Payment Is a Benefit and Why It Matters for Pediatric Trials

Abstract: Alan Wertheimer has argued persuasively that research ethics committees should be willing to count payment as a benefit when evaluating studies' risk-benefit ratios, hence potentially clearing the way to approval for riskier research. In this paper I begin by first recapitulating his argument and adding my own, complementary one. I then do two further things. First, I explain why the practical implications of these arguments for studies enrolling competent adults are less than fully clear. Second, I explain why the practical implication for trials enrolling children are clear and significant. I argue that we should be comfortable paying children to compensate them for undergoing research risks, and I propose that we do so by putting money into accounts that the child gains access to upon attaining majority.

Keywords: research ethics; risk/benefit analyses; children and families

1. Introduction

In a 2013 *bioethics* paper, Wertheimer argued that payments to participants ought to be counted as a benefit during the course of risk-benefit analyses as carried out by research ethics committees (RECs); that is, adding payment to a proposed trial should be able to "cancel out" an equivalent quantity of its risks.[1] Those arguments are powerful, yet have been ignored. This is surprising, given that the view that payment should *not* be counted as a benefit is the standard view in the field; it is widely accepted and enshrined in current regulatory policy.[2] Given the

[1] Wertheimer, A. (2013). Is payment a benefit? *bioethics* 27(2): 105-118.

[2] This claim is included in the classic synthesis presented in Emanuel, E. J., Wendler, D., & Grady, C. (2000). What makes clinical research ethical? *JAMA* 283(20): 2701-11. It is also the current guidance of the United States' Office of Human Research Protection. HHS. (2013). *OHRP revises its response to the question "when does compensating."* Retrieved from: https://www.hhs.gov/ohrp/news/announcements-and-news-releases/2013/ohrp-revises-its-response-to-the-question-when-does-compensating-subjects-undermine-informed-consent-or-parental-permission/index.html

apparent consensus the standard view commands, one might have expected it to receive prompt, vigorous defense.

It may be that Wertheimer's article has met with limited uptake because insofar as one focuses on trials enrolling competent adults, it's not clear that counting payment as a benefit has significant practical consequences. Perhaps partisans of the standard view have not felt the need to respond because they believe that regardless of the theoretical issues, the standard view is fully adequate to REC's practical needs in evaluating protocols.

But it is a mistake to focus only on studies enrolling competent adults. Consider instead pediatric research. It is common across jurisdictions to limit the degree to which the risks that participation in research imposes on children exceed the benefits they stand to gain—the "net risks"—to an extremely low level.[3] But if payment could be counted as cancelling risks, much more could be done while remaining within that limit. Counting payment could thus enable socially valuable research to go forward, while still ensuring that children expect to appropriately benefit from their participation. This requires a mechanism for paying children; I propose putting money into accounts which become available to them upon attaining majority.

My proposal may face difficulties in some jurisdictions, such as the United States, where there are additional requirements on pediatric research not directly related to net risks. To the extent that such restrictions are incompatible with enrolling children in expectably beneficial research, they should be modified. Properly taking account of children's interests involves furnishing them with beneficial opportunities, not denying them beneficial opportunities.[4]

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[3] In the US Regulations, see 45 CFR 46 § 404-407 and 21 CFR 50 § 51-54. See also guidelines 4.8.13 and 4.8.14 of Dixon, J. (1998). The international conference on harmonization good clinical practice guideline. *Quality Assurance (San Diego, Calif.)* 6(2):65-74. And see CIOMS' guideline 9. Council for International Organizations of Medical Science. (2002). *International Ethical Guidelines for Biomedical Research Involving Human Subjects.* Retrieved from: https://cioms.ch/shop/product/international-ethical-guidelines-for-biomedical-research-involving-human-subjects-2/

[4] Here and elsewhere in the paper, I use the term "beneficial" to mean beneficial *ex ante* or in expectation.

