HFEA License Applications	
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Author: Naomi Gardner, Research Governance and Integrity Facilitator	
Approved by: Ruth Nicholson, Head of Research Governance and Integrity	Date: Ruth Nicholson Digitally signed by Ruth Nicholson Date: 2024.01.09 12:52:14 Z

Version	**Date**	**Reason for Change**
Version 1.0	22 Jun 2007	Annual review
Version 2.0	23 Jun 2008	Annual Review
Version 3.0	08 Feb 2010	Formation of JRO and review of SOP content
Version 4.0	14 Jul 2011	Annual Review
Version 5.0	03 Dec 2012	Annual Review
Version 6.0	18 Feb 2015	Scheduled Review
Version 7.0	25 Oct 2017	Annual Review
Version 8.0	19 Oct 2020	Scheduled Review Template removed and administrative changes to SOP. JRCO name change to RGIT
Version 9.0	09 /Jan /2024	Scheduled Review

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1. PURPOSE

This Standard Operation Procedure (SOP) describes the procedure for applying to the Human Fertilisation and Embryology Authority (HFEA) for a license to carry out research activities that fall under the 1990 Human Fertilisation and Embryology Act (HFE Act).

2. INTRODUCTION

It is illegal to carry out certain activities without a license from the HFEA under the regulatory requirements of the 1990 HFE Act. Those activities requiring such a license are:

- Bringing about the creation of an embryo (including human admixed embryos) in vitro (embryo includes an egg in the process of fertilisation) either for treatment or research
- Keeping or using an embryo (including human admixed embryos) either for treatment or research
- Storing any gametes
- Using donated sperm or donated eggs during providing treatment services for any woman
- Treatment involving the use of fresh partner gametes
- Non-Medical Fertility Service

The HFEA issue licenses that cover treatment, storage or research. For up-to-date information, please consult the HFEA website. (cited 21/04.2023)

3. PROCEDURE

3.1. Application for an HFEA License

Please note – prior to applying for a licence for research, approval from a NHS Research Ethics Committee must be in place. For further details on how to do this, please see relevant SOP.

Researchers should contact the HFEA compliance team on 020 7291 8200 or via email: regulationofresearch@hfea.gov.uk to discuss their proposed research before they complete and submit an application for a licence through the secure Clinic Portal. The HFEA will set you up on the Portal and guide you through the licensing process, to enable you to submit your application with the appropriate fees.

The initial enquiry form can be obtained from the Clinic Portal. This form should be submitted by email to HFEAcompliance@HFEA.gov.uk

Existing licence holders can liaise directly with the HFEA Regulation Department on renewals and evaluations.

Guidance on how to apply for a research licence and the application processes is available from the HFEA website.

HFEA Code of Practice helps you to understand and comply with your legal requirements as a licensed centre.

The Code of Practice version 9.4 comes into effect from 26 October 2023. The Code of Practice is the key guidance document, setting out the law and our guidance so that fertility clinics can continue to deliver safe treatment in line with legal requirements.

Read the Code of Practice version 9.4.

General Requirements relating to all applications to the HFEA.

1. Applications to the HFEA relating to most categories must be made by completing and submitting the relevant on-line application, together with relevant supporting information via the 'electronic portal' located on the Authority's website.

2. Failure to submit a fully completed application form, pay the application fee or provide all the necessary information set out below will, in normal circumstances, result in the application not being considered until such times as these requirements have been satisfied.

3. Persons Responsible for centres which are licensed by the Authority to carry out licensed activities (treatment, storage, non-medical fertility services or research) must at all times have available the information set out in iv-xiv of paragraph 4 of this Direction and submit this information to the Authority when requested no later than 10 working days after the date of any written request.

Directions

Clinics are required to comply with Directions; if you fail to do so this would be a breach of a statutory licence condition, which might lead to the variation, suspension or revocation of a clinic's licence

3.2. Choose a Persons Responsible

You will need to nominate a named person to act as the 'person responsible' (PR) for your licensed centre. The law requires licensable activity to take place only under the supervision of a Person Responsible. The Person Responsible (PR) is the individual who ensures that all licensed activities are conducted with proper regard for the regulatory framework that governs treatment and research involving gametes or embryos. Consequently, the PR should have enough understanding of the scientific, medical, social, ethical and other aspects of the centre's work to be able to supervise its activities properly.

The PR is in charge of overseeing the clinic's activities, ensuring staff have an appropriate level of training to fulfil their roles and that they comply with clinic inspections. They're also responsible for submitting paperwork, fees and data in a timely manner. This PR role description sets out the behaviours we expect to see PRs demonstrate.This person must meet certain qualifying criteria as they will be charged with ensuring that:

- all licensing conditions are complied with
- the HFEA is notified about serious incidents or serious adverse reactions
- staff at your centre are of good character and are suitably trained and qualified
- the centre's premises are suitable
- proper equipment and suitable practices are used when carrying out licensed activities
- proper arrangements are made for the keeping and disposal of gametes and embryo

Further information on the skills and experience required for the Person Responsible role can be found on the HFEA website (cited 21/04/2023) and in the HFEA Code of Practice, 9th edition. which covers such things as professional conduct, clinical governance, quality management and confidentiality.

Please note that copies of your application and any other information you submit to the Authority may be published by the HFEA.

3.3. Information to accompany License applications

Requested documents should be sent together with treatment licence applications (as detailed) in the directions section on the website. (cited 14.12.2023)

The HFEA aim to process most applications within four months if they have all the information needed. Their Licence Committee considers applications every other month, so they recommend speaking with them regarding the best time to submit, to minimise delays.

