
Application for Initial HFEA Research Licence

Instructions:

- Please read the Notes for Guidance – Research Applications
- It is important that the language used in this application is clear and understandable to non-specialist lay members. All abbreviations should be explained.
- Please either email the complete form and supporting documents to:

regulationofresearch@hfea.gov.uk

or return the form and supporting documents to:

Regulation Department (Research)
Human Fertilisation and Embryology Authority
21 Bloomsbury Street
London, WC1B 3HF

- This document is a form for use with Microsoft Word. Comments may be made in grey fields. If you wish to edit the formatting of this form for ease of use, please right click on the MS Word toolbar and select forms. Then click on the protect form symbol (which looks like a padlock).
- Please note that copies of your application and any other information you submit to the Authority, in whatever form, may be published by the HFEA in accordance with its obligations under the Code of Practice on Access to Government Information and the Freedom of Information Act 2000. If you object to any of this information being published please highlight the relevant parts together with the reason(s) for your objections. Your comments will be taken into consideration by the Authority (but may not be determinative) in deciding whether disclosure of that material is still appropriate.

	For Office Use only
Date Received	
Application Number	
Centre Number	
Project Number	

Section 1 Check List

Please record the documents you are supplying with this application

- 1.1 Signed Application Form
 - 1.2 Application Fee
 - 1.3 CVs of all staff engaged directly in the Project
Please mark as 'Appendix A'
 - 1.4 Relevant clinical and laboratory protocols
Please mark as 'Appendix B'
 - 1.5 Patient information relating to the proposed project
Please mark as 'Appendix C'
 - 1.6 Consent forms regarding the use of gametes/embryos
Please mark as 'Appendix D'
 - 1.7 Up to three most recent relevant scientific publications
Please mark as 'Appendix E'
 - 1.8 Copies of the objectives and protocols sections of any
funding applications made, excluding financial details
Please mark as 'Appendix F'
-

Section 2 Project and Centre Contact Details

2.1 Name of centre/institution
(including department)

2.2 Project Title

2.3 Person Responsible [PR]

Name

Position

2.4 Nominal Licensee [NL]

Name

Position

2.5 Premises
where licensable activities will take place

Address

Post Code

2.6 Correspondence Address
if different to premises

2.6.1 Address

2.6.2 Post Code

2.7 Centre Telephone

Other Telephone

Fax

2.8 Centre email

2.9 Website

2.10 PR email

PR Telephone

2.11 NL email

NL Telephone

Section 3 Corporate Information

3.1 Type of Institution

Please read Notes for Guidance – Research Applications.

NHS

Please tick only one

NHS/Private Partnership

Private

University/Academic

- Charity
- Other – Please Specify
-

3.2 Business details of the centre owners
Please read Notes for Guidance – Research Applications

3.3 NHS Trust Headquarters

3.4 Limited Company

Section 4 Centre History

- 4.1 Is the centre HFEA licensed for Treatment and/or Storage activities? Yes No
- 4.1.1 If the centre already holds already holds an HFEA licence please indicate the HFEA centre number.
- 4.2 Does the centre hold any current HFEA research licences? Yes No
Please specify
-

4.3 Research History
See Notes for Guidance

Section 5 Licensable activities and purposes

5.1 Licensable Activities

You may tick more than one box

- | | | |
|-------|---|--------------------------|
| 5.1.1 | storage of embryos | <input type="checkbox"/> |
| 5.1.2 | storage of eggs | <input type="checkbox"/> |
| 5.1.3 | storage of sperm | <input type="checkbox"/> |
| 5.1.4 | creation of embryos <i>in vitro</i> | <input type="checkbox"/> |
| 5.1.5 | use of donated embryo for research | <input type="checkbox"/> |
| 5.1.6 | derivation of human embryonic stem cell lines | <input type="checkbox"/> |
-

5.2 Other specific activities involved in the project

- 5.2.1 **Culture and/or manipulations of Embryos**
e.g. fragment removal/storage of immature eggs or sperm/embryo biopsy
- 5.2.2 **Fixing of eggs or embryos for testing**
e.g. *in situ* hybridisation (FISH) analysis/PCR
- 5.2.3 **Other activities**
please specify
-

5.3 Purpose or purposes of the research project.
As defined by the HF&E Act 1990. Please pick from the following

You may tick more than one box.

