Directions given under the Human Fertilisation and Embryology Act 1990 (as amended)

Information to be submitted to the Human Fertilisation and Embryology Authority as part of the licensing process

Ref: 0008
Version: 7

These Directions are:	General Directions
Sections of the Act providing for these Directions:	Sections 12(1)(g) and 19B(1)
These Directions come into force on:	1 October 2009
These Directions remain in force:	Until revoked
This version was issued on:	1 August 2024

General requirement relating to all applications to the Authority

1. Applications to the Authority relating to categories A-M must be made by completing and submitting the relevant on-line application, together with relevant supporting information detailed below, via the 'electronic portal' located on the Authority's website. In exceptional circumstances and with prior approval from the HFEA, applications can be submitted using alternative means. An application fee (details of current fees payable are available on the Authority's website) must also be submitted.
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.

Information to be supplied with applications

A. Applications for a new (initial) treatment, storage and non-medical fertility services licence

4. An application for a new licence authorising:

   (a) activities in the course of providing treatment services; and/or
   (b) the storage of gametes, embryos or human admixed embryos; or
   (c) activities in the course of providing non-medical fertility services,
   (d) must be accompanied by the information specified below:

      i) where the proposed Person Responsible is not the applicant, a written confirmation from the proposed Person Responsible that the application is made with his or her consent;
      ii) a current CV of the proposed Person Responsible listing academic and professional qualifications; work experience and registration details with the relevant professional body;
      iii) a current CV of the proposed Licence Holder listing academic and professional qualifications; work experience and registration details with the relevant professional body;
      iv) the Person Responsible Entry Programme ("PREP") certificate number confirming satisfactory completion of the PREP by the proposed Person Responsible;
      v) a floor plan of the premises to be referenced on the licence;
      vi) a suite of information documents to be provided to patients undergoing treatment at the centre once licensed;
      vii) a completed self-assessment questionnaire submitted via the electronic portal;
      viii) a copy of the centre's organisational chart clearly defining accountability and reporting relationships for named individuals;
      ix) evidence that staff are registered with a professional or statutory body and are appropriately qualified and trained in techniques relevant to their work, or are in a programme of supervised training;
      x) a copy of the centre's induction and training programme that ensures that staff have adequate knowledge of the scientific and ethical principles, together with the regulatory context, relevant to their work;
      xi) evidence that a robust quality management system is in place;
      xii) a statement that all the equipment and processes to be used in activities authorised by a licence, and in other activities carried out in the course of providing treatment services that do not require a licence, have been validated;
      xiii) a detailed list of the quality indicators, a schedule of the audit programme and the reporting arrangements established for all activities authorised by a licence, and other activities carried out in the course of providing treatment services that do not require a licence; and
      xiv) a copy of the centre's multiple birth minimisation strategy (where applicable).

B. Applications to renew a treatment, storage or non-medical fertility services licence

5. An application for the renewal of a licence authorising:

   (a) activities in the course of providing treatment services; and/or
   (b) the storage of gametes, embryos or human admixed embryos; or
   (c) activities in the course of providing non-medical fertility services,
   (d) must be accompanied by the information specified below:

      i) where the Person Responsible is not the applicant, a written confirmation from the Person Responsible that the application is made with his or her consent;
      ii) a completed self-assessment questionnaire; and

iii) a suite of information documents to be provided to patients undergoing treatment at the centre (if different to those submitted with the original or previous renewal application).

C. Applications to vary the activities authorised by a current treatment, storage or non-medical services licence

6. An application to vary the activities authorised by a current licence in the course of providing treatment services or non-medical fertility services must be accompanied by the information specified below:

   (a) copies of information provided to patients relating to the new activity;
   (b) evidence that the process(es) and, where applicable, the equipment used in carrying out the new activity have been validated; and
   (c) a schedule of the quality indicators, and reporting arrangements, established for this activity.

