

# The role of trust in pediatric clinical research

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Patients' trust as fundament for research ethics boards.

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## ABSTRACT

Trust plays a fundamental role in patients' willingness to participate in research.

Some authors have suggested that empirical findings related to trust challenge the current model of research ethics, 'because that model is primarily focused on supporting individual autonomy.' We disagree. To the contrary, we argue that patients' trust confirms the rationale and necessity for the current model of research ethics. We argue the current model consists of more than informed consent, as the consent can only be asked for after a review process by a research ethics committee.

We substantiate this statement with results from interviews we did with parents and children about their willingness to participate in research.

## PREAMBLE

The article on which this chapter was based was an open peer commentary on a target article by Kraft and colleagues in *The American Journal of Bioethics*.<sup>1</sup> Although this chapter is a commentary it can be read and understood without reading the target article.

Kraft and colleagues presented results from their focus group study about biobank research with ethnically diverse people. They focused specifically on how to build long-term trusting relationships with participants. They discussed four points of consideration: 1) addressing the history and the role of trust; 2) tackling concerns about potential group harm; 3) addressing cultural values and communication barriers; and 4) integrating patient values and expectations in oversight and governance structures.

In this commentary we corroborated their empirical findings on trust, as we found similar results in our interview study. However, we drew different conclusions from these results. They state that their findings concerning patients' trust challenge the current model of research ethics; we think it rather underlines its importance.

## INTRODUCTION

Kraft and colleagues make a convincing plea for the importance of trustworthiness and trusting relationships between patient-participants and research professionals in medical research in their interesting article.<sup>1</sup> We do however not agree with the authors that their findings concerning patients' trust challenge the current model of research ethics, 'because that model is primarily focused on supporting individual autonomy'; to the contrary, we think it underbuilds the current research system.

Although Kraft and colleagues specifically researched trust in biobank research among ethnically and culturally diverse groups, we also found trust to be of major importance in an average Dutch population who were asked for participation in a clinical trial.

We interviewed parents and their children about their willingness to participate in clinical research, after observing informed consent conversations between them and research professionals. We wanted to know: what motivated them to participate, and what influenced their decision? Trust was one of the main issues that was put forward by them as an influencing factor. In this commentary we want to share our results and corroborate the results presented by Kraft and colleagues. But we also want to point out that we draw partially different conclusions from these results.

## TYPES OF TRUST INFLUENCING PARTICIPATION

In our own empirical research we asked over 30 parents and children what motivated them to consent or dissent to the clinical trial proposed to them. Together with anticipated burden and altruistic reasons, trust was mentioned by them as one of the most important factors influencing their decision and willingness to participate. We therefore completely agree with Kraft and colleagues that trusting relationships are very important in medical research.

Kraft and colleagues identified the trustworthiness of physicians, researchers, health care system, government and corporate institutions as important condition for ethnically and culturally diverse participants' willingness to participate in precision medicine research. Even though our own research was in a very different population and setting (Dutch parents and children asked for participation in a clinical trial), we identified identical types of personal trust and institutional trustworthiness influencing their decision.

### PERSONAL TRUST

As the authors address, we also found a type of personal trust, directly linked to the researcher. For many (chronically ill) patients, a personal relation with the researcher influences their decision to participate (table 1).

**Table 1:** Example personal trust

Participant	Quote
Mother (age 52)	<i>I just trusted his judgment. I asked him: 'what would you do in my place?' He then answered 'start immediately'. I just completely trusted that answer.</i>

For a potential participant to actually trust the researcher, it means that they believe that the researcher has designed and will conduct the research in their best interest. In a way they 'surrender' their health to the research professional.<sup>2</sup> This sense of trust is closely linked to the doctor-patient relationship, and therefore not entirely without moral problems. Patient-participants do not always distinguish the separate roles of their treating physician and research professionals. Their treating physician should act in the best interest of the patient, but for research professionals other interests are also at stake. Although a research professional will always need to minimize burden and risk and avoid harm to the participants, that does not mean that participation is always in the best interest of the patient. This physician- and research-role can conflate in practice and then potential participants' trust is not always based on correct assumptions. It is the responsibility of the researcher to make this distinction clear, so that the personal trust participants have in them is legitimate.

## INSTITUTIONAL TRUST

Second, our potential participants' willingness was also influenced by institutional trustworthiness. For example, for some respondents, the fact that a study was done with international collaboration or an academic hospital, enhanced their trust (table 2).

