Human embryo genome editing and pre-clinical studies: research ethics considerations

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Some talking points:

1. The value of human embryo research – engagement
2. Feasibility of reproductive uses of genome editing: safety and efficacy tests
3. Ethical concerns – ‘traditional’ and ‘strategic’

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1. The value of human embryo research – engagement
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GRANT/RENEW: RESEARCH

ADMINISTRATIVE REQUIREMENTS
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Does the inspection report summary confirm that the following administrative requirements have been met?

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- It contains the **supporting information required by General Direction 0008.**
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- (And, on the rare occasions the applicant is not the designated PR, that there are sufficient grounds to believe that the proposed Licence Holder is a suitable person to hold a Licence.)
- (If the applicant is **not** the designated PR, that the **proposed PR has consented** to act as such. *(Implied if they have completed the form.)*)
- The proposed licence applies to **one single research project** (as required by S2 para 4 (2) (a)).
- The appropriate **licence fee** has been paid.

Any ✗ | All ✓

ACTIVITIES APPLIED FOR

- **Which activities have been applied for?**

The activities that may be used on a research licence (see detailed table overleaf) are:

Creation of embryos in vitro
Keeping embryos
Using embryos
Mixing sperm with the egg of a hamster or other specified animal
Creation of human admixed embryos in vitro
Keeping human admixed embryos
Using human admixed embryos
Storage of gametes
Storage of embryos
Storage of admixed embryos

- **Does the proposed research project include the derivation of human embryonic stem cell lines for human application?** *(for reference later under 'PR Considerations').*

PERMITTED RESEARCH PURPOSES

For each, Is the activity to be licensed necessary or desirable for at least one of the purposes below?

S2 para 3A:

- Providing knowledge that, in the view of the Authority, may be capable of being applied for increasing knowledge about, or developing treatments for, serious disease or other serious medical conditions
- Increasing knowledge about serious disease or other serious medical conditions
- Developing treatments for serious disease or other serious medical conditions
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- Promoting advances in the treatment of infertility
- Increasing knowledge about the causes of miscarriage
- Developing more effective techniques of contraception
- Developing methods for detecting the presence of gene, chromosome or mitochondrion abnormalities in embryos before implantation
- Increasing knowledge about the development of embryos
- Such other purposes as may be specified in Regulations.

Yes / No

PROHIBITED RESEARCH ACTIVITIES

Are you satisfied that none of the proposed activities are prohibited by the Act, i.e. that none of the following apply?

- Placing in a woman any non-permitted embryos or non-permitted eggs or sperm (S3 (2) section 3ZA)
- Keeping or using an embryo after the appearance of the primitive streak (section 3 (3) (a))
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- Keeping or using a human admixed embryo in any circumstances prohibited by regulations (section 4A (5))
- BOTH mixing sperm with the egg of an animal AND creating, using and keeping human admixed embryos (these two activities cannot be the subject of the same licence, as per S2 para 3 (4)).

Yes / No

USE OF EMBRYOS

Are you satisfied that the proposed use of human embryos or human admixed embryos is necessary for the purpose of the research? *(Required by S2 Para 3(5))*

No / Yes

PR CONSIDERATIONS

- Does the PR **EITHER:**
  - Have **satisfactory qualifications and experience** as per S16 (2) (ca) **OR,**
  - **IF** the research involves the derivation of stem cells **intended for human application,** do they have S16 (2) (c) (i) - **Formal academic qualifications** and S16 (2) (c) (ii) - At least 2 years' **relevant practical experience?**

Are you satisfied that the character of the PR is such as is required for supervision of the licensed activities and that the PR will discharge the duties under S17 of the Act? *(Evidence based – e.g. compliance history and responsiveness to inspection findings, PREP completion, findings of other bodies, criminal convictions.)*

Any ✗ | All ✓

PREMISES
(As indicated by the inspection report)

S16(2)(d):
Are you satisfied that the premises to be licensed are suitable for the conduct of licensed activities there? *(Evidence based – e.g. inspection report findings, criteria in Code of Practice);* And (for research involving stem cells only) are you satisfied that any relevant third party premises are also suitable?

No ✗ | Yes ✓

DECISION STAGE
(Take into account all written evidence and your considerations under the previous stages)

- **ANY ADDITIONAL CONDITIONS?** *(i.e. in addition to S12-15 or other standard conditions; and on what basis?)*
- **HOW LONG A LICENCE?** *(Indicative Applications Criteria)*
- **FUTURE RENEWALS** to ELP, or reserved to Licence Committee?
- **WHAT TO LICENCE:** *See overleaf*
- **GRANT**

HAVE YOU EXPLAINED >>>
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Length of licence
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Whether consideration of renewals lies with ELP or LC
Any views you have formed about non-compliances and compliance performance
Your considerations regarding any Executive recommendations
Any other issues you wish to raise in the minutes

REFUSE – issue notice of proposal to refuse, OR **ADJOURN** - and seek further information

(Or, as an alternative to refusing or adjourning, the Committee may like to consider issuing a different licence, without some of the activities applied for)

GRANT/RENEW: RESEARCH

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Any ✗ | All ✓

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- Such other purposes as may be specified in Regulations.

Yes / No

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Yes / No

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Yes / No

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No ✗ | Yes ✓

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ANY ADDITIONAL CONDITIONS? *(i.e. in addition to S12-15 or other standard conditions; and on what basis?)*

HOW LONG A LICENCE? *(Indicative Applications Criteria)*

WHAT TO LICENCE: *See overleaf*

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Human Fertilisation & Embryology Authority

Scientific review of the safety and efficacy of methods to avoid mitochondrial disease through assisted conception: 2016 update

Report to the Human Fertilisation and Embryology Authority (HFEA)
November 2016

Review panel Chair: Dr Andy Greenfield, Medical Research Council (MRC) Harwell Institute and HFEA member

Some talking points:

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PGD: NEW CONDITION/TYPE