### **Features**

## Equal Work Demands Equal Pay, Even in Pediatric Research

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#### **ABSTRACT**

A common view in pediatric research ethics is that minors, especially younger children, are more easily susceptible to undue influence by offers of financial compensation for research participation. For research that compensates participants, then, it is posited that minors should be compensated in an age-appropriate manner: their compensation should be different from compensation given to adult research participants—adults and minors participating in the same clinical trial should be compensated differently. We argue that considerations of fairness and the opacity surrounding the notion of undue inducement support equal compensation for all participants: minors and adults who give equal time and effort and undertake the same burdens and risks deserve equal compensation.

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are more easily susceptible to being unduly influenced by offers of compensation in exchange for their participation in research.<sup>1-7</sup> For research that compensates participants, then, the common view is that minors—those who are under the legal age of consent—should be compensated in an age-appropriate manner. This means that their compensation should be different from compensation given to adult research participants: adults and minors participating in the same clinical trial should be compensated at different levels, with minors being compensated less than adults or not at all.1-10 In this article we argue that considerations of fairness and the problematic ambiguity surrounding the notion of undue inducement support equal compensation for all participants: minors and adults who give equal time and effort and undertake the same burdens and risks deserve equal compensation.

## PEDIATRIC DIFFERENTIAL COMPENSATION

There is a broad consensus that research participants or their parents/legal guardians should be reimbursed for out-of-pocket costs that are incurred by participating in clinical research (for example, mileage or parking). This removes financial barriers to participation,

thereby rendering research participation revenue-neutral, and addresses the concern that it is unfair to ask participants to bear additional costs that accrue from participating in socially beneficial research, including research that may not individually benefit participants.<sup>2</sup> Compensation payments, by contrast, are intended to compensate research participants for their time, burden, and inconvenience above and beyond the incurred costs of participation. There is little agreement on how much compensatory payments should be. Some propose a minimum wage standard while others propose a more sensitive payment model. There is agreement, however, that offering compensation is ethically defensible: to not compensate participants can be viewed as exploitative, as unfairly taking advantage of them, given the potential risks and burdens of participating in socially valuable research. Participants contribute something of worth to researchers and to society and should therefore receive something in return. 1,2,5-10 (There are other forms of payment, including incentive payments to encourage trial enrollment and appreciation payments to thank participants.1 The ethics of these kinds of payments are more contestable. We focus on compensation and note that our argument applies to other forms of payment.1)

In pediatric research ethics, there is a plausible case that parents/legal guardians should be reimbursed and that it can be ethically permissible to offer pediatric participants compensation directly. According to a National Institutes of Health document, Guideline for Investigators Regarding Paying Subjects for Research Participation,<sup>3(p2)</sup> "reimbursement can be directed to the parents who may incur outof-pocket expenses like mileage and parking. Compensation can be directed to the minor, enrolled in the research study." Parents/legal guardians are the ones who incur the costs associated with research participation, and so they should be reimbursed. It does not make sense to reimburse a young child for the cost of parking at the research site. By contrast, minors are the ones who participate in the research, and so they should be the ones compensated for their participation. It does not make sense to pay parents for the burdens their children bear while participating in socially valuable research—the inconveniences of research participation fall primarily on participants. In addition, compensating parents/legal guardians for their child's research participation could unduly influence them, since there is no risk to the parents/legal guardians. It is therefore preferable to compensate minors for their participation in research. There may be legal challenges to paying younger minors, and so compensation offered to minors may take a nonfinancial form (for example, a toy).

There is the concern that offers of financial compensation may unduly influence minors to participate in clinical research. The concern is threefold. First, minors are more susceptible than adults to undue influence by compensation for research participation, given their nascent development—minors, especially younger children, lack the cognitive maturity to properly weigh the compensation *vis-à-vis* the risks and benefits of research participation. They may be, as Resnik explains, "too young to understand the concept of money or make good use of the money."4(p56) Bagley and colleagues found that children younger than nine "generally have problems appreciating the role and value of money."5(p50) Second, minors have a comparative lack of opportunity to make money, as Ross observes: children "may be unduly influenced by the promise of minimum-wage payments for research participation because they have relatively few opportunities to earn money otherwise."6(p144) Third, parents/legal guardians who will not themselves bear the burden of participation may be more easily influenced by the offer of compensation to coerce their child to participate. 9,12 These three considerations suggest that compensation that would not unduly influence mature adults may unduly influence minors, especially younger children and their parents/guardians, thereby rendering the minors' participation involuntary or otherwise improper.

