

**REVIEW OF THE HUMAN FERTILISATION & EMBRYOLOGY ACT:  
A PUBLIC CONSULTATION  
DEPARTMENT OF HEALTH 2005**

**This pro forma repeats all of the questions and proposals in the above titled consultation document. The boxes below will expand as you type. When completed it should be e-mailed to [review-hfe-act@dh.gsi.gov.uk](mailto:review-hfe-act@dh.gsi.gov.uk)**

**The closing date for responses is Friday 25 November.**

<b>Personal details</b>	
Title:	
Names:	Julia Feast and Ann Haigh
Organisation: (if relevant)	Julia Feast - British Association for Adoption and Fostering Ann Haigh - Barnardo's
Address:	BAAF, Skyline House, 200 Union Street, London SE1 OLX Barnardo's, Family Connections, Cottage Number 1, Tanners Lane, Barkingside, Ilford, Essex IG6 1QG
E-mail address:	<a href="mailto:julia.feast@baaf.org.uk">julia.feast@baaf.org.uk</a> <a href="mailto:ann.haigh@barnardos.org.uk">ann.haigh@barnardos.org.uk</a>

### **About BAAF**

The British Association for Adoption & Fostering (BAAF) is pleased to respond to this consultation.

BAAF is the leading charity and membership organisation in fostering and adoption in the UK. We:

- promote the highest standards of child-centred policies and services
- speak out on behalf of looked-after children
- influence UK-wide policy and legislation
- provide much-needed information and advice
- promote greater public understanding of adoption and fostering
- support our members in their work

BAAF's main activities are the development, promotion and advocacy of best policy and practice; the provision of advice and information to our members and to the general public; training, consultancy and seminars; child placement services including the publication of our flagship monthly newspaper, *Be My Parent*. We also publish a quarterly professional journal, *Adoption and Fostering*, books and guides for professionals, academics, parents and carers and research studies. The main users of our services are our members comprising local authorities across England, Scotland and Wales, voluntary adoption agencies, independent fostering agencies and also individual social work, legal and medical

professionals and carers. We are currently developing our service to Northern Ireland.

## **About Barnardo's**

Barnardo's is a major children's charity with significant experience in adoption, and with staff members acting as children's reporters in applications of parental orders in cases of surrogacy.

## **Questions and proposals for consultation**

### The model and scope of regulation

**1.** The Government believes that both the development and use of human reproductive technologies, and their regulation in response to public concerns, should continue to be subject to legislation. (Paragraph 2.7).

**2.** On balance, the Government believes that the current model of regulation, whereby Parliament sets the prohibitions and parameters within which an independent statutory authority licenses activities, has worked well and should continue. (Paragraph 2.14).

**3.** However, the Government also accepts that legislation should be more explicit and provide Parliament with greater powers to debate and amend the law. In particular, the Government accepts the need to clarify the extent of any policy-making role of the regulator. (Paragraph 2.15).

**4.** The Government believes that legislation should make clear that all human embryos outside the body are within the scope of regulation and subject to the control of the statutory licensing authority regardless of the manner of their creation. (Paragraph 2.20).

**5.** The Government considers that the best approach is to define the forms of embryo which may be placed in a woman and in what circumstances, and to regulate other forms of embryo insofar as these are created and used for research. (Paragraph 2.22).

**6.** The Government proposes that eggs undergoing processes intended to result in the creation of embryos – whether fertilisation or other non-fertilisation processes – should continue to be subject to regulation. (Paragraph 2.27).

**7.** The Government believes that the potential use of artificial gametes raises safety issues and that some uses may also raise ethical concerns. Therefore the Government proposes that the use of artificial gametes in assisted reproduction treatment should not be permitted but that the HFE Act should contain a regulation-making power giving Parliament more flexibility to allow the use of artificial gametes in future should it wish to do so. (Paragraph 2.31).

**8.** The Government seeks views on the extent to which regulation should apply to the use of a couple's "fresh" gametes. Should this be limited to technical and safety issues only or should treatment involving a couple's fresh gametes be subject to the full requirements of the HFE Act where these are relevant? (Paragraph 2.37).

