

Status: Point in time view as at 01/10/2009.

Changes to legislation: Human Fertilisation and Embryology Act 2008, SCHEDULE 2 is up to date with all changes known to be in force on or before 15 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

SCHEDULES

SCHEDULE 2

Section 11

ACTIVITIES THAT MAY BE LICENSED UNDER THE 1990 ACT

Introductory

- 1 Schedule 2 to the 1990 Act (activities for which licences may be granted) is amended as follows.

Licences for treatment

- 2 (1) Paragraph 1 (licences for treatment) is amended as follows.
- (2) In sub-paragraph (1)—
- (a) after paragraph (c) insert—
- “(ca) using embryos for the purpose of training persons in embryo biopsy, embryo storage or other embryological techniques,”
- (b) in paragraph (d), omit the words from “or” onwards,
- (c) in paragraph (e), for “embryo” substitute “permitted embryo”, and
- (d) in paragraph (g), after “practices” insert “, apart from practices falling within section 4A(2),”.
- (3) For sub-paragraph (4) substitute—
- “(4) A licence under this paragraph cannot authorise altering the nuclear or mitochondrial DNA of a cell while it forms part of an embryo, except for the purpose of creating something that will by virtue of regulations under section 3ZA(5) be a permitted embryo.”
- (4) After sub-paragraph (4) insert—
- “(4A) A licence under this paragraph cannot authorise the use of embryos for the purpose mentioned in sub-paragraph (1)(ca) unless the Authority is satisfied that the proposed use of embryos is necessary for that purpose.”
- (5) At the end insert—
- “(6) In this paragraph, references to a permitted embryo are to be read in accordance with section 3ZA.”

Embryo testing and sex selection

- 3 After paragraph 1 insert—

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“Embryo testing

- 1ZA(1) A licence under paragraph 1 cannot authorise the testing of an embryo, except for one or more of the following purposes—
- (a) establishing whether the embryo has a gene, chromosome or mitochondrion abnormality that may affect its capacity to result in a live birth,
 - (b) in a case where there is a particular risk that the embryo may have any gene, chromosome or mitochondrion abnormality, establishing whether it has that abnormality or any other gene, chromosome or mitochondrion abnormality,
 - (c) in a case where there is a particular risk that any resulting child will have or develop—
 - (i) a gender-related serious physical or mental disability,
 - (ii) a gender-related serious illness, or
 - (iii) any other gender-related serious medical condition,
 establishing the sex of the embryo,
 - (d) in a case where a person (“the sibling”) who is the child of the persons whose gametes are used to bring about the creation of the embryo (or of either of those persons) suffers from a serious medical condition which could be treated by umbilical cord blood stem cells, bone marrow or other tissue of any resulting child, establishing whether the tissue of any resulting child would be compatible with that of the sibling, and
 - (e) in a case where uncertainty has arisen as to whether the embryo is one of those whose creation was brought about by using the gametes of particular persons, establishing whether it is.
- (2) A licence under paragraph 1 cannot authorise the testing of embryos for the purpose mentioned in sub-paragraph (1)(b) unless the Authority is satisfied—
- (a) in relation to the abnormality of which there is a particular risk, and
 - (b) in relation to any other abnormality for which testing is to be authorised under sub-paragraph (1)(b),
- that there is a significant risk that a person with the abnormality will have or develop a serious physical or mental disability, a serious illness or any other serious medical condition.
- (3) For the purposes of sub-paragraph (1)(c), a physical or mental disability, illness or other medical condition is gender-related if the Authority is satisfied that—
- (a) it affects only one sex, or
 - (b) it affects one sex significantly more than the other.
- (4) In sub-paragraph (1)(d) the reference to “other tissue” of the resulting child does not include a reference to any whole organ of the child.

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Sex selection

- 1ZB(1) A licence under paragraph 1 cannot authorise any practice designed to secure that any resulting child will be of one sex rather than the other.
- (2) Sub-paragraph (1) does not prevent the authorisation of any testing of embryos that is capable of being authorised under paragraph 1ZA.
- (3) Sub-paragraph (1) does not prevent the authorisation of any other practices designed to secure that any resulting child will be of one sex rather than the other in a case where there is a particular risk that a woman will give birth to a child who will have or develop—
- (a) a gender-related serious physical or mental disability,
 - (b) a gender-related serious illness, or
 - (c) any other gender-related serious medical condition.
- (4) For the purposes of sub-paragraph (3), a physical or mental disability, illness or other medical condition is gender-related if the Authority is satisfied that—
- (a) it affects only one sex, or
 - (b) it affects one sex significantly more than the other.