- 5.3.1 **promoting advances in the treatment of infertility**
Human Fertilisation and Embryology Act 1990 Sch 2 3(2)(a)
- 5.3.2 **increasing knowledge about the causes of congenital disease**
Human Fertilisation and Embryology Act 1990 Sch 2 3(2)(b)
- 5.3.3 **increasing knowledge about the causes of miscarriages**
Human Fertilisation and Embryology Act 1990 Sch 2 3(2)(c)
- 5.3.4 **developing more effective techniques of contraception**
Human Fertilisation and Embryology Act 1990 Sch 2 3(2)(d)
- 5.3.5 **developing methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation**
Human Fertilisation and Embryology Act 1990 Sch 2 3(2)(e)
- 5.3.6 **increasing knowledge about the development of embryos**
Human Fertilisation and Embryology (Research Purposes) Regulations 2001 s2(a)
- 5.3.7 **increasing knowledge about serious disease**
Human Fertilisation and Embryology (Research Purposes) Regulations 2001 s2(b)
- 5.3.8 **enabling any such knowledge to be applied in developing treatments for serious disease.**
Human Fertilisation and Embryology (Research Purposes) Regulations 2001 s2(c)

5.4 Explain briefly how the proposed research address the purposes
ticked in 6.3 above

Section 6 Duration of Project

- 6.1 Please give the proposed commencement date for the project.
- 6.2 Please give the period of time you wish the licence to be granted

Section 7 Funding

- 7.1 Please indicate how the project will be funded

Section 8 Lay Summary

- 8.1 Please provide a short paragraph as summary of the project in lay terms

The lay summary of the project should include the aims of the project, the activities involved e.g. creation of embryos and how these activities will address the aims of the project.

The Lay Summary will be published via the HFEA website

Section 9 Usage of Material

9.1 Please give the names of the centres that will be supplying materials for this project, together with an indication of the number of embryos and/or eggs they each will be providing.

9.2 Please indicate in the box below the estimated numbers of eggs and embryos you expect to use during the period of the licences. If more than one year has been requested please indicate the year usage in the appropriate boxes

Material	Year 1	Year 2	Year 3
Fresh Eggs			
Frozen Eggs			
Failed to Fertilise Eggs			
Fresh Embryos			
Frozen Embryos			

Section 10 Abstract

- 10.1 Please provide a summary in lay terms of the work you propose to undertake
maximum 500 words

The abstract of the project should include the aims of the project, the activities involved e.g. creation of embryos and how these activities will address the aims of the project.

Section 11 Background

- 11.1 Please state how the projects fits in to the current state of knowledge on this subject
(maximum of 1500 words)

Section 12 Methodology/Experimental Design/Analysis of Results

- 12.1 Please state the main objectives of the research and how this work is to be carried out. If the project involves either the creation of embryos and/or the derivation of human embryonic stem cell lines please provide justification.

Clearly state how you intend to dispose of the embryos after the research is complete. If human embryonic stem cells are to be created [see Section 6] clearly indicate the fate of the stem cells throughout the project and how they are to be disposed of after the completion of the project.

Section 13 Staff

13.1 Please list all the staff who will be involved in the proposed research.

Name	Profession/Positions	Qualification/ Experience NMC/GMC PIN No
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Section 14 Local Research Ethics Committee

14.1 Please state the Role of the ethics committee.

14.2 Please list the chair and membership of the ethics committee.

Chair

Members

Section 15 Declarations

15.1 Person Responsible

The information provided on this application form is to the best of my knowledge true and accurate. I accept that should the application be approved for licensing, I will be required to jointly prepare, sign and submit a report of the work undertaken at yearly intervals from the date of licensing. I agree to act as the Person Responsible.

Signed _____

Date _____

15.2 Nominal Licensee

The information provided on this application form is to the best of my knowledge true and accurate. I accept that should the application be approved for licensing, I will be required to jointly prepare, sign and submit a report of the work undertaken at yearly intervals from the date of licensing. I agree to act as the Nominal Licensee.

Signed _____

Date _____

15.3 Chair of Ethics Committee

The information provided in this form is to the best of my knowledge true and accurate. The Committee has given approval for this project.

Signed _____

Date _____