**9.** The Government intends to make the operation of internet services which involve the supply of gametes subject to regulation. Should the law (a) prohibit the operation of such services, (b) regulate the safety and quality aspects of such services, (c) regulate safety and quality and remove any anomalies with other methods of gamete donation? (Paragraph 2.42).

We are concerned about the safety aspects of internet services and are aware of the difficulty of controlling these, especially if they operate outside UK jurisdiction. Nevertheless, all practical efforts should be made to ensure the safety of these procedures as regards donors of genetic material, recipients, and children conceived or affected as a result of these services. We therefore favour option (c).

**10.** The Government seeks views on whether moving toward the transfer of a single embryo during a treatment cycle should (a) be a matter for legislation, (b) be a matter for the regulator, (c) be a matter for the professional bodies only. (Paragraph 2.47).

Decisions about the transfer of a embryos should be based on research.

**11.** The Government invites views on what, if any, powers the regulator should have in relation to the costs of assisted reproduction treatments provided to private patients. (Paragraph 2.49).

We consider that the charges set by clinics for private patients should not be directed by the regulator, but that as part of the licensing criteria, centres should be required to make transparent their charges for all services provided, including counselling.

**12.** The Government invites comments on the desirability of making the regulator's licensing powers more flexible, for instance (a) the ability to licence clinical trials, and (b) explicitly allow training of clinicians and researchers. (Paragraph 2.56).

### Welfare of the child

**13.** The Government seeks views on whether taking account of the welfare of the child who may be born as a result of treatment and any other child who may be affected should remain an HFE Act *obligation* on persons providing treatment services. (Paragraph 3.19).

We welcome the HFEA's recent report "Tomorrow's Children: Report of the policy review of welfare of the child assessments in licensed assisted conception clinics", and recommend that there should be a specific requirement on treatment centres to take all reasonable steps to satisfy themselves that neither the child to be conceived, nor any existing child affected by that child's birth (i.e. any existing child in the family of the recipient(s), donor or surrogate) are likely to experience significant harm as a result of providing the treatment. The definition of "significant harm" should be modeled on that contained in the Children Act 1989.

We recommend that there should also be a requirement to take account of the well-being of the child and any children affected.

We recommend that when patients are using donated gametes to create a family, it is particularly important that they have the opportunity to receive appropriate information and preparation, to ensure that they have a good understanding of the particular needs of donor conceived children. This would involve clinics being required to provide non-medical services which offer the important preparation of patients for forming a family through donor conception and for meeting the identity needs of a donor-conceived child, including being open with the child about his or her origins. We believe that a donor conceived child has a right to know about their genetic origins. Our experience in adoption has informed us that the lack of honesty creates problems for the future and can

have a detrimental effect on family life.

**14.** The Government seeks views on whether, if a welfare of the child requirement remains in the HFE Act, compliance with it should be a matter for “good medical practice” and the clinician’s judgement, rather than be subject to HFEA guidance and regulation. (Paragraph 3.23).

We believe that there is a strong case for guidance and regulation by the appropriate regulatory body. If left to ‘good medical practice’ there is more risk of the meaning of the welfare of the child being interpreted in different ways, leading to a variation of practice and standards. When the main objective of clinics is to assist patients to create a family, there is a risk that the welfare of the child could be overlooked. The welfare of the child is crucial and therefore should not be a matter for just “good medical practice”. It is important to have a multi-disciplinary approach. While we recognise the resource implications in carrying out a full assessment to ensure that the welfare of the child has been properly addressed, we would consider that enquiries could be made of the GP and police routinely.

**15.** If you agree with this, do you think that clinicians should only be required by the legislation to take account of the *medical* welfare of the child? (Paragraph 3.24).

We are strongly of the view that guidance should not be restricted to the child’s medical welfare only. See also our response to 13 and 14 above.

**16.** If a legal obligation to consider the welfare of the child is retained, should it be reformulated to refer to a risk of serious harm? For example, should it specify that treatment should not be provided where the clinician believes there is risk of significant harm? (Paragraph 3.26).

Yes – see our response at 13 above. Such decisions should be made following discussion with representatives of the multi-disciplinary team and after obtaining any additional information that is thought necessary – as indicated in the HFEA Report “Tomorrow’s Children”.

