (Golombek et al., 2007).

In the future of pharmaceuticals, an international process should be established to ensure that the most essential drugs are prioritized for pediatric development. Drug development must



consider a child's developmental stage, in such a way to assess the receptor development, create clinical tools to assess the relationship between how the body processes a drug and what response the drug triggers in adults and to determine if the same relationship will hold true for children of all ages (Field & Behrman, 2004). Also, pharmaceutical companies should find ways to alleviate the extra expenses of pediatric medications because it is for the good of society to create and promote medications for all age groups as is necessary.

#### *Minimal Risk*

Minimal risk is defined as the probability of harm or discomfort from the research that is not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (Wendler, Belsky, Thompson & Emanuel, 2005). However, the proposed difficulty with this interpretation is in direct response to the ethical principle of justice, a group of norms for distributing benefits, risks, and costs fairly, in that it unfairly puts a riskier population at more risk. For instance, children whose daily activities expose them to relatively higher risks in theory could also be the subjects who have the riskier exposure as compared to participants who are involved in less risky activities overall (Burns, 2003; Wendler et al., 2005).

It is difficult to create an assessment which lists the possible range of risks healthy children may encounter in daily life, as such there are no current tests that can adequately assess this. Interestingly, Wendler and colleagues (2005) explain that their extensive psychological research demonstrates that individuals make systematic errors when they assess the risks based on their own perceptions. For instance, people consistently judge less-familiar activities, as well as activities over which they seem to exert less control, to be riskier. According to the Centers for

Disease Control and Prevention National Center for Injury Preventing and Control, the risks of daily life include, riding in a car, which poses the greatest risk of death for healthy children and sports, which poses the greatest risk of injury for healthy children (Wendler et al., 2005).

In the future, the definition should be clearly stated to explain that all children be assessed on the same amount of “ordinary risk encountered in daily life.” Distributive justice should always be in place, regardless of the population, whether it is an infant, child, adolescent or adult population.

#### *Assent and Consent*

Individuals who are unable to make decisions for themselves are legally entrusted to the custody of adults such as parents or guardians (Kipnis, 2003). Assent policies must be rigid enough to provide protection and respect for children yet flexible enough to allow for varied cognitive and emotional levels and should appropriately address the diverse needs of pediatric participants (Kon, 2006). Also, it is important to explain that participation is voluntary and that dissent will not be penalized (Field & Behrman, 2004). The assent process should proceed with minimal stress, encourage children's involvement in decisions and ensure that their wishes and concerns are adequately communicated and considered before signing the assent form (Field & Behrman, 2004).

In general, parents can be trusted to make decisions in the best interest of their child. As Beauchamp and Childress (2001) explain, “trust is a confident belief in and reliance upon the moral character and competence of another person, it entails a confidence that another will act with the right motives and in accordance with appropriate moral norms.” Therefore, when the decision for a clinical trial is presented researchers can conclude that the decision being made

with both the child and the parent(s) is one which is a representation of their child's view as well. However, not all parents are comfortable with this responsibility because of the uncertainty it presents, such as unknown or unexpected future side effects and the possibility that the treatment their child receives might later be discovered to be ineffective or worse, harmful (Caldwell et al., 2004).

In response to parents' desire to make the most favorable choice with their child, it is possible that this does not always occur. For instance, Harris and Holm (2003) describe that parents make poor decisions for their children on a daily basis such as raising children in polluted and dangerous cities. It is also possible that proxy decision makers may, in certain contexts, underestimate the negative effects of pain and discomfort on children and that children sometimes may be an easily exploitable pool of research subjects (Harris & Holm, 2003).

Regardless of the parent's interpretation of the phrase "best interest," of paramount importance is the protection of the welfare of the child (Tait et al., 2003). In order to do this, parents should be given sufficient information to make an informed choice and be left in an environment conducive to decision making.

The maturity of the minor is considered as well. The more mature the minor, the more well-reasoned the decision will be and the greater the weight the decision will have on the study (Kipnis, 2003). For instance, even if a child is younger than 18, he or she may have had to mature a bit faster than others of the same age because he/she needs to understand his/her diagnosis and potential outcome. While his/her peers are playing outside worrying about what to do that night, he/she is in a hospital wondering what medical miracle may happen that night.