The administration fee is currently £500 to £750 depending on the project. Projects involving the derivation of human embryonic stem cells or cell nuclear replacement incur an administration fee of £750, which reflects on the increased complexity and rigour required for the licensing of such projects.

Detailed information on fees is available by clicking here.

3.4. Initial consideration of application

Applications together with the initial fee are now electronically submitted via the Clinic Portal and posting of hard copy is no longer required
Receipt of all applications will be acknowledged in writing by the HFEA. The HFEA will then check the application for any omissions and contact you if more documentation is required.

The HFEA Regulation Department then initiates peer reviews which determine whether the application;

- falls within the statutory requirements of the Human Fertilisation and Embryology Act 1990 (as amended)
- requires human embryos to fulfil its aims and objectives
- requires the number and types of embryos described in the application.

3.5. Initial Inspection

Under the terms of the HFE Act, the HFEA are required to inspect the premises where the proposed licensed activities will be carried out before granting a licence. By law research centres must also be inspected every two years to make sure they are continuing to operate safe, legal and quality services in line with HEFA Code of Practice. Sometimes a centre may be inspected more frequently if there is a cause of concern such as an incident or compliant. An inspection will be organised once a full application has been received and peer reviews have been completed.

Since the Covid-19 pandemic, the HFEA has adopted new inspection methodologies, adopting a hybrid approach which incorporates virtual technology (where appropriate). This involves a detailed desk-based assessment (DBA), which is used to develop a risk-based approach (RBA) for the inspection event.

Any request documents need to be sent about 12 weeks prior to the inspection date, which are to be submitted to the Lead Inspector, usually within four weeks. This means the inspection team can then start the DBA eight weeks before the inspection, which provides time to request further information if areas of concern are identified. The on-site inspections address any areas where concerns remain, or which cannot be reviewed remotely. The DBA process can reduce the time spent by on-site by the inspectors. (cited14.12.2023)

Request for documentation

In preparation for the interim inspection, the inspector who is allocated to lead will request that you gather and complete the list of information/documents (where relevant), The list of documents can be found via the website.

Visits will normally last between half a day and a full day depending on the size of the centre. On the visit the inspection team will be expected to cover the areas outlined in the HFEA's Inspection Protocols (www.hfea.gov.uk).

The inspection team will, after the visit, prepare a report on the centre for the HFEA Licence Committee considering the application.

For research applications the HFEA advise that the composition of the team that visits and elements of the inspection may need to be changed to assess the project appropriately.

Further information can be found on the HFEA website.

On 1 July 2022 new laws governing the storage of gametes and embryos came into effect. This version of the Code of Practice was published in 2021 and does not yet reflect the new storage laws. Areas of guidance that are no longer accurate under the new law have been struck through, and areas which are incomplete under the new law have been highlighted. Please refer to the Health and Care Act 2022 and HFEA Clinic Practical Guide on legal changes to storage limits and guidance for current law and guidance on the storage of gametes and embryos.

A plan to conduct a full update of the Code of Practice in 2023 after which it will reflect the new law governing storage of gametes and embryos. (cited 21/04/2023)

3.6. Consideration by a HFEA License Committee

The relevant HFEA Licence Committee will look at your application and the report of the inspection team together with any other information which the Committee considers relevant. The Committee will consider the application in relation to the requirements of the HFE Act, the Authority's directions and the provisions of the HFEA Code of Practice HFEA - How we regulate.

Once a Licence Committee has come to a decision regarding an application, it will write informing the named Person Responsible and any Nominal Licensee of its decision. This decision will be:

- **Granting of a licence** - if the Committee decides to grant a licence, it will inform the Person Responsible and the Nominal Licensee and, on receipt of any additional fee which is due it will issue the licence. Each licence is subject to certain standard conditions which are set out in sections 12 to 15 of the HFE Act.(Cited 21/04/2023)

- **Granting of a licence subject to specific conditions** - if the Committee decides to grant a licence subject to certain conditions, it will inform the Person Responsible and the Nominal Licensee of these further conditions (in addition to those set out in sections 12 to 15 of the HFE Act).

- **Refusal of a licence** - if the Committee refuses to grant a licence, you will be informed in writing (section 19(1) of the HFE Act).

The HFEA will only issue licences after the named applicant and the named Person Responsible have accepted the licence conditions in writing and paid any additional fee which is due. There is a 28-day appeal time within which you can appeal against any Licence Committee decision.

3.7. Appeals Procedures

The HFE Act provides applicants with the right of appeal when a Licence Committee refuses to grant or vary a licence. Full details are set out in sections 19, 20 and 21 of the HFE Act. (Cited 01/12/2023)

3.8. Progress and Final Reports

A research licence may be granted for up to three years. If a licence is granted for more than one year, then a progress report must be submitted on an annual basis. Progress reports can be accessed through the Clinic Portal on the HFEA webpage.
When the research licence has expired, and will not be renewed, then a final report must be submitted to the HFEA. Final reports can accessed through the Clinic Portal on the HFEA webpage.

Further Advice and Guidance

- Further advice and guidance can be found on the HFEA Website.
- Keep up to date with developments in their monthly newsletter for clinics.

4. REFERENCES

The Human Fertilisation and Embryology Act 1990. Cited 01/12/2023

The Human Fertilisation and Embryology Authority website. Cited 01/12/2023