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LETTERS

Is a requirement of personalised assent realistic? A case from the GABRIEL project

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Giesbertz *et al*'s[1] recent report regarding children decision-making status in paediatric research presents the interesting concept of personalised assent. The authors provide an excellent illumination of one of the aspects of paediatric research, among the many issues in the field of the regulation of research participated in by children which continue to await a meticulous study. There is a continued lack of a full explanation for many issues, including dissent, minimal risk, and the definition of same-population.

The participation of children in biomedical research is limited by many restrictions intended to guarantee them the greatest possible degree of safety. One of these methods is traditionally assent. However, Giesbertz *et al*[1] claim that this interpretation is incorrect. Better than assent in providing protection from harm are parental informed consent, strict regulations about acceptable risk, respect of dissent, researchers' integrity, and a high quality of RECs assessment. The authors argue that above all assent has educational value (as it fosters autonomy), and can also be an instrument making the communication of researchers with the child easier.

I have two doubts concerning this interpretation of the titular term. First, it assumes a positive, correct relationship of the children with their parents or guardians. Where this is not the case – in families in which the parent exploits the child – assent can still provide a form of protection. Yet, in this case, it will protect not so much from harm as from possible exploitation. Second, the idea of personalised assent with the idea of possible recontact and reconsent added seems rather unrealistic. In the EU itself, both the organisation and the differentiation of protocol assessment by RECs means that such a recommendation would be very hard to fulfil.[2]

Let me give one example. An article was recently published on the participation of children in one of the stages of the Gabriel project. This large-scale genome-wide association study of asthma took place in 14 European countries. The part of the research carried out in Poland involved taking blood samples, nasal swabs, and prick skin tests. The research was conducted in schools located in rural areas and small towns. The Polish part of the study was also accompanied by an additional one on opinions about participation in medical genetic research, in which 706 children aged 6–14 years took part.[3] This study showed that during the Gabriel study, no child was asked to express assent within the official study protocol. Only 42% of them were informed by their parents or the researchers about the genetic research in which they were to take part. Only slightly over half of them were asked by their parents for their opinion regarding participation. overall, 31% received no information on the study. All the children stated that in their opinion both parental consent and the child's assent to the research should be expressed.

I therefore believe that the good idea of personalised assent should be complemented with a clear and unambiguous recommendation as to the age of a child from whom assent should definitely be obtained. Further discussion and research is needed in order to ascertain this age.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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1 Giesbertz NA, Bredenoord AL, van Delden JJ: Clarifying assent in pediatric research. *Eur J Hum Genet* 2013; e-pub ahead of print 12 June 2013; doi:10.1038/ejhg.2013.119.
2 Waligora M: A European consistency for functioning of RECs? We just lost our chance. *J Med Ethics* 2013; **39**: 408–409.
3 van der Pal S, Sozanska B, Madden D *et al*: Opinions of children about participation in medical genetic research. *Public Health Genomics* 2011; **14**: 271–278.

Reply to Waligora

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We kindly appreciate the chance to reply to Waligora's[1] comments on what we call personalized assent. Assent understood from an engagement point of view does justice to the specifics of childhood. In practice, this can be translated into personalized assent, which means that both the process and the content of the assent procedure are dynamic and adjusted to the individual child and research context.[2]

Waligora[1] expresses two doubts concerning personalized assent. First, he argues that a positive relationship between children and their parents is assumed, as assent can provide protection against exploitation. Even if assent would offer some form of protection against exploitation by parents, we do not think that it alters our interpretation of assent. Assent from an engagement perspective gives rise to the moral obligation of the researcher to involve the child,