**17.** Do you think that the requirement to take account of “the need of the child for a father”, as part of considering the welfare of the child, should be removed from the Act? Alternatively, do you think that it should be replaced with “the need of the child for a father and a mother”? (Paragraph 3.32).

We consider that the current formulation of Section 13 (5) of the Act is anachronistic and erroneously correlates family structure with children’s welfare. There should be no specific requirement regarding either the child’s “need for a father”, nor for the child’s “need for a father and a mother”. We consider that all necessary welfare considerations will be accounted for in our recommendation at 13 above. Whatever the family makeup, the important consideration is whether

or not the family is stable and will be able to meet the child's needs.

The use and storage of gametes and embryos

**18.** The Government believes that on balance, the HFE Act's existing requirements for written consent remain proportionate and appropriate, and provide a valuable protection of the wishes of patients and donors. Do you agree? (Paragraph 4.10).

We agree fully with this proposal.

**19.** Should the requirement for *written* consent be extended to apply to all assisted conception treatments provided in licensed clinics, including treatment using a couple's own 'fresh' gametes such as IUI and GIFT? (Paragraph 4.11).

For consistency, we consider that this requirement should be extended to procedures using a couple's own "fresh" gametes.

**20.** The Government proposes that the law should allow the *storage* of gametes without the consent of a person lacking capacity where the gametes were lawfully removed. Do you agree? (Paragraph 4.16).

**21.** The Government proposes that a person's gametes stored in these circumstances may only be *used* with the consent of that person. Do you agree? (Paragraph 4.17).

We agree fully with this proposal.

**22.** The Government invites views on whether the law should be changed to require the withdrawal of the consent of *both* parties whose gametes were used to create an embryo in order to allow a stored embryo to perish, and that such an embryo should otherwise continue in storage until the statutory maximum storage period is reached. (Paragraph 4.21).

23. Do you think that the law should continue to set statutory maximum storage periods for gametes and embryos and if so how should these be determined? (Paragraph 4.25).

We note that the current storage periods for human gametes and embryos are somewhat arbitrary. The regulator should be given the power to modify maximum storage periods in the light of (a) scientific knowledge concerning the safety aspects of long-term storage (b) any psycho-social implications for the potential donor-conceived person, e.g. where any extension to the storage period makes it less likely that the donor will still be alive should their donor offspring wish to make contact once they have reached the age of 18 (or 16). The implications for any child born as a result of the use of embryos stored for very many years could have greater impact in the future when/if it becomes more common for donor-conceived people to seek information about the donor.

24. If you think that the law should continue to set statutory maximum storage limits, should the storage limits for donation be brought into line with the storage periods for treatment? (Paragraph 4.26).

25. The Government invites views on whether the requirement on licensed centres to provide “such relevant information as is proper” should remain a legal requirement. (Paragraph 4.35).

Yes, we agree that it should remain a legal requirement. It is crucial that individuals and couples considering assisted conception procedures have as much information as possible about the treatment, the implications and outcomes. We recommend that this information and preparation of individuals and couples is provided by the independent counsellor.

Therefore there should be a continuing requirement on licensed treatment centres to **provide** such information as is proper and the nature of that information should continue to be determined by the regulator, taking account of advice from relevant professional bodies.

26. If so, should that requirement be extended to require clinics to be specific about which treatments they provide are outside the National Institute for Clinical Excellence’s clinical guideline on infertility treatment? (Paragraph 4.36).

Yes. Full relevant information should be made available to all potential treatment recipients as part of ensuring that they are fully informed before consenting to any particular assisted conception procedure.

**27.** The Government invites views on whether the requirement on licensed centres to offer a suitable opportunity to receive counselling should remain a legal obligation. (Paragraph 4.40).

We recommend the requirement on licensed centres to offer suitable counselling should remain a legal requirement. Without this requirement, we doubt that many licensed centres would have provided counselling. Consequently, we are concerned that removal of the requirement to make counselling available will impact adversely on its continuing availability within licensed centres. It's important that patients undergoing infertility treatments have the opportunity to talk through the implications and impact this may have on them and their families.