2. Risk-Benefit Analyses and the Standard View

It is widely accepted that the risks research imposes on human subjects must be justified for the research to be ethical. RECs enforce this requirement. In the United States, Institutional Review Boards (IRBs) play this role, and are legally mandated with approving studies only when "[the r]isks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result" (45 CFR 46 § 111). But although this much is generally agreed upon, both national regulations and commonly cited international documents give little further elaboration. Nonetheless, existing frameworks generally agree on the following steps.[5]

First, an REC must determine whether the benefits of participation outweigh the risks for participants. The most influential approach to making this determination involves comparing the direct benefits associated with receiving the intervention under study against the full risks of participation.[6] In singling out direct benefits, this process ignores any indirect or "inclusion benefits," benefits which are associated with participation but independent of the study intervention itself—such as free, high-quality ancillary care, the psychological benefits of altruism, and/or any payments received.

If the expected direct benefits of participation outweigh the total risks, then the protocol is *net benefit*. By contrast, if the risks outweigh the benefits, the protocol is *net risk.* If those net

[5] Rid, A. & Wendler, D. (2011). A framework for risk-benefit evaluations in biomedical research. *Kennedy Institute of Ethics Journal* 21(2): 141-79.
[6] King, N. & Churchill L. (2008). Assessing and comparing potential benefits and risks of harm. In Emanuel E. J., Grady C., Crouch, R. A., Lie, R. K., Miller, F. G., and Wendler, D. *The Oxford handbook of clinical research ethics.* Oxford NY: Oxford University Press.

risks exceed an absolute upper threshold, unspecified for adults and specified and low for minors, then the study is not approvable regardless of other considerations. Otherwise, the REC should proceed to compare the sum of net risks to participants against the benefits of running the research to society. If the benefits "outweigh" the risks, or if the relation between them is "favorable," then the study is approvable; if not, it isn't.

The decision not to count inclusion benefits—and *a fortiori*, payment—as a benefit capable of cancelling risks means that some studies that would be approvable instead aren't. This is true even if researchers would like to offer them, and participants would like to enroll. What justifies that restriction?

3. Risk-Benefit Analyses and Participant Interests

First ask: why should RECs be in the business of regulating research's risks and benefits *at all?* Wertheimer's answer is that regulating studies' risk-benefit profiles is an instance of justified paternalism.[7] He prefers a *soft* paternalist justification: medical research is technically complex, and subjects are likely to suffer misunderstandings: as a result, even the apparently voluntary consent may fail to genuinely reflect the participant's values. Still, despite preferring a soft paternalist justification, he also recognizes the availability of *hard* paternalist rationales: perhaps some choices are just too imprudent to allow.

Regardless, Wertheimer holds that *both* justifications involve RECs taking it upon themselves to promote subjects' good in one way or another—either by ensuring their choices are truly autonomous, or just by forbidding imprudent, harmful choices directly. But neither

[7] His discussion is focused on the United States and thus he asks about "IRBs." I use "REC" as a more general term for the same entity.

justification can explain why IRBs should ignore payment. Not only is seeking payment an obvious ground for a fully autonomous choice, it is also prudent to seek and beneficial to receive.

Take a study which would fail a standard risk-benefit assessment, but where counting payment would properly leave it as net beneficial for participants. If an IRB refuses to approve such a study, it denies potential participants the chance to realize what is by description a beneficial opportunity. But *no* form of paternalism supports denying people access to beneficial opportunities.[8]

Importantly, the thought that payment is a benefit and should be counted as such is still compatible with maintaining that RECs must minimize the potential for undue inducement. Doing so with respect to study payments requires assessing whether specific monetary awards are so significant that they're likely to dazzle potential participants in ways that lead to distortions in their reasoning, for instance by causing them to fail to notice important information about risks and burdens. This mandate to prevent undue inducement is simply orthogonal to whether payment is a benefit. After all, people can also be unduly induced by the prospect of *medical* benefit, e.g., by the hope for otherwise unobtainable improvement in their conditions. There is no *special* issue here to justify the standard view's distinction.

4. The Objectivity of Assessment: Health vs. Money

Why would anyone think RECs *shouldn't* count inclusion benefits? King and Churchill have argued, influentially, that although inclusion benefits are indeed relevant to individuals' personal deliberations, REC review is both "logically" and "temporally" prior to enrollment

[8] Wertheimer explicitly says as much, though he also muddies the water a by relying on soft paternalism in his response to the "objective interests" objection. Wertheimer op. cit. note 1, p. 112.

decisions. [9] REC review is conducted before enrollment opens, so they do not have access to individualized information about potential enrollees. Instead, they must understand the risks and benefits of the study in a way that will be objectively valid across the whole population that meets eligibility criteria. But inclusion benefits are idiosyncratic. For instance, some people experience the extra attention that comes with frequent study visits as a benefit, yet others may experience it as a burden. Although they allow that *some* inclusion benefits may indeed be universally valued, they claim their value-sensitivity generally marks them out from medical risks and benefits.

