



Consultation Response

Review of the regulation and governance of medical research

Academy of Medical Sciences

Response by Genetic Alliance UK

Introduction

1. Genetic Alliance UK (formerly Genetic Interest Group) is the national charity supporting all those affected by genetic conditions. Genetic Alliance UK aims to improve the lives of people affected by genetic conditions by ensuring that high quality services and information are available to all who need them. Our membership represents more than 130 voluntary organisations working for a wide range of conditions, many of which pose complex health and social care needs.
2. Genetic Alliance UK speak from the perspective of those who look toward research as a means to deliver effective therapies for currently untreatable conditions. We welcome this review and the opportunity to respond.

Proposals to dissolve the Human Fertilisation and Embryology Authority and the Human Tissue Authority


3. The Arm's-length bodies review announced plans to dissolve both the Human Fertilisation and Embryology Authority (HFEA) and the Human Tissue Authority (HTA). Genetic Alliance UK views the work of both of these organisations with a great deal of interest, and values the insight and expertise that these organisations hold. The organisations have a number of similarities: they were both set up by statute, and they both regulate in a number of areas, including in both cases research.
4. Genetic Alliance UK's interest in the work of both of these bodies is not solely with their research regulating function. They are both involved in the regulation of certain healthcare procedures that interest us and our members. In the case of the HFEA it is in preimplantation genetic diagnosis (PGD); and in the case of the HTA our interest includes cord-blood collection, storage and use.
5. These healthcare regulating functions are not housed within these bodies arbitrarily. Their regulation requires expertise in fast changing fields of technology, and it is the view of Genetic Alliance UK that both the HTA and the HFEA have accumulated a great deal of knowledge and regulatory experience that allows them to regulate these areas sensibly and sensitively.
6. We have great concern with proposals to disband both the HFEA and the HTA and house their "healthcare regulating" roles in the Care Quality Commission (CQC) because of the likelihood of losing expertise and regulatory experience.
7. The function of the HFEA in licensing for preimplantation genetic diagnosis on a condition-by-condition basis, and in the case of preimplantation tissue typing for the conception of a "saviour sibling" a case-by-case basis, is a perfect example of this. This is not regulation of healthcare

provision, with an agreed set of rules and regulations to be adhered to; neither is it research regulation. The licensing committee of the HFEA makes an ethical decision on whether to permit a healthcare procedure.

8. It is the view of Genetic Alliance UK that the HFEA benefits from its expertise gained from involvement in the broader field of embryology in making decisions about its use for preimplantation genetic diagnosis. We would have serious concerns with any proposal to grant responsibility for decisions on PGD licensing to a body lacking in this experience and in experience of ethical decisions such as these.

The need for proportional regulation of research

9. As we stated in our response to the first call of evidence by the Academy of Medical Sciences, regulation is a major burden to smaller research projects, often funded and/or run by patient organisations.
10. Genetic Alliance UK's most recent experience of the frustration and waste of resources that can arise from research ethics approval and research governance is with a project named RAPID (rapid.nhs.uk), for which we intend to carry out research into patients' attitudes to non-invasive pre-natal diagnosis.
11. A three day-a-week part time post to carry out this work was filled by an experienced research officer, who had carried out the research ethics approval process and research governance within the NHS previously. The application process began in January 2010. One research ethics committee (since disbanded) rejected our proposals to interview patients on their views. Our appeal was waved through with mystification as to the reasons for failure, and ethical approval granted. This process took six months
12. The site specific research governance procedures are ongoing in September 2010, and no research work has yet been possible. Ethical approval and research governance for this three year project has taken a quarter of the time and funds allocated to the project. An organisation with less experience and resources than Genetic Alliance UK would most likely fail to deliver research outcomes if they were to enter into a similar research project.
13. Procedures governing research in the UK need to be proportional. Small scale research projects carried out by patient organisations should not be subject to the same regulation as large scale invasive clinical research.



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