We welcome the Government's recognition of the value of counselling "in helping patients make informed reproductive decisions and understand the implications of those decisions". We also note the House of Commons Science and Technology Committee's acknowledgement that the value of infertility counselling is not necessarily recognised by at least some clinicians involved in the provision of assisted conception services and therefore this confirms the importance of this being legislated for.

**28.** Alternatively, should the legal requirement to offer a suitable opportunity to receive counselling apply only in the case of treatment involving donated gametes and embryos? (Paragraph 4.41).

While we recognise that treatment involving donated gametes or embryos is likely to have additional implications, and therefore additional areas to address in counselling, we do not see that there should be any difference in the legal requirement on licensed centres to make counselling available to all those seeking and using treatment, i.e. those who are using both their own or donated gametes or embryos. See also our response at 27 above. However we consider that for individuals and couple who use donated gametes to create a family there should be a statutory requirement for them to receive information, preparation, and counselling so that they can understand the full implications of having a child that is not genetically related. The information and identity needs of children born as a result of donated sperm and/or eggs need to be understood and addressed and this may present particular issues for the prospective parents. For example, will they be honest and open with the child about his or her donor status?

**29.** The Government invites views on whether the appropriate level of compensation for donors should be set by the regulator or by Parliament by means of regulations, rather than by the HFEA as now. (Paragraph 4.45).

**30.** The Government invites views on whether payments for the supply of gametes (other than compensation for expenses or inconvenience) should be prohibited in

all circumstances, including research that is currently outside the scope of the HFE Act. (Paragraph 4.47).

We consider that payment for the supply of gametes (other than compensation for expenses) for **treatment** purposes should be prohibited, on the grounds that such payment risks commodifying the child. Where gametes are used for **research** purposes, compensation should at a similar level to that in comparable scientific and medical research.

Reproductive choices: screening and selection

**31.** The Government invites views on whether legislation should set out the general criteria under which embryo screening and selection can be undertaken. If so, what should those general criteria be? (Paragraph 5.19).

**32.** Do you think that there should be a prohibition on deliberately screening *in*, or selecting *for* impairments and disabilities – as opposed to screening *out*, or selecting against? (Paragraph 5.20).

**33.** Should the particular uses of embryo screening and selection remain a matter for decision and licensing by a statutory regulator in accordance with the general criteria set by Parliament? (Paragraph 5.21).

**34.** Alternatively, should the particular uses of embryo screening and selection be a matter for patients and clinicians, within the legal limits set by Parliament? (Paragraph 5.22).

**35.** What are your views on the regulation of PGD with tissue typing? Should the legislation set out criteria under which this should be allowed? If so what should they be? Beyond that should particular uses need to be approved by the regulator – or should patients with their clinicians be free to make their own decisions? (Paragraph 5.23).

**36.** The Government invites views on what statutory controls, if any, should apply to the screening and selection of gametes. (Paragraph 5.27).

**37.** The Government seeks views on sex selection for non-medical reasons. In particular, should this be banned? Or should people be allowed to use sex selection techniques for family balancing purposes as the Science and Technology Committee suggest? If so, how many children of one gender should a couple already have before being allowed to use sex selection techniques to try for a child of the other gender? (Paragraph 5.32).

**38.** The Government proposes that the prohibition in the HFE Act on genetic modification of embryos for reproductive purposes should continue and be extended to gametes used in treatment. We invite views as to whether the legislation should include a power for Parliament to relax this ban through regulations (rather than primary legislation) if assured of safety and efficacy. (Paragraph 5.38).

#### Information and the HFEA Register

**39.** The Government believes that it is essential to maintain a central register of donor treatment to which donor-conceived people can have access for information about their donor, and to find out if they are related to someone they intend to marry. Do you agree? (Paragraph 6.14).

Yes, we agree with this proposal. It is absolutely crucial for a central register to be maintained, but would favour the removal of the reference to intention to marry as a criterion for information release (see also 40 below). Clearly it would be important for donor conceived people to have access to information when they are considering entering a partnership which may lead to conception. The right to information needs to be absolute.

**40.** The Government invites views on whether people should be able to obtain information about whether they were donor-conceived and about their donor (including identifying information where lawful) from the age of 16 rather than, as now, from the age of 18. (Paragraph 6.18).