Whatever plausibility this argument has for marginal or particularly value-sensitive inclusion benefits, it is less plausible when applied to payment. Payment is quite generally valued. Granted, it is too simple to assume that payment is *only ever* desirable, as participants may sometimes prefer to act out of more pure intrinsic motivations. For instance, one study shows a small monetary incentive significantly suppressing blood donations.[10] But the evidence on the crowding out effects of payment mixed, even just in the case of blood donation.[11] With respect to research itself, participants report do report payment as a motivation—particularly for healthy volunteers.[12]

Still, it might be argued that even if money is widely valued, the precise *amount* that any given individual values money is still too variable for RECs to meaningfully estimate. For his part, Wertheimer allows that trying to balance medical risks against financial benefits is difficult

[9] They in fact offer three arguments. I leave the other two—that counting incidental benefits could allow researchers to balance out gratuitous risks, or that it might induce bad differences between clinical care and research—as already adequately addressed by Wertheimer. King & Churchill, *op. cit.* note 6.
[10] Lacetera, N., & Macis, M. (2010). Do all material incentives for prosocial activities backfire? The response to cash and non-cash incentives for blood donations. *Journal of Economic Psychology* 31(4): 738-48.
[11] Chell, K., Davidson, T. E., Masser, B., & Jensen, K. (2018). A systematic review of incentives in blood donation. *Transfusion* 58(1): 242-54.
[12] Grady, C. (2005). Payment of clinical research subjects. *The Journal of Clinical Investigation* 115(7): 1681-87.

because they are different kinds of thing. But he responds that it is no harder than other tasks they must undertake anyway.[13]

In my view, that response is too concessive. It appears to begin by conceding that medical-financial comparisons face a special difficulty that medical-medical comparisons don't. But it is worth asking: what is it even supposed to *mean* to compare two health risks? Is comparing the severity of different health risks like comparing the length of two rods, or the weight of two blocks? Weights and distances are real, and their relative amounts are given by the world. But even if there is some underlying objective reality ranking the healthiness of different conditions of people *qua* human organisms, it's dubious that it's what we care about with respect to our health. For instance, dyslexia is the same objective condition regardless of whether one lives in a literate or illiterate society, yet how it matters to us is clearly not fixed regardless.[14]

Rather, *the way that health matters to us* is most rigorously and systematically captured by summary measures of health-related quality of life. These measures map diverse health states onto a common scale, thereby enabling comparative assessments of "how bad" different conditions are (for instance, by scoring conditions according to "QALYs," or quality-adjusted life years).

But how does anyone decide exactly what quality level to assign a given condition? Current summary measures use surveys deploying preference elicitation tools, asking, for instance, what chance of death a people would be willing to assume in exchange for being cured

[13] i.e. comparing personal risks and benefits against social value, which are also comparisons of different kinds of thing, Wertheimer *op. cit.* note 1, pp. 112-113.
[14] Compare with Hausman's reconstruction of an argument due to Broome. Hausman, D. (2015). *Valuing heath: well-being, freedom, and suffering.* New York: Oxford University Press, 66-68.

of something. Under some further assumptions about respondent values, direct queries of a tractable number of health states yield an implicit valuation of hundreds of thousands more.[15]

This methodology renders health risks commensurable with monetary ones in both an obvious way and a subtle way. The obvious way is that such measures are used in cost-effectiveness analysis to literally put a price on health: the point of quantifying health gains is to rationalize payments. But the more subtle way is this: although the survey questions which inform summary health measures ask respondents *about* health states, what they *measure* is those respondents' preferences across those states. They could just as well ask about their preferences across other kinds of state and, e.g. monetary ones, and in principle return equally valid results.

Concretely: a person's answer to *what chance of death would you be willing to accept to cure a limp in one leg that moderately limits your mobility and causes minor chronic pain?* tells you something about how bad they think that condition is, relative to not having that condition. But, by the same token, so too does person's answer *what chance of death would you be willing to accept if doing so came with a million dollar check?* tells you something about how bad they think not having a million dollars is, relative to having a million dollars.

