

Consultation Response

Consultation on regulations to implement the Human Fertilisation & Embryology Act 2008

Department of Health

Response by the Genetic Interest Group



The Genetic Interest Group (GIG) is an umbrella organisation working for more than 130 member groups, who support patients of inherited conditions and their families. Many of the conditions represented by our member groups are incurable and intractable, with no cure or treatment on the horizon. GIG speaks from the perspective of those who have a keen interest in the undertaking of high quality ethically sound biomedical research into the links between genetics and human health and disease, and the prevention, cure and/or treatment of such disease.

GIG is therefore primarily concerned with Proposals 8, 9, and 10 of the consultation on regulations to implement the Human Fertilisation & Embryology Act 2008.

Preimplantation Genetic Diagnosis (PGD) is a vital tool for the prevention of genetic disease. As an extension of the In Vitro Fertilisation (IVF) process, PGD inevitably delivers a relatively low pregnancy rate. It is further complicated by technical issues arising from the diagnostic process. This technology will benefit from research using the data on use of PGD held by the HFEA. GIG is therefore interested in this research being made possible, whilst the confidentiality of the patients involved is protected.

GIG approves of proposals 8-10, particularly the involvement of the Patient Information Advisory Group, provided they are given assistance on technical matters by the HFEA where necessary.

However, there are two regulations that seem to deliver difficulties to parties making research proposals:

- Regulation 8 states that applications will be refused if the research does not have ethics committee approval. GIG understands that ethics committee approval may be withheld in cases where the researcher has not obtained permission to use data for research; thereby creating a situation where a researcher may not be able to satisfy the HFEA or a research committee, due to one party requiring prior approval from the other party. This problem appears to be minor, and could be solved with a conditional approval arrangement.
- Regulation 11 states that there is a three year maximum period for a single authorisation. This time frame seems too short to allow any research project to proceed in its entirety without necessitating a renewal of its authorisation. Further, it appears that a research group would have to continue to renew its authorisations to be able to refer back to original data from previous research projects when continuing their work. Provided proper data protection arrangements are observed, GIG would propose a loosening of this condition.

The Genetic Interest Group is grateful for the opportunity to comment on these proposed regulations, and would be happy to comment further if necessary.