We agree that current anomalies should be removed. In Scotland adopted people are able to access information at the age of 16 where as in England and Wales it is 18. If the age is dropped to 16 then this may have implications for adoption legislation in England and Wales. There may be particular implications for a young person obtaining identifying information at the age of 16, possibly without her parents' knowledge and agreement that needs to be considered. The young person could be placed in a more vulnerable situation if they attempted to trace the donor.

We would suggest that counselling is mandatory if the young person is under 18 years of age before they receive identifying information.

**41.** The Government proposes to enable donor-conceived people to access information to discover whether they are related to someone with whom they intend to form a civil partnership, and would welcome comments. (Paragraph 6.20).

If the age at which a donor conceived person can access information is reduced to 16, this provision will become redundant. We do not accept that either the intention to marry or the intention to form a civil partnership is a legitimate requirement for accessing information. The ability to access information should be available to all, either on the basis of a “Gillick-competence” test or at age 16.

**42.** The Government invites views on whether the law should specify what non-identifying information about offspring can be released to gamete and embryo donors. (Paragraph 6.23).

We agree that donors should be entitled to have some non-identifying information about children conceived as a result of their donation. This should comprise:

- The number of children born as a result of their donation
- The sex of children born as a result of their donation
- The ages of children born as a result of their donation (we suggest providing information regarding the year in which children are born, since this will not lead to unintended disclosure of the child’s identity)
- The number of families into which children have been born as a result of their donation

**43.** The Government seeks views on whether donor-conceived people should be able to access information about their donor-conceived siblings (where applicable). If so should this be limited to non-identifying information? (Paragraph 6.25).

Donor-conceived people should be able - as a matter of right - to access **non-identifying information** about any donor-conceived siblings they may have (see also our response at 42).

We favour maximum possible transparency, with the proviso that no information that would identify an individual should be disclosed to another party without the express consent of the person whose identity is to be disclosed.

Donors and recipients should also be advised of the merits of encouraging any other children they may have to place their details on the register. Legislation should allow for opening the register to non-donor-conceived siblings to register. We considered whether parents should make this decision on behalf of their children who are minors, but decided that this decision should be made by the children only, once they are mature enough to do so.

See also our response to 41 above.

**44.** Should the natural children of donors be able to access information about their donor-conceived siblings (where applicable) and vice-versa? If so should this be limited to non-identifying information? (Paragraph 6.26).

We consider that children of donors should be able to access non-identifying information about siblings that have been born as a result of donor assisted conception and vice versa.

See our responses to 42 and 43 above.

**45.** The Government seeks views on what measures would be appropriate, if any, to ensure that parents tell children conceived through gamete or embryo donation that they are donor-conceived? (Paragraph 6.31).

All people have a right to know their genetic heritage and this should apply to donor conceived people. It is unacceptable that there are thousands of children who have been born as a result of donor assisted conception have not been told.

We have a responsibility not to collude with the parents who have chosen not to be truthful with their child about his and her genetic origins. Prospective adoptive parents would not be approved as adoptive parents if it was thought that they would not tell their child that s/he was adopted. As mentioned before this is why it should be a statutory requirement for prospective parents of a donor conceived child to undergo an assessment and preparation period, where such matters can be addressed.

One way of encouraging parental disclosure would be to annotate birth records in a way analogous to adoption and parental order registration. The birth record should not endorse a biological untruth and if parents know that the information is recorded somewhere in official documentation it may prevent deceit and secrecy. The “short” birth certificate, which can be used for most purposes, would not indicate the individual’s status as donor-conceived. A [possible] disadvantage of this suggestion is that it depends on parental compliance in a way that adoption and parental order registrations – as records of court orders – do not. At present, we are not aware of any means by which information about pregnancies resulting from assisted conception services, births reported to the HFEA and to the Registrar of births are – or can be - linked. Treatment centres are not required to demonstrate what measures they have taken to follow up treatment outcomes and registration of birth details with their patients. Intuitively, it seems that parents who are unlikely to tell their child are unlikely to provide this information at birth registration. So one clear dilemma is whether compliance could be assured in practice. We strongly believe that a more robust system for follow-up should be required of treatment centres. There could be immediate follow up

when the pregnancy is confirmed and then at delivery, so that the birth record includes this information from the start. This would also offer the opportunity to remind parents of services to help them with 'how to tell'. This should be monitored through clinic inspections and good practice disseminated.