7. An application to vary a licence to allow mitochondrial donation through maternal spindle transfer (MST) or pronuclear transfer (PNT) must be accompanied by the information specified below:

   (a) copies of information provided to patients and donors relating to treatment involving mitochondrial donation and the benefits of participating in follow-up;
   (b) information to demonstrate the competence of the embryologist(s) proposed to conduct the technique(s) being applied for, as follows:

      i) a CV and references of the embryologist(s), to support their experience and knowledge
      ii) key performance indicator data relating to the proposed embryologist's/embryologists' experience in carrying out the technique(s) on human eggs or embryos as follows:

         a. whether they have carried out the techniques in treatment, training or research
         b. embryo survival rates – must exceed 70%
         c. blastocyst development rates – which must be no less than 50% of that observed in the control embryos at day five. Where possible, controls should be age-matched to the karyoplast donor
         d. rate of carryover of mtDNA – should not, on average, exceed 2% and no greater than 10% per embryo

      iii) any other information that may demonstrate competence (such as their experience of performing micro-manipulation on human or animal (eg, mice) eggs or embryos)

   (c) evidence that the equipment, and process(es) where applicable, used in carrying out the new technique(s) has been validated;
   (d) a schedule of the quality indicators, and reporting arrangements, established for the new treatments; and
   (e) procedures for the follow-up of children born as result of mitochondrial donation, including the arrangements the centre has in place with a mitochondrial disease expert centre.

   An application to add or vary the name of the embryologist(s) practising MST or PNT need only include section 7(b) (i-iii).

D. Application to carry out a licensed activity using a 'new' process

8. Where centres want to carry out a licensed activity using a process that has not been authorised by the Authority (ie does not appear on the authorised processes list), an application must be submitted to the Authority for approval and accompanied by the information specified below:

   (a) Validated evidence that the process does not render tissues or cells clinically ineffective or harmful to the recipient;

(b) evidence that the process and, where applicable, the equipment used in carrying out the new activity have been validated;
(c) a schedule of the quality indicators, and reporting arrangements, established for this process; and
(d) copies of information to be provided to patients relating to the proposed new process.

9. If authorised by the Authority, the process will be subject to a period of enhanced mandatory reporting, whereby the centre using the process is required to report such information to the Authority as required by the Scientific and Clinical Advances Advisory Committee (SCAAC).

(a) Centres wishing to carry out any process which is subject to enhanced mandatory reporting, can do so in accordance with the licence they hold and provided they fulfil any additional requirements as specified by the SCAAC, including any reporting requirements.
(b) Centres wishing to carry out any process subject to enhanced mandatory reporting are required to inform the Authority (via the appropriate mechanism) of their intention to do so at least 28 days in advance of undertaking the process.

E. Application for a new (initial) research licence

10. An application for a new licence authorising activities for a research project must be accompanied by the information specified below:

(a) where the proposed Person Responsible is not the applicant, a written confirmation from the proposed Person Responsible that the application is made with his or her consent;
(b) the PR Entry Programme ("PREP") certificate number confirming satisfactory completion of the PREP by the proposed Person Responsible;
(c) a floor plan of the premises to be referenced on the licence;
(d) copies of all information provided to patients and/or donors relating to the proposed research project;
(e) copies of the consent forms to be used to authorise the use of gametes, embryos or human cells in the research project;
(f) evidence of ethics approval of the research project from a properly constituted research ethics committee

This will normally be a NHS Research Ethics Committee (NHS REC). Research centres outside the NHS may refer projects to a NHS REC or may establish (or seek approval from) an independent ethics committee. The independent ethics committee will be considered to be properly constituted if it meets the standards set out in relevant Health Research Authority guidance; and

(g) a completed self-assessment questionnaire.

11. For applications for a new licence authorising activities in connection with the derivation from embryos of stem cells that are intended for human application, the following additional information must be submitted with the application:

(a) evidence that the proposed Person Responsible possesses a diploma, certificate or other evidence of formal qualifications in the field of medical or biological sciences, awarded on completion of a university course of study, or other course of study recognised in the United Kingdom as equivalent and has at least two years' practical experience which is directly relevant to the activity to be authorised by the licence; and
(b) evidence that the centre has, or is obtaining, a licence from the Human Tissue Authority.

F. Application to renew a research licence

12. An application for the renewal of a licence authorising activities for a research project must be accompanied by the information specified below:

    (a) a completed self-assessment questionnaire;
    (b) evidence of ethics approval of the research project from a properly constituted research ethics committee;
    (c) copies of all information provided to patients and/or donors relating to the proposed research project (if different to those submitted with the original or previous renewal application); and
    (d) copies of the consent forms to be used to authorise use of gametes, embryos or human cells in the research project (if different to those submitted with the original or previous renewal application).

13. For applications to renew a licence authorising activities in connection with the derivation from embryos of stem cells that are intended for human application, the following additional information must be submitted with the application:

    (a) evidence that the centre has a licence from the Human Tissue Authority.