Ultimately, the more coherent the consent and assent forms are, the better received they

will be by participants and their families. One factor to consider is that these forms should be developmentally appropriate; therefore, the content and purpose of assent must vary depending on the child's developmental stage (Kon, 2006). If investigators do not consider the developmental stage of their participants, it is possible that the investigators will focus more on the signing of an assent form rather than the assent process. Beyond developmentally appropriate forms, they should also be easy to understand while still describing the process in as much detail as possible. Reviewers of the consent forms argue that they should be more readable (Field & Behrman, 2004). Reviewers described that the forms generally required a reading level of grade 12 or above and the pamphlets required a reading level of grade 11 or higher. In reality, researchers explain, the inner-city parents at one institution had a median reading level of just below the seventh grade. In the future, it is absolutely necessary to cater to the populations needs, and include forms that are at one's reading level. It is more often that people will not participate in a study because they did not understand the consent, assent or description of the study because it was not portrayed in an accessible manner.

#### *Family System Approach*

Since pediatric research can and will effect the entire family system, there has been an effort for more family centered ethics. Typically, there is a triadic relationship within the research study: the child, his or her parents, and the physician (Harrison, Kenny, Sidarous & Rowell, 1997). A family centered ethic is the best model for understanding the interdependent relationships that depend upon the child's situation (Harrison et al., 1997). Simply put, this ethic is one of shared decision making. This kind of decision making is helpful because often children's stable sense of self, established values and mature cognitive skills are undeveloped or

under-developed; by including the family, others can help the child learn and absorb what should happen. However, it should not be left unsaid that when more people are involved in a decision, it may be more difficult to come to a conclusion. Despite this, if the decision made is in the child's best interest one would assume the conclusion be universal.

#### *Autonomy and Competency*

The American Academy of Pediatrics categorized children as (1) those who lack decision making capacity; and (2) those with a developing capacity; and (3) those who have decision making capacity for health care decisions (Ross, 1997). If autonomy is based on competency, then competent children should have the ability to make their own decisions in health care (Ross, 1997). Therefore, if a child is intellectually mature and aware of his/her surroundings in the medical environment then he/she should have the right to his/her autonomy; assent should not be necessary.

#### *Population*

Participants for pediatric research are not as easily accessible as adult participants are. Consequently, it takes considerable effort to enroll and retain enough participants who meet the criteria for the study (Field & Behrman, 2004). Also, a concern for many institutional review boards is that economically disadvantaged children or their families might enroll in research studies in disproportionate numbers as a means of income (Rice et al., 2004). Tait et al. (2003) describe, "Parents who volunteer their children for research have lower self-esteem, are more introverted, exhibit greater anxiety, and are less educated and more socially disadvantaged compared to the parents who decline their child's participation." People who are less disadvantaged may view research studies as a benefit due to payment, and equal access to more

appropriate medical centers. In Ross' (2006) look at minority representation in pediatric research, her finding was that African American children are over-represented in medical research overall which is in contrast to their decreased access to pediatric health care. Again, perhaps the African American population which was studied was more disadvantaged and more likely to agree to biomedical research.

#### *Culturally Aware Research*

Further, like all research conducted, child research should be culturally appropriate for each participant. Subjects can benefit from a culturally diverse research team (Fisher, Hoagwood, Boyce, Duster, Frank, Grisso, et al., 2002). A culturally diverse team can provide services such as a translator or interpreter for families if the parents are non-English speakers. The close attention to culture is especially in demand for ethnic minority children and youths, who require culturally validated mental health services but who are also most vulnerable to harms that can arise when ethical procedures do not adequately protect their rights and welfare (Fisher et al., 2002).

#### *Necessary Improvements*

On the surface, there are many improvements to be made for pediatric research. Unfortunately, until each researcher, doctor, and clinician is aware of these changes and the implications that they hold for future research they will not be put into effect. Until this awareness is raised there is no possibility for change. Consent and assent procedures need to be adapted for children, various types of measurements and data-collection strategies and recruitment techniques should all be part of the progression of pediatric research (Rice & Broome, 2004). Perhaps the most ambitious and lofty goal, but most worthwhile goal is to

conduct longitudinal pediatric data. This is especially needed because as Jensen, Bhatara, Vitiello, Hoagwood, Feil, and Burke (1999) state, most psychiatric disorders of childhood and adolescence tend to be chronic, frequently requiring long-term pharmacological treatment. However, it should be noted that the National Child's Study, which is a multi-year research study following 100,000 children from birth until age 21 to determine the effects of environmental influences on health, is currently one of the most challenging pediatric longitudinal studies- but it has begun. Potentially, as investigators notice that pediatric studies are being completed, even with their many demands, pediatric research will grow, and as a result society will profit.

