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Ross Thacker

From: [REDACTED]
Sent: 01 June 2004 18:12
To: Chris O'Toole
Subject: Re: HFEA

The bottom line was that I recommended that a licence be granted even with what was previously submitted. I don't care to comment in detail on their response.

j

On Jun 1, 2004, at 11:40 AM, Chris O'Toole wrote:

Dear [REDACTED]

Thank you for reviewing the application from the International Centre for Life in Newcastle upon Tyne, United Kingdom who has applied for a licence to derive stem cell lines from embryos created through cell nuclear replacement.

In your review you raised a few queries which have been feed back to the centre, anonymously. I have attached a copy of the centre's response and I would be grateful if you would comment on whether they have addressed all of your initial concerns to a satisfactory standard. If possible, would you let me have your comments by 7

th June 2004.

Applicant: Dr Miodrag Stojkovic

Title of the project: Derivation of Human embryonic stem cell lines using nuclear transfer and parthenogenetically activated oocytes

Area of research

This proposal falls into 3 categories contemplated in the Act:

- 1- to increase the knowledge of developing embryos;
- 2- to increase knowledge about serious disease;
- 3- to enable such knowledge to be applied in the developing of treatments for serious diseases.

Importance

This reviewer considers this proposal of outmost importance to address the categories listed above.

Originality

At the time the applicant submitted this proposal there was no other report on this work. Currently there is one original article showing the generation of ES cells from a somatic cell in humans. However, this work must be repeated. The applicant also proposes to develop parthenogenetically derived human ES cells, this work has not been reported. This proposal then covers unique areas of research that must be explored further.

Justification

Yes, this work must now be done in human. Animal work has already been done extensively and proven to work.

Creation of embryos for research

There is no other alternative for this work. Human embryos must be created.

Methodology

Objectives are clear. Methodology is vague. This reviewer would have liked to see more information on specific experimental protocols to be used. Given the experience of the PI one can assume that these 'unspecified' protocols will be used. However they are not stated in the proposal.

Analysis of the results

Number of necessary gametes are given however no statistical analysis have been proposed.

Duration

Appropriate.

Applicant

The applicant has the necessary credentials to perform the work. The environment is excellent.

Overall Assessment

Accept in the current form.

Signature:

Date: