HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY

# Application for Renewal of a Licence for Treatment and/or Storage of Gametes and Embryos

| | |
|---|---|
| Centre Name | CREATE –<br>Centre for Reproduction and Advanced Technology |
| Centre Number | 0299 |
| Centre Address | 3-5 Pepys Road, West Wimbledon<br>London SW20 8NJ |
| Person Responsible | Geeta Nargund |
| Nominal Licensee | Professor Stuart Campbell |
| Date of Current Licence Expiry | 31.07.2009 |

The completed form should be returned to:

Human Fertilisation and Embryology Authority,
21 Bloomsbury Street
London
WC1B 3HF

For guidance on how to fill in this application form and general information on HFEA licence applications please refer to ***Licence Applications - A Guide for Centres*** which is included in the HFEA *Manual for Centres.*

**1. Details of Centre**

1.1 Name of centre CREATE –Centre for Reproduction and Advanced Technology

1.2 Address:

3-5 Pepys Road
West Wimbledon
London
SW20 8NJ

Address for correspondence (if different):

1.3 Tel No: 020 89479600

Tel No:

1.4 Fax No: 020 89445800

Fax No:

1.5 Email address (if applicable): geetanargund@gmail.com

1.6 Website address (if applicable): www.createhealth.org

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**2. Corporate Information**

2.1 Is the centre a NHS facility or a private operation? (Please tick appropriate box.)

| | | | | | |
|---|---|---|---|---|---|
| **NHS only** | | **NHS/Private Partnership** | | **Private only Yes** | |

2.2 If private, please give the following information:

**i. Limited Company**
Company Name: CREATE HEALTH LIMITED
Registration No: 04103133
Registered Offices: Shah Khazemi, Herne Hill ,London

**ii. Partnership**

Names of Partners:

**iii. Sole Trader**

Name of Owner:

2.3 Is the centre registered with the Healthcare Commission under the Health and Social Care (Community Health and Standards) Act 2003 (Please tick appropriate box.)

| | | | |
|---|---|---|---|
| **Yes** | Y | **No** | |

If not, please explain why below:

(Please use a continuation sheet if required.)

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**3. Details of the Person Responsible**

Name: Geeta Nargund

Position: Medical Director

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**4. Details of the Nominal Licensee**

Name: Professor Stuart Campbell

Position: Senior Consultant and Head of Ultrasound

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**5. Details of the Accredited Consultant** (applicable only to centres carrying out IVF)

Name: Geeta Nargund

Position Medical Director

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## 6. Information about treatments to be offered

6.1 Please tick the appropriate boxes below to indicate the treatments for which the centre wishes to be licensed:

| Type of treatment | Currently licensed | Remove From Licence |
|---|---|---|
| Storage of Eggs | Yes | |
| Storage of Sperm | Yes | |
| Storage of Embryos | Yes | |
| Insemination | Yes | |
| Processing of Gametes and Embryos | Yes | |
| GIFT | No | |
| Treatment with Donor Gametes and Donor Embryos | Yes | |
| Preimplantation Genetic Screening (PGS) | No | |
| Subzonal Sperm Insertion (SUZI) | No | |
| Zona Drilling | No | |
| In Vitro Fertilisation (IVF) | Yes | |
| Procurement and Distribution of Gametes and Embryos | Yes | |
| Preimplantation Genetic Diagnosis (PGD) | No | |
| Intra Cytoplasmic Sperm Injection (ICSI) | Yes | |
| Zygote Intra-Fallopian Transfer (ZIFT) | No | |
| Chemical Assisted Hatching | No | |
| Mechanical Assisted Hatching | Yes | |
| Laser Assisted Hatching | No | |
| Non Medical Fertility Services | Yes | |

If you wish to vary your licence to include additional treatments then please refer to the HFEA website for information on the procedures required for variation.

6.2 Will the centre provide Transport or Satellite IVF services for other Assisted Conception Units? (Please tick appropriate box.)

In "Transport IVF" the laboratory work and embryo transfer will take place at your centre. "Satellite IVF" is where egg collection will take place at your centre in addition to the laboratory work and embryo transfer.

| Yes | | No | |
|---|---|---|---|

If the answer is yes, under each heading please give the name and address of each secondary centre for which your centre supplies transport and or satellite services and the name of the contact person:

**TRANSPORT**

None at the moment

**SATELLITE**

None at the moment

6.3 Please give details below of any other unlicensed treatments to be offered (e.g. ovulation induction):

Ovulation induction

## 7. Additional Information

Is there is any other information regarding your centre which you may wish to bring to the attention of the Authority which is pertinent to this application and which has not been addressed on this form?

CREATE was licensed in August 2008 and we started to offer licensed treatments from the 18th August.

I am delighted to inform the HFEA that the clinic has achieved a good success rate for the type of patient population we treat and high staff and patient satisfaction. We believe that "success of a fertility clinic" should be measured by the clinic's commitment to help couples/women to promote their natural fertility and to offer less invasive, low-cost and more effective treatments where necessary. We conduct extensive free patient and GP information sessions on life-style and prevention of infertility.

As regards to the "**success of IVF treatment**" is concerned, it should be measured in reducing risks, complications and offering low-cost, safer methods with acceptable "term live birth" rates. Our clinic emphasises on the need to put the "**welfare of the woman**" at the top of the agenda in addition to the "**welfare of child**". Therefore we use "**Mild and Natural IVF"** in most cases which helps **to reduce multiple births.**

***Following achievements since the last inspection are highlighted for your attention***:

1.We have established our own Ethics Committee consisting of a Consultant Gynaecologist & Obstetrician, Social worker, Paediatric nurse ,Counsellor, Patient representative, Scientist and Lawyer.

2. We have received no formal (1 informal) complaints from patients.

3.We have received several e mails and correspondence with positive and constructive patient feed back

4. We are setting up a patient support group.

5. We run active monthly patient open days and GP study days.

6.We have had NO cases of ovarian hyper-stimulation syndrome (OHSS)

7.We have established a policy for elective single embryo transfer (SET)

8. We have recruited highly trained and caring staff. The staff members work well as a team with excellent communication

9.We have recently recruited a third trained embryologist

10.We have also recruited an additional accredited and highly skilled consultant

11.The staff have published several peer-reviewed scientific papers in journals and spoken at many international meetings.

12. We are involved in conducting workshops in assisted conception techniques and advanced ultrasound both nationally and internationally.

The Medical director has been appointed as a Visiting Professor to two internationally renowned universities and also as the Chairperson of ESHRE Task Force on Mild ART and a member of WHO Expert Group on infertility in developing countries.

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(Please use a continuation sheet if required)

## 8. DECLARATIONS

**Persons signing this application should note that Section 18 of the Human Fertilisation & Embryology Act 1990 states that "a Licence Committee may revoke a licence if it is satisfied that any information given for the purposes of application for the grant of the licence was in any material respect false or misleading". They should also note that under Section 41(3) provision of false or misleading information, knowingly or recklessly, is a criminal offence.**

### 8.1 Person Responsible

The information provided on this form and its appendices is to the best of my knowledge true and accurate. I agree to act as the person responsible.

Signed.....Name.....Geeta Nargund.....Date.....17.02.2009.....

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### 8.2 Nominal Licensee

The information provided on this form and its appendices is to the best of my knowledge true and accurate. I agree to act as the nominal licensee.

Signed.....Name.....Stuart Campbell.....Date.....17.02.2009.....

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### 8.3 Accredited Consultant (IVF centres only)

The information provided on this form and its appendices is to the best of my knowledge true and accurate. I agree to act as the accredited consultant.

Signed.....Name.....Geeta Nargund.....Date.....17.02.2009.....