Granted, there are complications; the details of the development and validation of survey tools are beyond the scope of this paper. Still, the in-principle point is important. It establishes a burden of proof on those who advance the idea that health risks, because intrinsically similar, are more comparable with each other than with financial benefits. But what's being compared? Is it the health state itself, independently of how much anyone cares about it? If so, it's unclear why that should guide anyone's decisions, and it's also dissonant with how we handle other inter- and

[15] The Health Utilities Index 3, for instance, generates values for 972,000 discrete health states, (ibid: Ch. 5).

intra-health tradeoffs at the policy level. In instead we compare much *we value* different health states, then, well, we value different financial states too.

The widespread sense that health-health comparisons are easier than health-money comparisons may be an artifact of standardly used examples. So, for instance, I agree that trying to decide the *exact dollar amount* that a lumbar puncture is "worth" seems difficult. But the same thing could be said of suitably parallel health tradeoffs. Consider a person who is considering a course of highly toxic chemotherapy. It will either extend their life for an estimated two to three years, or fail, shortening it, and adding significant suffering from toxicities. What *exact* chance of increased survival makes treatment "worth it?" Just as with money, there is no perfectly general answer—it will depend on many aspects of a person's life situation, which is why people in that situation have protracted, difficult conversations with family and health providers. A "correct" *exact percentage of increased survival* seems neither easier to come up with nor more generally valid than a "correct" *exact dollar amount*.

Fortunately, RECs don't need a complete theory of how to trade off money and health. They only need to make the specific comparisons in front of them. Those need not be precise, and sometimes may be quite easy. So, for instance, when it comes to comparing health to health, it seems clear that a broken finger is, *ceteris paribus*, less bad than a broken arm is bad. But similarly, when it comes to comparing health to money, it seems clear that the discomfort of a blood draw is, ceteris paribus, less bad than $100 is good. There's no reason an REC would need to struggle with *either* judgment. Regardless, they seem on a par. In either case, there might be some individuals in odd life situations for whom these assessments fail: the rich may have no need for $100; a hand model may care more about their finger than their arm. But in either case,

RECs can reason ahead of time about how researchers should plan to take into account those possible edge cases.

The fact that RECs only need to be confident in the specific comparison in front of them deserves emphasis. Suppose I was wrong in my earlier arguments, and that health-money comparisons really are systematically harder than health-health comparisons. Even so, so long as an REC can confidently make *at least some* health-money comparisons, that's all they need to approve a study containing only those specific elements. And the idea that an REC could never be confident in *any* health-money comparisons is incredible. When it can do so confidently, it should be willing to make the comparison.

5. Consequences for Adults

Suppose RECs were to consider money as a benefit in at least those cases where they are adequately confident in their judgments. What would the practical consequences be? In studies which enroll competent adults, that change *might* allow riskier research to be conducted. But it also might not. It's complicated.

To illustrate, consider a study which would *fail* a standard risk-benefit assessment due to the unacceptably high net risks it imposes on enrolled individuals.[16] How high is unacceptably high? For illustrative purposes, take Miller & Joffe's proposal that nontherapeutic, solid organ

[16] Recall that having unacceptably high net risks was *one* way a study could fail a risk-benefit assessment (sect. 2). It is not the only one, however, and payment might be relevant also in other cases. For instance, it might be thought to be able to justify the risks involved in studies with no social value. It also might be thought to be able to justify the risks of studies which involve some net risk, though not so much that it would have been too high in absolute terms, and also some social value, but where the amount of social value was insufficient to justify the net risks. However, studies without social value are independently ethically controversial, and studies of the latter type are, for reasons too involved to go into here, extremely difficult to identify. Hence the decision to focus in the main on unacceptably high net risks.

removal represents a level of individual net risk which is too high to permit in research: on that view, no matter the social value doing so might produce, it is never permissible to remove a kidney purely for research purposes.[17]

The qualification "purely for research purposes" is crucial. If, in addition to providing an opportunity to learn something important, removing the kidney also produced some clinical benefit, then that benefit would also need to be weighed against the risks. A large benefit might outweigh the risks entirely. In that case, it would be perverse to forbid the procedure as "too risky." It the *net* risks *after* benefits are subtracted that are relevant to determining when risks are too high.