The response to the concern of undue influence is to advocate for age-appropriate compensation, meaning minors should be compensated in a manner that does not unduly influence them or their parents/guardians. A corollary of this is that pediatric participants should be compensated differently than adult participants. There should be different compensation to pediatric and adult participants, and minors should be compensated less than adults. The Institute of Medicine's Ethical Conduct of Clinical Research Involving Children posits that researchers should "provide reasonable, age-appropriate compensation for children" and that what "is acceptable for competent adults is, however, often not acceptable for children."

of one amount is undue for an individual, then an offer of compensation at a lesser amount may not be undue for that same individual. For instance, if a 10-year-old would be unduly influenced by compensation of US\$100, they may not be unduly influenced by compensation of US\$25.

3. Compensation can be ethically offered to research participants. For reasons discussed above, compensating participants for the time and inconvenience of participating in research can be ethical.

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7(p226) This view echoes the recommendation of Wendler and colleagues that children should be allowed "to be paid less than adults in identical studies."1(p170) Some scholars, such as Bagley and colleagues,<sup>5</sup> recommend that younger children be given tokens of appreciation, thereby allowing younger minors to be compensated differently and less than older minors participating in the same research. For example, adults may receive US\$100, mature minors (for example, 16-year-olds) may receive US\$50, and young minors (for example, six-year-olds) may receive a toy worth US\$20 for participating equally in the very same clinical trial. Other scholars, such as Resnik, argue that younger children should not be compensated at all.<sup>4,8</sup>

The case for pediatric differential compensation relies on the conjunction of four plausible theses, which can be set out as follows:

- 1. The effects of an inducement are agentrelative. If an offer of compensation is undue for one person, the very same offer may not be undue for another person. For example, a 10-yearold may be unduly influenced by compensation of US\$100, while a 55-year-old wealthy retiree may not be unduly influenced.
- 2. Whether an inducement is undue is a function of its size. If an offer of compensation

4. Undue inducements should be avoided. Undue inducements have a detrimental impact on potential participants and should be prevented. The concern of undue influence is codified in regulations and guidelines around the world.

We take it that each of these theses are true, and that their conjunction is integral to the defense of pediatric differential pay.

## AGAINST PEDIATRIC DIFFERENTIAL COMPENSATION

There are at least four reasons to doubt whether the truth of the four theses above establish pediatric differential compensation. First, it is *prima facie* unfair, because equal work demands equal pay. 13-16 Compensation should be, in the words of Bierer and colleagues, "equivalent for and offered to all participants at a given location." This is grounded in the equal inherent worth of all human beings. All individuals should be afforded equal respect and consideration. If you hire two gardeners to mow your lawn on alternating weekends, it would be *prima facie* unethical to pay one gardener more than the other. That being said, there may be a justifiable reason to pay them

differently. For instance, if one gardener does more work or takes on greater risk than the other, then differential pay can be justified. Similarly, different compensation for research participation can be appropriate, as Persad and colleagues explain, "when some research participants commit more time or assume greater burdens than other participants."<sup>17(p319)</sup> When research participants assume the same time and burden, they should be compensated equally.

The proposed justification for different compensation for pediatric participants—namely, they (or their parents/legal guardians) are more susceptible than adults to being unduly influenced by money, and so they should be compensated less than adults—is not compelling. If it were, then adult research participants should be compensated differently, and this view is considered unethical. In adult research ethics, there is an assumption that economic vulnerability may result in the same compensation unduly influencing one person but not another. For instance, a payment of US\$100 for research participation may unduly influence an out-of-work single parent but not unduly influence an affluent single parent. To assume that economically disadvantaged people will exercise poor judgment in response to an offer of compensation, Levine explains, "fails to recognize their autonomy and treats them with condescension."18(p435) The response is not to offer the out-of-work single parent less than the affluent single parent to participate in research—this would be unfair and disrespectful. Instead, the proper response is to stress the importance of institutional review board (IRB) oversight of the selection of participants, study design, and the informed-consent process to ensure that no participants are being taken unfair advantage of, and that everyone is able to freely consent to participate. Since it is considered unethical to offer differential compensation to adult participants, even when the same compensation may affect some participants differently than others, it should likewise be considered unethical to offer different compensation to minor participants.

The second reason to doubt the case for different compensation for pediatric participants is

that minors may be overrepresented in research due to their economic vulnerability, and thereby may shoulder an unfair burden of research. If a group of researchers can enroll 16- and 17-yearolds at US\$50 per participant or legal adults at US\$100 per participant, the researchers might include more minors than they otherwise would, on the grounds that doing so would be less expensive or would yield more participants. In this case, minors would bear the burdens of socially beneficial research only because they cost less to employ in research, not because they alone are uniquely tied to the study objectives. Their social-positional vulnerability grounds their over-inclusion, and this is unfair. The selection of participants should be determined by research objectives and should not overburden one group, especially a vulnerable group.

