HEMPSONS

The Regulation of Gene Editing in the UK

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HFEA Regulation: Research (1)

Human Fertilisation and Embryology Act 1990 (as amended in 2008), Schedule 2(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."

Unlicensed research (or research outside the terms of a licence) is a criminal offence

HFEA Regulation: Research (2)

HFEA Licence Committees follow a 'Decision tree':

1. Identify activities to be authorised
2. Is the activity to be licensed permitted?
3. Does the project involve 'hamster test' and creation, use and storage of admixed embryos?
4. Is each activity necessary or desirable for a specified purpose,

   or

   is it necessary or desirable for the purpose of providing knowledge that may be capable of being applied for increasing knowledge about or developing treatments for serious disease or other serious medical conditions?

HFEA Regulation: Research (3)

- 'Principal' permitted research purposes (3A(2) of Sch.2):
  - Increasing knowledge about serious disease or serious medical conditions;
  - Developing treatments for serious disease or other serious medical conditions;
  - Increasing knowledge about causes of any congenital disease or congenital medical condition;
  - Promoting advances in infertility treatments;
  - Increasing knowledge about causes of miscarriages;
  - Developing more effective techniques for contraception;
  - Developing methods for detecting presence of gene, chromosome or mitochondrion abnormalities in embryos before implantation; or
  - Increasing knowledge about the development of embryos

HFEA Regulation: Research (4)

Decision tree (contd):

5. Is the Committee satisfied that the use of embryos (or admixed embryos) is necessary for the purpose of the research?
6. Has the applicant provided evidence of ethics approval?
7. Is the Committee satisfied with the patient information and consent forms?
8. Should licence be granted subject to conditions?

- Condition of all research licences that embryos used/created cannot be used in treatment

HFEA Regulation: Treatment (1)

Section 3ZA(2) and (4):

- A 'permitted egg' is one "whose nuclear or mitochondrial DNA has not been altered"
- An embryo is a 'permitted embryo' if "no nuclear or mitochondrial DNA of any cell of the embryo has been altered"

Section 3ZA(5):

- Regulations may provide that -

  (a) an egg can be a permitted egg, or

  (b) an embryo can be a permitted embryo,

  even though the egg or embryo has had applied to it in prescribed circumstances a prescribed process designed to prevent the transmission of serious mitochondrial disease.

HFEA Regulation: Treatment (2)

Schedule 2, section 1(4):

A treatment licence "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".

Unlicensed use of embryos in treatment is a criminal offence

EU Regulation (1)

- Article 9(6) of the **EU Clinical Trials Directive** prohibits trials which "result in modifications to the subject's germ line genetic identity".
  - But CT Directive concerns clinical trials "on medicinal products for human use", whereas gene editing in an embryo involves the application of a *process* or *technique*.
  - It does not create a product, still less a 'medicinal product' because they it does not create any 'substance' (something separate to the human being in question that is used by or administered to such a human being with a view to restoring, correcting or modifying physiological functions).
- By contrast, **EU Tissues and Cells Directive** makes clear that decisions by Member States as to whether or not to prohibit certain uses of human tissues or cells are outside scope of Directive and expressly left over to the exclusive competence of Member States

EU Regulation (2)

- Article 3(2) of the **Charter of Fundamental Rights of EU** (Right to the integrity of the person) states:

  "In the fields of medicine and biology, the following must be respected in particular:

  …

  (b) the prohibition of *eugenic* practices, in particular those aiming at the selection of persons; … "

- Added to Charter on recommendation of the European Group on Ethics in Science and New Technologies in a Report on Charter's implications for technological innovation

EU Regulation (3)

- Prohibition of eugenics intended to address two concerns:
  - *"Practices which involve for instance forced sterilization, forced pregnancies or abortions, ethnically enforced marriages, etc, all acts which are expressly regarded as international crimes by the Statute signed in Rome on July, 18, 2000 to create the permanent International Criminal Court.*
  - *Eugenics … may also involve genetic manipulations on human beings such as the modification of the germ line in view of enhancement, without any therapeutic aim."* (my emphasis)
- EGE Report further states that

"…eugenics differs from other individual practices carried out to avoid the birth of a disabled child (preimplantation or prenatal diagnosis on severe and incurable diseases for instance)".

Conclusions

- Basic research using human embryos is permitted in the UK, but the use of such embryos in treatment is prohibited
- UK model offers a stable, flexible and potentially permissive framework for the regulation of gene editing:
  - Protects patients
  - Allays public concerns
  - Protects researchers
  - Provides an environment within which scientific innovation and progress may flourish
- No basis for a moratorium
- PGD and mtDNA offer a useful model for robust regulation of therapeutic applications
- Need for transparency and open dialogue between researchers and policy makers