But once we count payment as a benefit, then payment can function the same way. Adding payment to a protocol adds benefits, and adding benefits lowers net risks. Indeed, one might think that *any* level of risk, no matter how high, could theoretically be zeroed out by just adding more and more payment. Removing a solid organ for research *could* have an acceptable risk profile, if participants were paid enough. So one might think that the practical upshot of counting payment as a benefit ends up being the abolition of risk limits entirely—at least, if the researchers' pockets are deep enough.

But there are reasons to doubt that it follows. To see why, continue imagining that we are considering a solid organ extraction, and that we hope to use payment to cancel its risks.

The payment could be large or small. If solid organ extraction is only barely above the threshold for maximum allowable individual risk, then perhaps only a small payment would be necessary to nudge it back under. But the maximum threshold is uncertain and I doubt that an REC would ever feel confident enough to make finely grained judgments in this regard. So it is

[17] Miller, F. G. & Joffe, S. (2009). Limits to research risks. *Journal of Medical Ethics* 35(7): 445-49.

more plausible to imagine *large* payments convincing reviewers that they are adequate to cancel the risks of organ extraction. But then there are two further difficulties with using large payments to counterbalance serious risks.

The first difficulty is that it is harder to make out when it is personally beneficial to trade off large sums against serious medical risks. It may be easy to say that $100 is more than enough to compensate for a blood draw, but difficult to say whether $50,000 is enough to compensate for a kidney. As before, the difficulty of making *some* medical-financial comparisons should not dissuade us from making *any*. But the issue here is that comparisons of large financial benefits against serious medical risks may systematically fall among those that RECs feel least confident in, and, worse yet, where the consequences of mistakes are most serious.

The second difficulty is that large payments are more likely to have third-party effects. Recall that the basic argument we earlier borrowed from Wertheimer holds that insofar as limits on research risks are grounded in any kind of paternalism, they ought to be oriented toward the benefit of the subject, and insofar as they are oriented toward the benefit of the subject, they ought to count payment. But this is only applicable insofar as risk limits really are about protecting the subject, and that may be true in most but not all cases. With large payments, it may be that other purposes become more salient, such as maintaining social trust in the research endeavor. Regardless of the underlying ethics, large payments for serious risk-taking may be inherently prone to producing public scandals. And the aftermath of the Jesse Gelsinger case shows how damaging scandals can be.

Beyond public trust, there are also legitimate concerns about how it would shape society were participation in high risk research generally available as an extremely lucrative form of

unskilled labor. Would unscrupulous loan sharks begin demanding their poor marks participate to pay off debts? And so on.

For my own part, in closely related context I have been convinced by Luke Semrau that the sale of kidneys for clinical use could be effectively regulated and managed in such a way as to avoid these sorts of negative social consequences.[18] If kidney sales can be managed in a socially responsible way, I don't see why research couldn't be one of the purposes for which they are bought. Hence, *pace* the above concerns, I am inclined to suspect that counting payment as a benefit would, in the end, form a reasonable ground for permitting some extremely risky research. So the point here is not to argue that it definitely wouldn't. Rather, the point is to show that it all depends on one's other views on several independently controversial topics. It's non-obvious what practical consequences follow *just* from taking payment to be a benefit—at least, that's true for studies enrolling competent adults.

6. Consequences for Children

The situation is different for studies enrolling children, which are governed by different ethical and regulatory standards. Across jurisdictions, regulations largely agree that only very low levels of net risk can be justified. For instance, in the United States net risk studies can impose at most a "minor increase" over minimal risk, and this standard is the one I focus on.

This feature of the regulations for children departs from those for adults by insisting that only personal benefits, and not broader social value, can play a role in justifying significant risks

[18] Semrau, L. (2015). The best argument against kidney sales fails. *Journal of Medical Ethics* 41(6): 443-46; Semrau, L. (2017). Misplaced paternalism and other mistakes in the debate over kidney sales. *bioethics* 31(3): 190-98.

to a given child. This choice is understandable. Children still cannot give full and voluntary informed consent for themselves. Since children cannot validate the tradeoff between their interests and others, researchers cannot impose it on them either. Instead, researchers must only offer trials which are either net beneficial to individual participants or which, at worst, impose relatively trivial net burdens.