Third, different compensation for pediatric participants opens the door to the charge of exploitation. Even if minors are not over included in research, different compensation is exploitative. Imagine a researcher who could easily pay a participant US\$200 to participate in a study and that this would be a fair compensatory rate, but the researcher offers to pay an out-of-work parent US\$50 to participate in the research. In this scenario, the researcher takes unfair advantage of the out-of-work parent's economic vulnerability to advance their own ends, particularly if other participants are paid US\$200 to participate in the very same research. In this case, compensating minors less than adults for incurring the same burden exploits minors' age and social-positional vulnerability.

Finally, different compensation may sow distrust in scientists and research among the general public and among minors participating in research. Paying minor participants less than adult participants for the same time and burden appears exploitative to the public, especially given the long history of child exploitation in research and labor. Resnick observes that it "might be the case that the public would be more distrustful of the research enterprise if payments to participants are too low," and this may be especially true if the public learns that minor participants are paid less than adult participants and bear the same burdens. 8(p11) In

addition, minor participants who learn of different pay may feel discriminated against or exploited. These concerns may hinder recruitment efforts and promote distrust in clinical research among minors who may benefit from participating in research. Rather than facilitate participant enrollment among minors, different compensation may have the opposite effect. If a minor knows that other participants are being paid US\$250 for the same activity, the minor may not want to participate for US\$50.

These four considerations suggest a fifth thesis, one that captures the importance of equals being treated equally. It can be stated as follows:

5. Compensation should be fair. Individuals who give equal time and effort and undertake the same burdens and risks deserve equal compensation.

This thesis does not negate any of the previous four theses. The tension among the five theses does not invalidate any, because there are other ways to protect participants from undue influence.<sup>5</sup>

The response to the recognition that the same compensation may unduly influence one adult and not another is to ensure rigorous research oversight and participant freedom. IRBs and researchers who propose to compensate participants must ensure that participants are protected from participating in excessively risky research and that they are able to freely give their informed consent. The same must apply to pediatric research that compensates participants—rather than compensate minors less than adults, there must be rigorous research oversight to ensure that minors are not exposed to excessive risk, that they are able to freely assent (if possible), and that their parents or legal guardians are able to give their free and informed consent.

It is important to respond to a concern that child labor laws may prevent financially compensating minors, especially younger minors, directly or in the same amount as adult participants. <sup>19</sup> The legality of compensating pediatric research participants is an issue that is well-taken, but there is a solution readily available. That participants are compensated in an equal amount does not necessarily require that they

be compensated in the same manner. Compensation may look different for different participants. We agree with Duenas and colleagues that researchers "should consider how they can be flexible with the timing or types of payment provided to participants." Researchers may pay adult and mature minors US\$250 to participate and provide younger children US\$250 worth of toys. There might be other options the research team can take to compensate younger minors, but regardless of how it is offered, all participants should be compensated equally.

The position that compensation should be the same amount but not necessarily the same type also addresses the concern that minors may not yet be able to adequately understand money and financial power. True, young minors do not conceptualize the value of money appropriately, but the answer is not to forgo or lessen compensation. This is unfair. The answer is to find age-appropriate compensation at the same level as other participants. Age-appropriate compensation does not justify different compensation.

#### AGAINST UNDUE INDUCEMENT

All participants, minors and adults alike, who give equal time and effort and undertake the same burdens and risks must be compensated the same amount. Nevertheless, the concern of undue inducement receives plenty of attention. What does it mean to say that compensating minors the same amount as adults to participate in research will unduly influence minors or their parents/legal guardians? This is an area of considerable debate, for, as Grady observes, "defining undue inducement has proven elusive." There are three possible conceptualizations of what an undue inducement is, and each fails to justify different pay for pediatric patients.

The first way to conceptualize undue inducement is in terms of what the participant might decide if the compensation was not offered. Ross writes that payment unduly influences a person if it encourages him or her "to do something he would not otherwise do." <sup>6(p145)</sup> Similarly, Ramsey writes that for people to be unduly influenced is for them to "participate"

in the research against their better judgment." <sup>22(p.S16)</sup> For example, imagine a researcher offers 15-year-old Asef US\$150 to participate in a Phase III drug trial that promises little personal benefit and some risk and inconvenience. If Asef assents to participate on account of the monetary offer—that is, he would otherwise rather not participate—then the offer is undue. If he would participate in the absence of the offer, then the US\$150 is not undue.

This cannot be right, and for clear reason: you get paid by your job to perform certain du-

ment irresistibly pushes people to partake in research that "exposes them to unreasonable risks," which is to say that there is "sufficiently high probability that he or she will experience a harm that seriously contravenes his or her interests."<sup>23(p9)</sup> For example, imagine Asef is offered US\$150 to participate in a Phase III drug trial that poses a serious risk to individuals with an underlying heart condition, a condition that Asef knows he has. If Asef is pushed to enroll, despite the serious risk because of the compensation offered, then the compensation is undue.