The possibility of marking the child's medical card could also be explored, particularly as questions around the child's genetic inheritance may be crucial when making a decision about medical intervention and treatment.

An alternative - or additional - possibility is that the regulator could contact any donor-conceived person about whom it has records when that person is entitled to ask for information held on the register (at age 18 or 16). The regulator could use this opportunity to advise them of their status and their rights to access information. If parents were informed that this would occur both at the time of treatment and subsequently, this might act as an encouragement for disclosure. However, as with annotated birth records, this may encourage non-compliance on the part of parents who do not intend to tell their children and so they would not register their children as donor-conceived in the first place.

Alternatively, if parents register their child's details, but then do not tell their child, this proposal could result in the contact from the regulator being the means by which the donor-conceived person learns of his or her status for the first time. In our view, such contact would be unethical in any circumstances as it could carry substantial risk to the donor conceived young adult, since the information would be received in an uncontrolled way, and potentially without prior warning, preparation or support. In addition there may be too many practical difficulties. The HFEA – or whoever held the register – would not necessarily have an up-to-date address of the donor conceived person. This particular dilemma could be at least partially resolved if the regulator made contact first with the young person's parents; in the event that parents have not yet told their child(ren), this would afford them the opportunity to do so and to avail themselves of counselling services. Unless the law is changed to make such counselling mandatory, this contact with parents should also include a strong recommendation to seek competent counselling.

46. The Government invites views on whether, in future, the HFEA's data register should continue to record and publish information on all licensed treatments including outcome data (where it is satisfied that they are not misleading). (Paragraph 6.39).

We consider that it is important that prospective patients are able to access reliable outcome data so that they are able to make an informed choice about particular treatments and particular clinics.

The continuing availability of accurate outcome data is also a valuable resource for research purposes. See also response to 47 below.

**47.** If the HFEA's data register is to continue to collect information on all licensed treatments, should the dataset be expanded to facilitate more effective follow-up research? (Paragraph 6.40).

Yes.

**48.** Alternatively, if the HFEA's data register is to be restricted to information on licensed treatments involving donated gametes or embryos, should licensed clinics be required to maintain local databases of additional information for research? (Paragraph 6.41).

See 47 above.

**49.** The Government proposes that the confidentiality provisions of the HFE Act should be revised so that information about assisted reproduction treatment is treated in the same way as other medical information and subject to the same safeguards. Do you agree? (Paragraph 6.44).

We agree fully with this proposal.

### Surrogacy

**50.** The Government invites views on what, if any, changes are needed to the law and regulation as it relates to surrogacy. (Paragraph 7.17).

We regret that earlier government action regarding surrogacy was not taken following the Brazier review. However, we are also mindful that this review may now be outdated - as acknowledged by Professor Brazier herself. We welcome the Government's decision now to consider the need to review the law concerning surrogacy arrangements. There is now considerable practice experience in this area.

**51.** If changes to the law and regulation on surrogacy are necessary, do the recommendations of the 'Brazier Report' represent the best way forward? (Paragraph 7.18).

We believe there is a more balanced attitude towards surrogacy today than in the past. Given there is now a greater wealth of professional experiences, the time is ripe for a review of surrogacy arrangements. The Adoption and Children Act aligns the Welfare of the Child with its position in the Children Act and Parental Order Legislation should place the welfare principle at its heart. Current legislation has many loopholes. We have particular concerns about arrangements that distort generational relationships and can lead to complex relationships for the child achieved through such arrangements.

There needs to be clarity about what constitute reasonable expenses, for

example most courts have accepted a recuperative holiday. However there is also the danger of under the counter payments and although the children's reporter can ask to see bank accounts etc, this will not prevent deception. Cots and Surrogacy UK use a contract and make a recommendation of £8,000. Surrogates and commissioning parents appear to find this acceptable.