What is a "minor increase over minimal risk?" Minimal risks are defined as those which are no greater than the risks of daily life or routine physical and psychological examinations; the size of an acceptably "minor" increase over that minimal risk is not defined. Neither standard is completely clear, but the operational consensus is one of caution.

Consider allergy skin testing. The World Allergy Organization reports the rate of systemic reaction to allergy skin testing serious enough to require epinephrine as 20 per 100,000.[19] A survey of the American Academy of Allergy, Asthma and Immunology physicians was able to identify a single fatal reaction to an allergy skin testing as having occurred in the years 1990-2001.[20] Still, a survey of chairpersons of pediatric IRBs found that 70% categorized allergy skin testing as more than minimal risk, and 27% categorized it as more than a minor increase over minimal risk.[21]

Suppose that researchers wanted to do a study that involved performing allergy skin tests on children, but which lacked any potential for direct benefit for the children being tested. Regardless of how valuable we stipulate that this research might be, the 27% of pediatric IRB

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[19] Kowlaski, M. L., Ansoegui, I, Aberer, W., Al-Ahmad, M., Adkis, M, Ballmer-Weber, B. K., Beyer, K. … Zuberbier, T. (2016). Risk and safety requirements for diagnostic and therapeutic procedures in allergology: World Allergy Organization statement." *The World Allergy Organization Journal* 9(1).

[20] Bernstein, D. I., Wanner, M. Borish, L., Liss, G. M., & the Immunotherapy Committee of the American Academy of Allergy, Asthma, and Immunology. (2004). Twelve-year survey of fatal reactions to allergen injections and skin testing: 1990-2001. *Journal of Allergy and Clinical Immunology* 113(6): 1129-36.

[21] Shah, S., Whittle, A., Wilfond, B., Gensler, G., & Wendler, D. (2004). How do institutional review boards apply the federal risk and benefit standards to pediatric research? *JAMA* 291(4): 467-82.

chairs who found skin testing to be a more than minor increase over minimal risk would find the study unapprovable.

Of course, it would be different if there were some clinical benefit associated with the test. Suppose there were enough that participation was actually net beneficial. Then the study would be approvable—as it should be! Children cannot offer their own full and voluntary informed consent, and this may prevent them from entering into—or perhaps more properly, being entered into—arrangements that sacrifice their interests in favor of the interests of others. But it would be perverse to take their inability to defend their interests and use it as grounds to exclude them from *studies that are in their interests*. Children cannot give full informed consent to be fed dinner, either, but we shouldn't let them starve.

Why should this point be any different depending on whether we are discussing health or monetary benefits? Suppose the researchers aim to offer financial benefits in exchange for the children receiving a skin test. If those benefits were sufficiently large, the result would again be a study that was in the children's best interest to enter.

Of course, the fact that children lack the capacity to manage their own affairs complicates the act of providing them monetary compensation. If one pays a child's parents, then one faces the prospect of parents using their children as a fundraising resource. To some extent, this worry may be misplaced: most parents care deeply for their children and furthermore are best positioned to make decisions about how a given sum of money might be most effectively used to aid a child. Nonetheless, it is reasonable to be leery of paying parents directly and it makes sense to avoid even the mere *appearance* of buying off parents to surrender their children.

Fortunately, there are alternatives. One is to offer in-kind gifts to the child themselves, e.g. toys, gift cards, and the like. But our topic is payment. And although in-kind gifts may

reasonably compensate some risks, it is worth exploring the more significant magnitudes of benefit that can be provided specifically by payment.

The precise vehicle for payment would depend on the legal tools available in the jurisdiction of research. Generally, compensation could be put into an instrument which only becomes available on majority and/or only releases funds to specific "worthy" expenses, e.g. education or healthcare. Trusts can be arranged in this style. Yet there are also expenses involved in establishing and managing trusts. Whether that overhead is sensible as a share of overall budgets will depend on the research.

Some creativity may reveal other options. Consider, for example, the fact that some US governmental organizations and nonprofits have begun to experiment with establishing college savings accounts for children; Maine has been offering them to every child since 2008.[22] These accounts typically start with some seed money and may include limited future matching. If researchers were able to arrange deposits, then they would be freed of the administrative and legal burdens associated with managing the money themselves. They would just need to conduct their research using a community where such accounts had been established.