# That participants are compensated in an equal amount does not necessarily require that they be compensated in the same manner.

ties; if you were not paid, you would otherwise not perform those duties. Employment compensation is not thereby undue. This account of undue inducement thus overgeneralizes. Reimbursements that are intended to reduce barriers to participating in research may become undue inducements on this account, since, in their absence, individuals may not participate in research—for some people, the offer of reimbursement for the cost of parking, say, tips the scales toward participating, and yet reimbursement for costs borne is not considered undue. Similarly, discussions of compensation often focus on their role in helping to recruit research participants, adult and pediatric alike—offering compensation for time and inconvenience may help recruitment efforts. 1,16 But this account of undue inducement requires that all compensation that nudges participation is undue, not only excessive compensation. This is surely too strong and cannot therefore support different pediatric compensation.

A second way to understand undue inducement builds on the first account by specifying that the offer pushes a possible participant to undertake risk he or she otherwise would not undertake. Emmanuel posits that undue induce-

This account of undue inducement does not support different compensation for pediatric participants. If the risks of participation are too high, the research should not be approved to begin with, as Largent and colleagues explain: "If ethics review determines that research is reasonable without considering the benefit associated with any offer of payment (as required), then no amount of payment can make the research unreasonable."24(p1) In other words, minors should not be exposed to unreasonable risks by participating in research, and, so, undue inducement understood in this way should not be a concern in IRB-approved research. Given this view, there is no case for different pediatric compensation.

Offers are undue that incline participants to lie or mislead researchers and by doing so place themselves at greater risk. Asef, for example, may know that he has an underlying condition that, if known to the researchers, rules him ineligible to participate in a trial that offers US\$500 in compensation. Pediatric research, however, involves parents' or guardians' consent, and, so, it is of less concern that children may be tempted to lie or mislead researchers for compensation. Parents or guardians, who

themselves will not be compensated, are less inclined to lie or mislead researchers on behalf of their children. Most parents or guardians would not lie to enroll their child in research that they have clear reason to believe is risky. More importantly, this possibility does not support different compensation; instead, it supports rigorous participant screening and selection to minimize the possibility. The role of an IRB is to minimize the risk of undue burden, not too eliminate the risk altogether.

has a strong desire to not work in the employ of capitalists, the offer of payment would not seem to amount to an undue influence, contrary to what the account here would seem to posit. Perhaps this person has a strong interest in paying rent and buying groceries, and so this is a case of conflict. But consider Asef again and let us add that, while he is a practicing Jehovah's Witness, he also cares deeply about being financially independent. For him, financial freedom is important, but he has limited options. To

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A third way to understand undue inducement is the inherent value conflict that may result. Dickert and Grady write that undue inducements "are so attractive that they lead individuals to participate in research studies to which they normally have important objections."25(p388) The offer of compensation may incline a participant to "set aside deeply held values" to participate in research. 25(p389) For example, imagine that Asef is a practicing Jehovah's Witness and is against blood transfusion for religious reasons. If he considers participating in a research trial that involves a blood transfusion in exchange for US\$500, his personal integrity may be compromised. If he decides to participate because of the monetary offer, then the offer is undue—he does something solely for the sake of money that he has deep objections to.

There are at least two problems here. First, it is unclear what deeply held values and important objections are, and why setting them aside to do something for compensation is undue. Consider a staunch anti-capitalist who lives in the State of Texas. Working in a capitalist society is contrary to this person's deeply held beliefs and values, and yet this person needs a job to buy groceries and to pay rent. While this person

him, participation in the study may appear to be a conflict of interests, because he cares about financial freedom, but he also cares about his faith. Is he setting aside his values, or is this a mere conflict? The answer is unclear.

Second, minors, especially young children, lack settled self-defined interests or deep moral convictions that can be influenced by compensation, as Teti and Silber explain: young children "will not yet have formed any such normative preferences." This may mean that compensating young children can never be undue, since young children lack settled desires and beliefs. No offer of compensation is contrary to their values, because they lack settled values to in the first place. Thus, this account does not support different pediatric compensation.

This discussion highlights the difficulty of specifying what makes an offer undue. This difficulty leads Largent and Lynch to write that payment conservatism, or the practice of paying research participants less, "overestimates the scope of undue influence. . . . From our perspective, rigorous review to determine that study participation is a reasonable offer for the target study population will satisfy an IRB's regulatory responsibilities."<sup>27(p10)</sup> We agree in the case of pediatric compensation: the answer

to the concern of undue inducement is not to pay minors less than others. The answer is to ensure proper oversight.

#### **CONCLUSION**

Pediatric research participants should be compensated the same amount as adult research participants who undertake the same burdens in the absence of extenuating reasons, and age is not an extenuating reason. This does not mean that minors necessarily must receive the same form of payment, only the same amount. Our arguments apply to other vulnerable groups, and set precedence for the equality of compensation of all participants.

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