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# HFEA Research Licence Committee Meeting

15 July 2009

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 3

**CREATE Centre for Reproduction and Advanced Technology (0299)**

Members of the Committee:

Emily Jackson (lay) – Chair
Richard Harries (lay)
David Archard (lay)
Lesley Regan (clinician)
Hossam Abdalla (clinician)

Committee Secretary:
Kristen Veblen

Legal Adviser:
Sarah Ellson, Field Fisher Waterhouse

Declarations of Interest: members of the Committee declared that they had no conflicts of interest in relation to this item.

The following papers were considered by the Committee:

- papers for licence committee (36 pages)
- no tabled papers.

The Committee also had before it:

- HFEA Protocol for the Conduct of Licence Committee Meetings and Hearings
- 7th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- HFEA (Licence Committees and Appeals) Regulations 1991 (SI 1991/1889)
- Decision Trees for Granting and Renewing Licences and Considering Requests to Vary a Licence; and
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009.

1. The Committee noted that the Centre had been licensed since August 2008 and that the current licence would expire on 31 July 2009.

2. The Committee therefore agreed that the minutes of the meeting should be expedited.

3. The Committee considered the papers, which included the renewal inspection report, the renewal application form and the previous Licence Committee minutes from 24 July 2008.

4. The Committee noted that the renewal inspection had taken place on 30 April 2009 and that the Person Responsible (PR) had provided a response to the inspection report on 19 June 2009.

5. The Committee agreed that it was satisfied with the response of the PR in relation to the breaches identified in the report and the response to the issue of non-compliance with 7th Code of Practice G.10.2, in relation to access to records and information.

6. However, the Committee were concerned that the response of the PR to non-compliance in relation to 7th Code of Practice G.13.1 needed to be clarified. The Inspection Report suggested a review of the witnessing procedures was required as a number of the double witnessing stages were not being carried out including those for ICSI procedures.

7. The Committee considered that the PR's response might suggest that a single embryologist was the sole person responsible for the witnessing; the wording of this response did not make clear whether the Centre's current practice was for one person to witness at two different points in the process, or for two people to perform the witnessing, as required.

8. G.13.1 requires centres to have witnessing protocols in place "to double check the identification of samples and the patients or donors to whom they relate", at the time each of the specified clinical or laboratory procedures took place in line with HFEA guidance and model protocols. For injecting sperm into eggs this was verification of identifying information on the dishes and tubes and confirmation that the sperm should be injected into oocytes. The Committee agreed that it could not be satisfied on the basis of this response that the Centre was compliant with G.13.1.

9. When considering the changes from the last inspection the Committee noted that a documented staff induction process was still not in place and reiterated to the Centre that this should be implemented.

<u>The Committee's Decision</u>

10. The Committee noted that there were no issues regarding the character, qualifications or experience of the Person Responsible or her ability to

perform her duties under section 17 of the HFE Act 1990 (as amended). It was noted that the PR had completed the PR Entry programme. On this basis and her past experience, the Committee was satisfied as to the PR's suitability.

11. The Committee noted and were satisfied by the response of the PR to concerns expressed in the inspection report about the sperm production facilities, and on the basis of this response, together with the other information in the inspection report agreed that the premises were suitable.

12. The Committee agreed that, given the response from the Person Responsible in relation to the breaches and instances of non-compliance outlined in the report, aside from the issue of witnessing, that appropriate action had been taken or was ongoing, therefore agreed it was satisfied that the Centre had suitable practices.

13. It was agreed that the Committee had sufficient and satisfactory information to make a decision, and noted that it was in receipt of a signed application form and that the necessary fee had been paid.

14. The Committee noted that the application was made for the licence to be renewed for three years and that the Executive supported this request.

15. The Committee decided to renew the licence for 3 years with no additional conditions.

16. However, the Committee recommended that, given that there was not sufficient clarity about whether there was in fact a breach in relation to witnessing, the Executive should follow up the witnessing procedures with the PR to establish whether witnessing is, in fact, happening in accordance with 7th Code of Practice G.13.1.

17. Further, the Committee requested that if the PR had been unable to satisfy the Executive that witnessing procedures were compliant by 1 October 2009, the issue be referred back to a Licence Committee for further consideration.

Signed..... Date 22.7.09.
Emily Jackson (Chair)