#### *Institutional Review Board*

The Institutional Review Board (IRB) consists of a group of people responsible for approving and reviewing biomedical research including human research with the intent to protect the rights of the participants. However, each review board may have slightly different interpretations of norms and ethically sound research. Caldwell et al. (2004) explained that a review of the IRB system in the United States showed that IRBs are under-resourced, over-burdened, and ill-prepared to handle the sheer volume and complexity of research that they are asked to review. Although this acknowledges that as a society, there is more research in progress, this research cannot proceed unless it is approved by the IRB. If a company is under-resourced and over-burdened it is (1) difficult to keep up with all of the paperwork and (2) difficult to find enough time to thoroughly assess the project (study) at hand. Caldwell et al. (2004) continued to explain another serious concern: the inconsistent interpretation of regulations and lack of education and training of IRB members in common ethical principles and standards, specifically in relation to children. It is unsettling that the supposed ethics committee of human research

lacks the education needed to make informed ethical decisions. It is unacceptable that the research be approved by people who lack the education needed to make such judgments. Another aspect of the IRB is to bring in the expertise needed to review the research involving infants, children and adolescents; the disconcerting truth is that federal regulations on children do not explicitly require that IRBs include a member with child expertise (Field & Behrman, 2004). As noted earlier, glorification of working with the pediatric population is not everlasting, as such, many people do not choose to specialize in this population. The Society for Pediatric Research and the American Pediatric Society recommended creating ways to combine pediatric resources, for example through regional pediatric advisory committees or review bodies that could assist local IRBs (Field & Behrman, 2004).

#### *Resources*

Adequate resources are needed for research decisions to be made. The involvement of child development experts and children's advocates in the review and implementation process could provide added protection for the pediatric population (Kipnis, 2003). Specific to the consent process of research, there should be an appropriately trained and neutral third party to be available during research trials of seriously injured or ill children, such as traumatic brain injury patients. Without these additional resources, there is the potential for misunderstanding during the research process which could result in unintended coercion to participate or therapeutic misconception (Natale, Joseph, Pretzlaff & Silber, 2006). For the most favorable response to the research protocol multiple perspectives, such as families, investigators, funding agencies and society need to be considered and innovative approaches must be identified (Natale et al., 2006).

#### *Ethical Concerns in Pediatric Research*



Aside from the immediate changes that should be made, ethical questions and dilemmas that have been on review should be entertained in pediatric research. It is unethical to treat children as they have been treated in the past. This negative treatment of children as a means to an end is an unacceptable practice. As the Kantian theory describes, by treating people simply as means it is to “disregard their personhood by exploiting or otherwise using them without regard to their own thoughts, interests and needs,” (Beauchamp & Childress, 2001). Using children as a means to an end further disregards their worth and compromises their dignity. On the other hand, children should not be left to be “therapeutic orphans” as Shirkey (1999) described because they were often forgotten in biomedical research after the initial injustices against them. Children have been both devalued and forgotten in medical research when they are in actuality a significant and critically important population to study.

The utilitarian perspective is one that holds significant weight in pediatric research, but not without controversy. This theory focuses on the maximization of good and the minimization of harm; it is the overarching goal to maximize the good in society. By conducting studies with children, it will minimize the potential harm that could be caused if pediatric studies were simply assumed to have the same results as adult studies. For instance, as mentioned previously, toxicity in medications or over-dosing children with medicine may be an adverse effect of such extrapolations. Still, pediatric research, much like adult research does benefit society in reference of scientific progress. As Beauchamp and Childress (2001) mention, “we ought to maximize the public benefits to scientific research, clinical medicine and public health measures.”

The ethical principle of beneficence which evaluates the benefits against the risks and costs of a study will be of important consideration to the populations of healthy child participants

versus sick child participants. Children themselves are unaware of the biomedical research that is conducted on a daily basis and therefore, they cannot readily volunteer themselves for a study (although, their parents can). As mentioned, the pediatric participant population is limited. Moreover, the population that is most readily available consists of those individuals who are already in the hospital for medical illness, in other words, sick children. However, if a child is already sick should he/she really be put through a medical trial? What if this medical trial had to take blood samples, and this child already has irregularities in his/her blood? Should this child really be participating in a study that potentially risks his/her health even more?

One may propose using only healthy children in pediatric research. This is because as Kodish (2005) states, it is imperative to protect sick children. If a child is already ill, then he/she is already going through what may be a traumatic process. Distributive justice states that there should be a fair, equitable and appropriate distribution in society. Therefore, it is not ethical to always burden the child who is already in a medical hospital because he/she is a convenient participant. If this was the case, the sick children would not only be sick, but also have to go through all of the pediatric research studies which could be even more detrimental to their health.