These contracts also address post birth contact. Applicants for Parental Orders have experienced a welcoming response from families when they attend mother and baby groups pre birth and appear to be committed to openness both on surrogacy and egg donation (sometimes more reticent on sperm donation), but when considering issues of identity and genetic mapping etc have moved on this issue as well. They accept the different form of birth certificate. They welcome suggestions about telling being a process not a one off.

**52.** If changes to the law and regulation on surrogacy are necessary, should they be taken forward as part of the review of the HFE Act, or in separate legislation? (Paragraph 7.19).

We do not consider that there is need for separate legislation and that the necessary changes in legislation regarding surrogacy can be accommodated within a review of the HFE Act.

### Status and legal parenthood

**53.** The Government invites views as to whether the HFE Act should treat an unmarried man as the father of a child resulting from treatment in the same way it treats a married man. If so, how would this be achieved given that there is no legal definition of an unmarried couple? (Paragraph 8.16).

We consider that married and unmarried couples should be treated in the same way. It is therefore important that the government produces legislation that provides a legal definition of an unmarried couple. This gives rise to some complex issues. In adoption law, where unmarried couples are now to be allowed to adopt, there is a court, and, in many cases, an agency process for assessing them and in particular considering the stability of their relationship. Currently the Act does treat the male partner of a woman as the father of a child born to his partner following gamete donation if they are 'receiving treatment together'. This definition does give rise to some difficulties, but if clinics are to play a role in considering the welfare of any child who might be born as a result of treatment, then this should include an assessment of the stability of the environment where the child is to be brought up. A formal consent from the proposed legal father, and an acknowledgement of his responsibilities (including financial responsibilities) towards the resulting child, together with the mother's agreement that she accepts his role as father, should make the situation clear. Under current law, if he then jointly registers the birth of the child with the mother he will share parental responsibility. Logically it is hard to see why the lesbian partner of a

mother should not be able to be treated in the same way; she like the man in the above scenario, has no genetic relationship; however since birth registration only allows the naming of two parents of opposite sexes we are not sure how this can be achieved. Obviously the partner can acquire parental responsibility through a parental responsibility agreement after the ACA comes into force, or via adoption.

**54.** Should a court be able to make a parental order in favour of unmarried as well as married couples in surrogacy cases? (Paragraph 8.18).

Yes. See our comments at 51 and 53 above.

**55.** The Government seeks views on whether:

- a court should be able to make a parental order (following surrogacy) in favour of civil partners, subject to the same rules and requirements that apply to married couples
- where one of the civil partners carries a child as the result of assisted reproduction treatment, the other civil partner should be treated in law as the parent of the child in line with married couples. (Paragraph 8.22).

Yes, in respect of both questions. See comments above.

**56.** The Government seeks views on whether the status and legal parenthood provisions in the HFE Act should apply to same-sex couples who *do not* form a civil partnership. If so, how would any automatic recognition of parenthood be achieved given the lack of legal ties between the couple? (Paragraph 8.24).

We do not think this question can be answered in the absence of an acceptable and workable legal definition of unmarried couples, whether they are in a heterosexual or same sex relationship. See comments above.

### Research

**57.** In common with the Science and Technology Committee, the Government believes that there is no case at present for either an extension or a reduction to the 14 day time limit for keeping an embryo. Any change would remain a matter for Parliament. (Paragraph 9.15).

Agreed

**58.** The Government believes that research undertaken on embryos using the cell nuclear replacement technique for the purpose of studying mitochondrial diseases should be permissible in law, subject to licensing. (Paragraph 9.22).

Agreed

**59.** Further, the Government invites views on removing the current prohibition on

“replacing a nucleus of a cell of an embryo with a nucleus taken from the cell of any person, another embryo or a subsequent development of an embryo” for research purposes, subject to licensing. (Paragraph 9.23).

We feel very uncomfortable about this

**60.** The Government invites views on whether the law should permit altering the genetic structure of an embryo for research purposes, subject to licensing. (Paragraph 9.28).

No

**61.** The Government invites views on whether the law should permit the creation of human-animal hybrid or chimera embryos for research purposes only (subject to the limit of 14 days culture in vitro, after which the embryos would have to be destroyed). (Paragraph 9.35).

