

Our two points are relevant to the Any Comments section, but the second could also be applied to Question 11 “Do you think the current regulations strike the right balance between promoting clinical research in children, protecting child participants, and involving children in decisions about their own participation? What (if anything) would you like to change?”

1. In research all participants need to be protected. However, with children it is doubly conflicted as often the adults might not be able to understand the key issues let alone be able explain them to their children. So in the absence of a funded way forward of transparent full informed consent the Hippocratic test must stand; ‘first do no harm’. In essence, if any harm possible either physically or psychologically we should not carry out the research. In addition, once a study is finished all material should be fully anonymised or destroyed.
- 2.
3. Research related to wellbeing and service provision of children with complex needs – learning difficulties, mental health issues, from excluded families, or looked after children – can easily be hampered by research restrictions designed for research into potentially harmful drugs etc. These barriers can make what could be very inclusive, empowering research aimed at finding answers to complex service problems, expensive and difficult to carry out in a cost-effective way. We need governance procedures which actively facilitate real involvement of children, families, carers and communities in research into health and social care research designed to 1) gain a deep and accurate understanding of problems and potential solutions, 2) develop potential solutions into individual and service level interventions and 3) evaluate such interventions robustly.