G. Applications to vary a research licence to vary the purposes for which the research is licensed

14. An application to vary a research licence to vary the purposes for which the current research is licensed must be accompanied by the information specified below:

    (a) evidence of ethics approval of the research project from a properly constituted research ethics committee;
    (b) copies of all information provided to patients and/or donors relating to the proposed research project (if different to those submitted with the original or previous renewal application); and
    (c) copies of the consent forms to be used to authorise use of gametes, embryos or human cells in the research project (if different to those submitted with the original or previous renewal application).

H. Applications to vary a licence to either relocate to new premises or change existing premises

15. An application to vary a licence to either relocate to new premises not authorised by a current licence for the conduct of licensed activities (treatment, storage, research and non-medical fertility services) or to alter premises authorised by a current licence for the conduct of licensed activities (treatment, storage, research and non-medical fertility services) must be accompanied by the information specified below:

    (a) where the Person Responsible is not the applicant, a written confirmation from the Person Responsible that the application is made with his or her consent;
    (b) a floor plan of the premises to be referenced on the licence, and;
    (c) confirmation that any re-commissioned equipment has been tested and validated.

I. Applications to change the Person Responsible or the Licence Holder

16. An application to change the Person Responsible or the Licence Holder of a licence authorising licensed activities (treatment, storage, research and non-medical fertility services) must be accompanied by the information specified below:

    (a) a current CV of the proposed Person Responsible listing academic and professional qualifications; work experience and registration details with the relevant professional body;
    (b) a current CV of the proposed Licence Holder listing academic and professional qualifications; work experience and registration details with the relevant professional body; and

(c) the PR Entry Programme ("PREP") certificate number confirming satisfactory completion of the PREP (applications for a change of PR only).

J. Applications to authorise preimplantation genetic diagnosis

17. An application to authorise preimplantation genetic testing (PGT) for a condition which has not previously been authorised by the Authority is subject to an application as per paragraph 1.

K. Applications to authorise human leukocyte antigen tissue typing

18. An application to authorise human leukocyte antigen (HLA) tissue typing, in isolation or in conjunction with PGD must be accompanied by the information specified below:

(a) a copy of a signed letter of support from a clinician responsible for the care of the sibling child providing information on the:

i) degree of suffering associated with the disease of the affected sibling,
ii) speed of degeneration in progressive disorders,
iii) prognosis for the affected sibling in relation to all treatment options available,
iv) availability of alternative sources of tissue for the treatment of the affected sibling, now and in the future, and
v) availability of effective therapy for the affected sibling now and in the future.

L. Applications to authorise mitochondrial donation for a specific patient

19. Applications for authorisation of mitochondrial donation for a specific patient must be made by completing the relevant application and submitting this to the HFEA.

20. An application should include information that demonstrates why PGD may be deemed inappropriate or likely to be unsuccessful, ensuring that the patient identified for treatment is (or is predicted to be) highly heteroplasmic or homoplasmic for a particular mtDNA mutation in their germ line.

M. Applications for Special Directions to export gametes or embryos

21. An application for a Special Direction to export gametes or embryos must be accompanied by the information specified below:

(a) a letter from the intended export destination centre/clinic confirming that it is willing to accept the gametes or embryos for the purpose specified in the application form.

Notifying the Authority of information relating to licensed activities

22. Persons Responsible must notify the Authority, through the electronic portal located on the Authority's website, of all processes undertaken in the licensed centre in carrying out a licensed activity.

Additional information to be submitted to the Authority as part of on-going compliance

23. Persons Responsible for centres licensed by the Authority must complete and submit to the Authority the self-assessment questionnaire (SAQ) published on the Authority's website no later than six weeks prior to the date on which the Authority has confirmed it will carry out an inspection visit. Before submitting the SAQ, Persons Responsible must confirm that the information they have provided on that document is true and accurate.

24. Where a member of the Authority's Compliance Department requests the Person Responsible to submit a further SAQ in addition to that required by paragraph 21 above, the Person Responsible must submit this to the Authority no later than 15 working days after the date of the written request.

25. Where a member of the Authority's Compliance Department requests the Person Responsible to submit a further PREP, the Person Responsible must submit this to the Authority no later than 21 working days after the date of the written request.

Julia Chain **1 August 2024**

Chair, Human Fertilisation and Embryology Authority

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