Power to amend paragraphs 1ZA and 1ZB

- 1ZC(1) Regulations may make any amendment of paragraph 1ZA (embryo testing).
- (2) Regulations under this paragraph which amend paragraph 1ZA may make any amendment of sub-paragraphs (2) to (4) of paragraph 1ZB (sex selection) which appears to the Secretary of State to be necessary or expedient in consequence of the amendment of paragraph 1ZA.
- (3) Regulations under this paragraph may not enable the authorisation of—
- (a) the testing of embryos for the purpose of establishing their sex, or
 - (b) other practices falling within paragraph 1ZB(1),
- except on grounds relating to the health of any resulting child.
- (4) For the purposes of this paragraph, “amend” includes add to and repeal, and references to “amendment” are to be read accordingly.”

Licences for non-medical fertility services

- 4 In paragraph 1A (licences for non-medical fertility services) after sub-paragraph (1) insert—
- “(1A) A licence under this paragraph cannot authorise the procurement or distribution of sperm to which there has been applied any process designed to secure that any resulting child will be of one sex rather than the other.”

Licences for storage

- 5 In paragraph 2 (licences for storage)—
- (a) after sub-paragraph (1) insert—

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- “(1A) A licence under this paragraph or paragraph 3 may authorise the storage of human admixed embryos (whether or not the licence also authorises the storage of gametes or embryos or both).”, and
- (b) in sub-paragraph (2), after “such storage” insert “ as is mentioned in sub-paragraph (1) or (1A) ”.

Licences for research

6 For paragraph 3 substitute—

“Licences for research

- 3 (1) A licence under this paragraph may authorise any of the following—
- (a) bringing about the creation of embryos *in vitro*, and
 - (b) keeping or using embryos,
- for the purposes of a project of research specified in the licence.
- (2) A licence under this paragraph may authorise mixing sperm with the egg of a hamster, or other animal specified in directions, for the purpose of developing more effective techniques for determining the fertility or normality of sperm, but only where anything which forms is destroyed when the research is complete and, in any event, no later than the two cell stage.
- (3) A licence under this paragraph may authorise any of the following—
- (a) bringing about the creation of human admixed embryos *in vitro*, and
 - (b) keeping or using human admixed embryos,
- for the purposes of a project of research specified in the licence.
- (4) A licence under sub-paragraph (3) may not authorise the activity which may be authorised by a licence under sub-paragraph (2).
- (5) No licence under this paragraph is to be granted unless the Authority is satisfied that any proposed use of embryos or human admixed embryos is necessary for the purposes of the research.
- (6) Subject to the provisions of this Act, a licence under this paragraph may be granted subject to such conditions as may be specified in the licence.
- (7) A licence under this paragraph may authorise the performance of any of the activities referred to in sub-paragraph (1), (2) or (3) in such manner as may be so specified.
- (8) A licence under this paragraph may be granted for such period not exceeding three years as may be specified in the licence.
- (9) This paragraph has effect subject to paragraph 3A.

Purposes for which activities may be licensed under paragraph 3

- 3A (1) A licence under paragraph 3 cannot authorise any activity unless the activity appears to the Authority—
- (a) to be necessary or desirable for any of the purposes specified in sub-paragraph (2) (“the principal purposes”),

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- (b) to be necessary or desirable for the purpose of providing knowledge that, in the view of the Authority, may be capable of being applied for the purposes specified in sub-paragraph (2)(a) or (b), or
 - (c) to be necessary or desirable for such other purposes as may be specified in regulations.
- (2) The principal purposes are—
- (a) increasing knowledge about serious disease or other serious medical conditions,
 - (b) developing treatments for serious disease or other serious medical conditions,
 - (c) increasing knowledge about the causes of any congenital disease or congenital medical condition that does not fall within paragraph (a),
 - (d) promoting advances in the treatment of infertility,
 - (e) increasing knowledge about the causes of miscarriage,
 - (f) developing more effective techniques of contraception,
 - (g) developing methods for detecting the presence of gene, chromosome or mitochondrion abnormalities in embryos before implantation, or
 - (h) increasing knowledge about the development of embryos.”

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