However, often it is not the direct participant in the study that is benefiting from the research- even if he/she is in need of this clinical trial (e.g. a child cancer study). The greatest benefit of pediatric research is the pediatric population as a whole, not the individual. In fact, because there are so many medical diseases that have unknown causes and treatments, one study will not be the determinant of the cause or treatment; rather, one study may give researchers more insight as to what to focus on in the future- helping them by finding a piece to the puzzle. As a result, the incremental progress against disease will likely come too late for some of the

patients own personal benefit (Kodish, 2005). It is important to present the study in a non-biased manner, one that does not lead participants and their families to think that a medical trial will cure the participant's disease. Investigators must not delude themselves or their subjects into thinking that there will be an ultimate exchange for their participation (Kodish, 2005).

Researchers and participants should be aware that scientific research is a slow progression. In the short term, the patient may be benefiting from the study, but it is the population which will benefit in the long term from the results of the study.

One population should not bear the burden of biomedical research. The ethical principle of justice is based on a group of norms for distributing benefits, risks, and costs fairly (Beauchamp & Childress, 2001). As Ross (2006) highlights, the location of many academic medical centers is in poor urban sites with a large minority population. This has the potential to lead to more minorities enlisting in medical research due to their proximity. Also, there is compensation in almost all research studies, most typically in the form of financial gain (money, gift cards, etc.). It is possible that ethnic minorities, living in poor urban areas choose to participate in studies because they need extra money to provide for themselves or their families. As a result, ethnic minorities may be over-participating in research studies. Although initially, high participation rates are favorable for researchers, the results of their data may not be generalizable to the population as a whole if the population studied is uniform. Even though this is a reality, and researchers are aware that some participants are doing their studies for financial reasons, the question becomes is this wrong? Discouragingly, the researchers cannot help participants in any way beyond allowing them to participate in a study- so the researcher who acknowledges this reality and works along with the participant is confronted with a challenge.

Living in a scientifically advanced society may promote the obligation or duty to participate in medical research. Kant's moral duty may impose that it is part of a person's duty to participate in research, because this will continue the scientific progression of society. However, simply because children have a right to participate in research, it does not imply that they have an obligation to do so (Kon, 2006). There is, however, a moral obligation for parents and pediatricians to address a child's concerns throughout the research process, especially because children are typically dependent on adults to guide them through the process (Kodish, 2005).

Unfortunately, once a specific case has been deemed ethical or in need of modification, this case cannot apply to all studies of the same moral question. Researchers are not able to use the, "One size fits all" logic. For instance, what one person should do may not be what other persons should do, even when they face the same problem (Beauchamp & Childress, 2001). Although information can be drawn from this case study, the exact participant may not generalize to all participants within the specific medical illness. However, casuistry *should* be considered given the lack of adequate pediatric research. This theory focuses on decision making using particular cases, where judgments reached rely on judgments reached in previous cases (Beauchamp & Childress, 2001). Even if the cases in pediatric research cannot directly be applied to every case concerning the same issue, the generalizations that can be made should be acknowledged and considered when a new medical case specific to children is discussed.

#### *Should Children be Involved in Research?*

Without any hesitation, children should be involved in research. Although there are many modifications presented and financial barriers to overcome, this does not change the necessity to conduct research on children. If we do not allow this population to be included in medical

research it will only be hurting society, which is in direct contrast to the utilitarian perspective of maximizing the good for society.

Researchers need to learn from their mistakes and in many ways they have; from the 1930's Monster Study to the National Child Study of the 21<sup>st</sup> century, the research community has developed into a reformed and well respected aspect of current society. As the pediatric population becomes recognized, perhaps it will entice professionals entering the field to consider working with children or becoming child advocates. Regardless of one's motive to enter a pediatric specialty, as long he or she will be focusing on the ethics specific to children his or her involvement will be beneficial.

In a perfect scenario, for every study that mistreated children, there should be two studies advancing children's medical health. Although this is an optimistic and lofty goal, science should be up for the challenge. Furthermore, child specialists should be considered just as important as adult specialists. In a recent conversation with a child psychiatrist, he explained, "Although I am a child psychiatrist, I still see adults. Often, I think people forget that adults with mental illnesses may have had a difficult time as children as well (if it was early onset). It is incredibly helpful for me to connect an adult patient with a child patient because it allows me to think how the adult was as a child." Even though all adult medical cases cannot be traced back to childhood, researchers, doctors and clinicians should recognize the beginning of the story. The importance of children in research can be summed up by a statement from the American Academy of Pediatrics (2004), "We believe in the inherent worth of all children. They are our most enduring and vulnerable legacy."

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