No

**62.** The Government invites views on whether the current list of legitimate purposes for licensed research involving embryos remains appropriate. (Paragraph 9.38).

Yes

**63.** The Government believes that the purposes for which research using embryos may legitimately be undertaken should, as now, be defined in law and research projects should continue to be approved by a national body in order to ensure compliance with the law, national consistency and appropriate ethical oversight. (Paragraph 9.41).

We agree with this proposal

**64.** The Government invites views on what, if any, additional regulatory requirements should apply to the procurement and use of gametes for purposes of research. (Paragraph 9.45).

**65.** The Government invites comments on the desirability of allowing the creation of embryos for the *treatment* of serious diseases (as distinct from *research* into developing treatments for serious diseases which is already allowed). (Paragraph 9.47).

The Regulatory Authority for Tissues and Embryos

**66.** The Government proposes that RATE, in common with the HFEA and HTA, will be headed by a lay chairperson, and have substantial lay representation among its membership. The membership will also need to have, or have access to, sufficient medical and scientific expertise in relation to the activities that come within its remit. (Paragraph 10.4).

---

**67.** The Government proposes that:

- RATE will be an executive non-departmental public body. Its primary function will be to consider applications for licences to undertake those activities which Parliament decides should be subject to licensing. It will be funded principally from fees levied on licence-holders
  - RATE will be responsible for regular inspections of premises where licensable activities are carried on.
  - RATE will issue codes of practice giving guidance to persons undertaking those activities within its remit
  - RATE will maintain a central database of, at least, information relating to the use of donated gametes and embryos, and children born as a result.
- (Paragraph 10.5).
- 

**68.** Both the HFEA and the HTA currently have statutory functions including to monitor or review developments relating to the activities within their remits, and to provide advice to the Secretary of State where appropriate or where asked to do so. The Government believes that a similar 'advisory' function would be appropriate for RATE as this body will be well placed to observe and monitor developments through its licensing and inspection procedures and its information gathering function. (Paragraph 10.6).

---

**69.** The Government proposes that:

- the chairperson and members of RATE will be appointed by the NHS Appointments Commission
  - RATE will publish an annual report, which must be laid before Parliament
  - legislation will set out requirements for consultation and approval of codes of practice
  - RATE will publish summaries of embryo research licence applications received. (Paragraph 10.7).
-

**70.** The Government invites views on whether legislation should define a formal role for the professional bodies in advising RATE on the content of technical standards for assisted reproduction and embryo research. (Paragraph 10.10).

**71.** The Government invites views on what sanctions should be available to the regulator to ensure compliance whilst promoting service improvement. (Paragraph 10.13).

**72.** The Government invites views on whether the maximum penalty of ten years imprisonment under the HFE Act should be altered, and if so, what should the maximum penalty be? (Paragraph 10.16).

Miscellaneous

**73.** The Government invites views on the extent to which the principles of good regulation are upheld in the Government's proposals, and any other comments or information about the regulatory impact of the measures described in this consultation document. (Paragraph R1.16).

**74.** Finally, we would welcome your views on any other issues that you feel should be considered or changes that you would like to see made to the HFE Act 1990.

1. Revised legislation should include an explicit statement of underlying core principles. Such statements are evident in similar legislation in other jurisdictions (e.g. Human Reproductive Technology Act 1991 - Western Australia; Infertility Treatment Act 1995 – Victoria; Assisted Human Reproduction Act 2004 – Canada; Human Assisted Reproductive Technology Act 2004 - New Zealand; Assisted Reproductive Technology Bill 2003 - New South Wales).

2. The Government should clarify the position relating to any financial obligations of men who donated sperm before 1990. We share the concerns of the House of Commons Science and Technology Committee that ambiguity about such responsibility may deter these donors from providing information to any donor-conceived offspring.

3. The government should take steps to protect from the risk of destruction of all existing records of donor procedures undertaken in the UK before implementation of the Human Fertilisation and Embryology Act.

4. There should be a legal obligation to provide intermediary services for donor-conceived people who wish to access information from the Register of Information and seek contact with their donor(s). If the law is revised to include a right of access to information to wider groups of those affected, the right to intermediary services should similarly be extended.

**THANK YOU**