**Table 2:** Example institutional trust

Participant	Quote
<b>Father (age 48)</b>	<i>That the study was done internationally played a big role, so yes, then you already have faith in it. If it were a study of just the [x]-hospital, their own in-hospital research, that would be a different picture.</i>

For this type of trust it is not so much the personality of the individual researcher that influences the decision of the potential participant, but the characteristics of the institute in itself (e.g. international collaboration is better, academic hospital is better).

## TRUST IN RESEARCH IN GENERAL

We also found that potential participants' trust can be linked to a trust in research in general. We quite frequently encountered a positive stance towards research and an optimism regarding the possible benefits: 'what is being investigated is new, and what is new, is better' (table 3).

**Table 3:** Example trust in research in general

Participant	Quote
<b>Boy (age 16)</b>	<i>They're, of course, not going to do something they think does nothing. A lot of people believe that this is better</i>

We consider this form of therapeutic optimism (or maybe even therapeutic misconception, since research should be based on clinical equipoise), as an expression of trust in research. Potential participants can believe that research means progress and conclude from that, that new/experimental is always better. This type of therapeutic optimism and the link to trust is also identified and emphasized by other authors.<sup>3</sup> It is crucial that research professionals are realistic about the rationale of the study and its anticipated benefits and do not to take advantage of this type of trust.

## TRUST IN OVERARCHING SYSTEM

The last type of trust we identified, also in line with the authors' results, is trust in the overarching system. Our respondents told us that they expect that immoral and unsafe research would not be allowed and offered to them, and that any research that is allowed in an academic hospitals such as ours, must therefore be safe (table 4).

**Table 4:** Example trust in overarching system

Participant	Quote
Father (age 48)	<i>Of course, there are some risks attached, but even so, once they're testing on humans a lot of steps have been made towards this point, so it'll be safe</i>

You could say that by this type of trust they outsource their concerns about risks. They assume the research that is offered to them is adequate and safe, otherwise it wouldn't be offered to them; and they expect that processes are in place that protect them.<sup>4</sup> This trust in an overarching system, a type of institutional trust as Kraft and colleagues call it, shows the importance of the ethical review system and the 'filtering' role of research ethics committees (RECs).

## FILTERING ROLE OF THE RESEARCH ETHICS COMMITTEE

As presented above, we found in our own research results parallel to those by Kraft and colleagues. Our conclusions differ, however. They state that their results challenge the current model of research ethics, *'because the current model of research ethics...focuses primarily on supporting individual autonomy'*.<sup>1</sup> We conclude the opposite: The trust that patient-participants have in the overarching system actually confirms the rationale and necessity for the current model of research ethics and the importance of RECs.

Consensus exists about the primary role of RECs to protect participants, whilst not standing in the way of advancing science. However, according to some, there is a threat of RECs being overprotective and acting as a gatekeeper to filter research.<sup>5-7</sup> Several authors have argued that this 'filtering' role gives RECs the inappropriate capacity to prevent research from being conducted, since participants, as long as they are competent, are best placed to decide on what are appropriate risks when deciding whether to take part in research.<sup>8</sup> We argue, based on the results presented above, that this filtering is a legitimate and even fundamental task of a REC.

In order to deserve the trust that patients have in the system (allowing only morally and medically acceptable research), the 'filtering' role of a REC is crucial. A REC needs to make a decision whether a specific research protocol is scientifically and ethically adequate before it can be proposed to potential participants. This filtering task is moreover laid down in important ethical and legal rules and legislation, like the Common Rule and the Declaration of Helsinki.<sup>9 10</sup> Our research shows potential participants assume that this filtering has taken place; they rely on the filtering by the REC. In this way they outsource a part of their decision-making process to the REC.

## CONCLUSION

We therefore do not agree with the authors that autonomy seems to be the only important element in research ethics, nor that it should be. Of course, respecting autonomy, by making sure every potential participant has given informed consent, is a cornerstone for research ethics, but it is not the whole building. Kraft and colleagues' results, combined with the results we just presented, concerning patients' trust emphasize this.

Informed consent can only be given after a REC has evaluated the protocol and executed their legitimate filtering role. The large influence that patients' trust has on the decision of potential participants emphasizes the necessity of this prior review of a REC and its filtering task.

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