



Making life better for people  
with genetic disorders.

Unit 4D, Leroy House  
436 Essex Road  
London NI 3QP

Tel: 020 7704 3141

Fax: 020 7359 1447

Email: [mail@gig.org.uk](mailto:mail@gig.org.uk)

Website : [www.gig.org.uk](http://www.gig.org.uk)

Professor the Lord Darzi of Denham KBE  
Department of Health  
Richmond House  
79 Whitehall  
London SW1A 2NS

25<sup>th</sup> January 2008

Dear Lord Darzi,

The Genetic Interest Group (GIG) is an umbrella group for patient organisations supporting patients of inheritable conditions and their families. The majority of the conditions that these patient organisations represent are without cure or treatment; they therefore look toward innovative biomedical research with hope and expectation for the delivery of cures and/or treatments.

Great Ormond Street Hospital for Children NHS Trust (GOS), and the UCL Institute of Child Health (ICH), are the largest centre for research into childhood illness outside the United States. They treat and research many children with rare complex and life threatening disorders. The institutions are committed to the principle that children should be involved in decisions about, and consent as they have capacity, in both treatment and research.

### **We write in regard to Lord Patel's amendment number 76 to the HFE Bill.**

The HFE Bill currently makes no provision for the collection of somatic cells from children for the purpose of Somatic Cell Nuclear Transfer (SCNT) to create embryos for research, unless the children concerned are themselves competent to give their consent. GIG and GOS/ICH would like the Government to reconsider its position on this point for these reasons:

- Research in this area is critical to the development of cures and treatments for life-limiting childhood diseases.
- All research in the UK is governed under the robust framework provided by COREC, including proper procedures for securing informed consent from parents/guardians where children are concerned.
- We believe the regulatory framework provided by the HFEA and the HTA is sufficient to protect against misuse of children's genetic material.

For many of the conditions that GIG supports, a child with the condition will never itself reach competency, and will never be able to give their own consent:

- Children with Tay Sachs will die by the age of six. Tay Sachs is a progressive neurological disease caused by a lysosomal storage disorder.

- Children with the most severe form of Spinal Muscular Atrophy (Infantile SMA or Werdnig-Hoffmann disease) will die at around twelve months of age.
- Children with Batten Disease will begin to show symptoms between five and ten years of age. By their mid-teens, they will have become blind and suffer severe dementia (and are therefore unlikely to demonstrate Gillick competence). They will normally die before they reach the age of twenty.
- The brains of children with severe forms of Lissencephaly do not develop normally beyond about six months of age. They will most likely die of respiratory failure.

Research using SCNT allows cells with the condition under investigation to be examined live in vitro. This is vital in furthering our understanding of the disease mechanism, and thus underpinning research into suitable treatments or cures. Additionally, at the June 2007 conference of the Jennifer Trust (one of GIG's members), Dr Stephen Minger, an internationally prominent stem cell scientist at King's College London, explained that he felt the most important use for stem cell technology for Spinal Muscular Atrophy was in testing potential therapies. This would require cells obtained through SCNT.

In the UK, the burden of consent for health and research rests with a child's parent or guardian until they reach competency. Parents or those with parental responsibility may, for example, consent to high-risk surgery on behalf of their child and to clinical trials, which involve experimental interventions. SCNT by comparison is a very low risk procedure.

The Bill, as it stands, imposes a barrier to one of the most potent tools for research into the most severe childhood diseases. Given the existing regulatory framework that provides for proper informed consent procedures where children are concerned, there is an overwhelming moral argument for the Bill to be amended so that consent is brought into line with other health and research activities.

**Both the Genetic Interest Group and Great Ormond Street Hospital / Institute of Child Health would like to see this barrier to the development of cures and treatments for serious life-limiting childhood disease lifted.**

Yours sincerely,

**Alastair Kent**

Director, Genetic Interest Group

**Dr Jane Collins**

Chief Executive, Great Ormond Street Hospital for Children NHS Trust

**Professor Andrew Copp**

Director, UCL Institute of Child Health

CC:

Baroness Royall of Blaisdon

Lord Naren Patel

Dawn Primarolo MP