

Dr. Sue Mayer
Director
Genewatch UK
The Mill House
Manchester Road, Tideswell
Buxton, SK17 8LN

17 November 2004

Dear Dr Mayer

Request for information on research application RO152

Thank you for your letter dated 11th October 2004.

In note your request for disclosure of information in relation to the above research application under the Code of Practice on Access to Government information ("the Code"). I can respond to your request as follows:-

1. The Application for Research

The Authority seeks and receives applications from licensed centres on the basis that they will be treated as confidential. Paragraph 3 of the standard licence application form makes it clear that, but for the lay summary, all other information provided in the application remains confidential.

The Authority has a statutory duty to keep confidential all information "obtained by any member or employee of the Authority on terms or in circumstances requiring it to be held in confidence"¹.

However, in this particular case the centre has consented to the disclosure of the application, therefore enabling the Authority to lawfully disclose it. Copies of both the application and further representations submitted by the centre are enclosed.

¹ Section 33(2)(b), Human Fertilisation & Embryology Act 1990

2. Opinions on the application from two peer reviewers

I am enclosing with this letter, copies of the anonymised opinions of the two peer reviewers and the centre's comments on them. The reviewers were asked to review the application and comment on the project's merits covering:

- Whether the research fulfils at least one of the categories for which embryo research is permitted
- The importance of the research in the field
- Whether research has been done before
- Whether the research requires human embryos to fulfill its aims and objectives
- Whether the research requires the numbers and types of embryos outlined in the application
- The suitability of the methods
- The length of the study
- The applicant's qualifications

As you will see, the Authority received the report from the first peer reviewer on 1st May 2004. The reviewer considered that the research fell within the 3 purposes set out in the Human Fertilisation and Embryology (Research Purposes) Regulations 2001, namely that the activities were necessary or desirable for the purpose of:

- (i) increasing knowledge about the development of embryos,
- (ii) increasing knowledge about serious disease, or
- (iii) enabling any such knowledge to be applied in developing treatments for serious disease.

The first peer reviewer's overall assessment was that the application be 'accepted in its current form'. The reviewer did raise a number of issues mainly relating to the submission of more detailed protocols. The issues raised by the first peer reviewer were sent, in an anonymised form, to Professor Murdoch on 17th May 2004. Professor Murdoch submitted the centre's response to the issues raised by the first peer reviewer to the HFEA on 1st June 2004. This response was subsequently forwarded to the reviewer on 1st June 2004. The peer reviewer did not wish to provide any further detailed comment given the peer reviewers existing recommendation that the application be accepted.

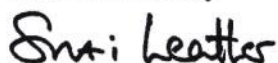
The Authority received the report from the second peer reviewer on 21st May 2004. The second peer reviewer also concluded that the proposed research fell within the same 3 purposes under the 2001 Regulations. The second peer reviewer recommended that the application be 'accepted in its current form' but also raised a number of issues, mainly relating to the fact that the methodology

contained in the original application was vague and more detailed protocols should be submitted. The issues raised by the second peer reviewer were sent, in an anonymised form, to Professor Murdoch on 24th May 2004. Professor Murdoch sent the centre's response to the issues raised by the second peer reviewer to the HFEA on 1st June 2004. This response was subsequently forwarded to the reviewer on 1st June 2004. The second peer reviewer responded on 2nd June 2004 confirming that the peer reviewer was satisfied with the centre's response.

3. Minutes of the licence committee meetings on 16th June and 3rd August 2004

I enclose the licence committee minutes for 16th June and 3rd August 2004.

Yours sincerely

A handwritten signature in black ink that reads "Suzi Leather". The signature is written in a cursive, slightly stylized font.

**Suzi Leather
Chair**