

## Storage of gametes for seriously ill patients: a technical note.

### Licence Requirements (Section 4 of the 1990 Human Fertilisation and Embryology Act (as amended))

Gametes can only be retrieved or procured at UK hospitals which have a licence from the HFEA or which have a third party agreement with a clinic that is licensed by the HFEA.

Gametes can only be stored at premises which are licensed by the HFEA.

This means that unless a hospital is licensed by the HFEA or (in the case of procurement or retrieval only) has a third party agreement with a clinic that is licensed by the HFEA, it would be illegal for staff at that hospital to procure, retrieve or store gametes.

A list of all clinics and storage facilities licensed by the HFEA can be found at <http://www.hfea.gov.uk/fertility.html>

It may be useful to note that HFEA licensed facilities may not be equipped to process testicular or ovarian tissue for transplantation. It is recommended that where transplantation is intended, guidance should be sought from local HFEA licensed facilities and from the HFEA and the Human Tissue Authority.

### The need for consent (Schedule 3 of the Act)

The legislation requires that consent should be obtained from the gamete provider **before** gametes are clinically retrieved or stored.

The legislation also requires that this consent should be **in writing**. Verbal consent from the gamete provider or consent from a spouse or family member is not sufficient.

Clinics licensed by the HFEA use specific consent forms which have been designed to remove any legal ambiguity and to comply fully with complex legal requirements. These forms also allow the gamete provider to state what should happen to the gametes in the event of their death.

If the gamete provider is unable to sign the consent form because of illness, injury or physical disability, but still has the mental capacity to consent, the form may be signed by someone else at the gamete providers direction. However, the form must be signed in the presence of the gamete provider **and** in the presence of at least one witness.

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Where the gamete provider does not have the capacity to consent (e.g because he/she is in a coma, or deceased) **no one else** has the power to provide consent on his/her behalf. This means that the spouse or family cannot sign a consent form on behalf of the person from whom the gametes are to be retrieved or the person whose gametes are to be stored.

Recent court cases suggest that it is doubtful whether even a court would have the power to provide consent on behalf of the gamete provider.

It is important to note that ordinary hospital consent forms which allow the family of a deceased or terminally ill patient to consent to retrieval /storage or donation of other body tissues and organs **cannot** be used to provide consent for the purposes of retrieving or storing gametes.

### **Exception to the need for consent to storage** (Paragraph 10 of Schedule 3 to the Act)

The legislation sets out a very limited exception to the need for consent to storage of gametes. Consent is not required if the following conditions are met:-

- Condition A is that the gametes are lawfully taken from a person who is aged 16 years or above.
- Condition B is that, before the gametes are first stored, a registered medical practitioner certifies in writing that the person is expected to undergo medical treatment and that in the opinion of the registered medical practitioner-
  - (a) the treatment is likely to cause a significant impairment of fertility,
  - (b) the person lacks capacity to consent to the storage of the gametes,
  - (c) the person is likely at some time to have that capacity, and
  - (d) the storage of the gametes is in the person's best interests.

This exception is not likely to be applicable where individuals are not undergoing treatment or are unlikely to recover capacity to consent.

### **Legal parenthood**

The law relating to the parenthood of children born as a result of fertility treatment using stored gametes is complex. Clinics licensed by the HFEA use specific forms which allow a person providing gametes to legally consent to being the father of any child born using those gametes, after their death.

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## Summary

The HFEA has no power to authorise the storage in the UK of gametes which have been retrieved or stored in breach of the requirements of the Act.

Gametes which have been retrieved or stored in breach of the requirements of the Act can not lawfully be used in fertility treatment in the UK. Such gametes may have to be allowed to perish.

Breaches of some requirements in the Act may amount to the commission of criminal offences under Section 41 of the Act.

Hospitals expecting to encounter circumstances where they may wish to preserve gametes for those having treatment that may impair their fertility should consider establishing third party agreements with clinics licensed by the HFEA or apply directly to the HFEA for a licence.

Finally, many HFEA licensed facilities offer services to individuals wishing to store their gametes to preserve their future fertility. Such services may be useful to consider where individuals may be exposed to environments that could affect their future fertility. Individuals considering options to preserve their fertility should be provided with information and counselling about fertility issues and legal requirements relating to consent

If you would like further information please contact Debra Bloor at the HFEA ([Debra.Bloor@HFEA.gov.uk](mailto:Debra.Bloor@HFEA.gov.uk))

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