

15th December 2006

Donating eggs for research: Safeguarding donors
Human Fertilisation and Embryology Authority
21 Bloomsbury Street
London
WC1B 3HF

Dear Sir / Madam,

Thank you for the opportunity to respond to the consultation by the HFEA on *Donating eggs for research: Safeguarding donors*. The Nuffield Council on Bioethics has not considered the issues raised by this specific topic, and is therefore unable to comment on the questions listed in the consultation document.

Consent is clearly central to this issue. In this context, the general considerations outlined in two previous reports by the Council are summarised below, which may be of interest to you.

Stem cell therapy: the ethical issues (2000)

In this Report the Council discussed issues of consent related to embryo donation for stem cell research. We endorsed the recommendations of the US National Bioethics Advisory Commission (NBAC) Report (1999) that:

During the presentation about potential research use of embryos ... the person seeking the donation should:

- *disclose that the ES cell research is not intended to provide medical benefit to embryo donors;*
- *make clear that consenting or refusing to donate embryos to research will not affect the quality of any future care provided to prospective donors;*
- *describe the general area of the research to be carried out with the embryos and the specific research protocol, if known;*
- *disclose the source of funding and expected commercial benefits of the research with the embryos, if known;*
- *make clear that embryos used in research will not be transferred to any women's uterus, and*

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- *make clear that the research will involve the destruction of the embryos.(20)*

Researchers may not promise donors that ES cells derived from their embryos will be used to treat patient-subjects specified by the donors.(21)

Extract from *Human tissue: ethical and legal issues* (1995)

Consent considerations

General

6.17 So far we have discussed **types of ethically acceptable action**. However, not every act of an acceptable type of action will be ethically permissible. A particular act of an acceptable type of action involving the removal of tissue may be wrong if the person from whom tissue is removed does not consent, since its removal without consent in these conditions would constitute impermissible injury. For example, use of some persons as organ banks for others without their knowledge or consent, or the removal of a person's tissue for experimental purposes without his or her consent, or body-snatching for medical research would all be seen as ethically impermissible. Such acts do grave injury by treating one person's life or body or body parts as means to others' therapy or well being without the relevant consent. The ethical failing here is not that every use of organs, tissue or cadavers is unacceptable, but that these particular ways of procuring them violate consent considerations.

6.18 The basic idea behind the notion of consent is captured in the old adage: *volenti non fit iniuria* - *no wrong is done to one who is willing*. The basic considerations are common in all domains of life: if you take my bicycle, and I lent or gave it you, then I am willing, so am not injured, by your riding off. On the other hand, if I neither lent nor gave, indeed am unwilling, then I am wronged when you ride off on my bike. This ancient principle has proved of great value in medical ethics, and is constantly invoked: if a surgeon operates on a willing patient, then the operation is legitimate and the patient is not wronged (even if things turn out badly); if a surgeon operates on an unwilling, ie unconsenting, patient then the patient is wronged (even if no physical harm is done). In general, action that is clearly guided by a

therapeutic intention must also be consented to by the particular patient or volunteer if it is to be ethically permissible.

Caveat on consent

- 6.19 Expressions such as 'informed consent' and 'fully informed consent' are often used in discussions of medical ethics. They are somewhat misleading. Consent can be given to some course of action (for example, an operation, other therapy, donation, participation in medical or scientific research) only **as described in a specific way**. Since description can never be exhaustive, consent will always be to action that is incompletely described; moreover the descriptions offered are often incompletely understood. This incompleteness cannot be remedied by the devising of more elaborate consent forms and procedures for patients, donors and relatives. 'Fully informed consent' is therefore an unattainable ideal.
- 6.20 The ethically significant requirement is not that consent be **complete**, but that it be **genuine**. Ensuring that consent is genuine is mainly a matter of care in detecting and eliminating lack of consent. Both in law and in ethics, consent requirements are not met wherever anything rebuts or defeats the presumption of consent. The ascription of consent is **defeasible**: the presumption of consent can be defeated by any of numerous circumstances, including violence, coercion, deception, manipulation, tendentious misdescription of action, lack of disclosure of material facts or of conflicts of interest and the like. A complete list of the circumstances that would defeat a presumption of consent is not feasible.
- 6.21 Evidently in medical and scientific practice involving human volunteers or the removal of tissue from cadavers, there are well developed (if necessarily incomplete) understandings of circumstances that defeat the presumption that proper consent has been granted. These will include failure to require patients, volunteers or relatives to read and sign the usual consent forms. However, such forms are only evidential, and signatures on forms, however carefully obtained, will not prove that consent is 'fully informed'. Obtaining genuine consent requires medical practitioners to do their best to communicate accurately as much as patients, volunteers or relatives can understand about

procedures and risks, and to respect the limits of their understanding, and of their capacities to deal with difficult information. If all reasonable care is exercised, adequate and genuine consent may be established, although it will necessarily fall short of fully informed consent.

All reports of the Council can be downloaded at:
www.nuffieldbioethics.org/go/publications/latest_30.html

Please do not hesitate to contact us if you require clarification on any of the information contained in this letter.

Yours sincerely,

A handwritten signature in black ink that reads "Catherine Moody". The script is cursive and fluid, with the first name and last name clearly distinguishable.

Dr Catherine Moody
Acting Director