Abstracting away from implementation: imagine that researchers, interested in running the nontherapeutic allergy study described above, decided to offset the risks of participation by putting $1,000 toward each participating child's higher education. Individual children's financial situations will, of course, be different (much as their health and social situations are different). Nonetheless, it is hard for me to imagine that it wouldn't be in the interests of a great many children to enroll in such a trial.

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[22] Mercer, M. (2015). *Children's savings accounts help states create 'college-going culture.'* Retrieved from http://bit.ly/1NNawCM ; Pender, K. (2019). *Newsom wants to expand programs that open a savings account for every kid.* Retrieved from: https://www.sfchronicle.com/business/networth/article/Newsom-wants-to-expand-programs-that-open-a-13638549.php

What does a $1,000 gift accomplish? One recent piece of reporting puts the average yearly tuition for an in-state community college at $3,660—factoring in room and board, the cost rises ($12,320), but factoring in grants and aid it falls again ($8,270).[23] Participating in paying research could offset the cost of education, and even partial offsets could be significant. Among full time college students in the US, approximately half are employed and approximately a quarter work more than 20 hours a week; the numbers are substantially higher for part time students.[24] Suppose a working student is fortunate enough to take home $20 an hour, after taxes. The single allergy skin test they received as a youth could offset 50 hours of work. It could be 50 hours of study; it could be 50 hours of leisure and self-care.

Perhaps the thought of children submitting to medical research in order to ease the burdens of their education is chilling. But recall: we are talking about an allergy skin test. The "minor increase over minimal" risk ceiling used in pediatric research is *extremely low.* That is why it is easy to imagine studies which are above that threshold, when payment is excluded, but where once payment is counted they become obviously net benefit. This doesn't require making complicated normative and empirical judgments trading off traumatic or long-term debilitating injuries against money—how much is that kidney worth, really?—for the sake of a child which cannot speak for themselves. I don't know precisely how much a kidney is worth, but I'm extremely confident that the discomfort involved in an allergy skin test is worth less than a thousand dollars. Furthermore, once it is conceded that it does indeed *benefit* the children, ruling it out cannot be justified in terms of any type of paternalism. As we saw in section three,

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[23] Hess, A. (2019). *Tuition at community colleges is $3,600 a year on average—but here's how much students actually pay.* Retrieved from https://www.cnbc.com/2019/04/12/tuition-at-community-colleges-is-3660-a-year-on-average.html

[24] National Center for Education Statistics. (2019). *The condition of education 2019.* Retrieved from: https://nces.ed.gov/pubsearch/pubsinfo.asp?pubid=2019144

paternalism is about promoting (one or another conception of) a person's good; one does not promote a child's good by denying that child beneficial opportunities.

This point also dispatches various further regulatory objections—for instance, the point that even if payment is counted as a benefit *generally*, there are reasons to think it still would not satisfy US regulations, which stipulate that benefits only cancel risks when they result from the same intervention. Given that the act of giving payment is not inherently part of the skin test, the above proposal may fail this test. Now, it is not fully clear how to best understand the US regulations on this point.[25] Nonetheless, once it is conceded that a trial of this form would be genuinely beneficial for the enrolled child, if the regulations nonetheless cannot be reconciled with it, then it is the regulation, not the trial, that is the problem.

7. Conclusion

People benefit from getting more money and suffer from losing it. Anyone who seriously doubts that is invited to send a substantial cashier's check to the address of the corresponding author. So: payment is a benefit. But what happens when RECs start counting it as one?

It is unclear how much classifying payment as a benefit matters to the ethics of trials in competent adults. This is because the function of counting payment as a benefit is to cancel risks, but the acceptable risk ceiling for adults is both high and vague; as argued, this introduces its own complications. By contrast, counting payment as a benefit would make an obvious difference to trials in children, where the risk ceiling is much lower and clearer. Here I think we have a highly credible case for potential "win-win" trials. Children could win, by having the

[25] Friedman, A., Robbins, E., & Wendler, D. (2012). Which benefits of research participation count as 'direct'? *bioethics* 26(2): 60-67.

chance to enroll in more-than-minor-increase over minimal risk trials which nonetheless compensated them generously enough to be net beneficial. And society could win at the same time, as paying out the cost of generous compensation could still be “worth it” in comparison to the value of the knowledge gained. The ethical and regulatory apparatus should not stand in the way of win-win trials without an extremely good reason.