**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**

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

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**PROGAR (Project Group on Assisted Reproduction)** was set up originally at the time of the Warnock Inquiry in the 1980s, taking forward work carried by a predecessor group which had submitted evidence to that Inquiry on behalf of the British Association of Social Workers. The British Association of Social Workers is the largest professional association for social workers in the UK. The Association has more than 10,000 members employed in frontline, management, academic and research positions in all social care settings.

PROGAR continues to be administered by the British Association of Social Workers and draws on the knowledge and expertise of social workers in the fields of infertility counselling, adoption and fostering, child care, family work and health care.

PROGAR is now also supported by other individuals and organisations involved in adoption, child welfare, infertility counselling and the provision of support, counselling and information for families that have used assisted conception and for donors of gametes and embryos:

- Barnardos
- British Association for Adoption and Fostering
- British Infertility Counselling Association
- Donor Conception Network
- South East Post Adoption Network

PROGAR has contributed to policy discussions and policy formation in assisted conception on many occasions. The principles underlying PROGAR's work have always been that people with a personal involvement with fertility problems, especially people undergoing investigation and treatment, donors of gametes and embryos, and those conceived as a result of donor procedures, should receive the best care possible, including access to counselling and support.

We welcome the opportunity to participate in this consultation.

**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).

| We agree fully with this proposal |
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**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).

| We agree fully with this proposal |
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**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).

| We agree fully with this proposal |
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**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).

| We agree fully with this proposal |
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**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).

We agree fully with this proposal

**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).

We agree fully with this proposal

**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).

We agree fully with this proposal

**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).

Since the successful application of reproductive technology will result in the conception of a child, our view is that requirements in the Act concerned with the welfare of the child should also apply when a couple's own fresh gametes are used. See also our response to 13 below.

**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).

We favour option (b) – although we would expect the regulator to take account of current relevant clinical and scientific evidence and the views of competent professional bodies.

**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. In addition, all clinics should be required to offer implications counselling free of charge as part of the licensing criteria.

**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).

We have no corporate view on this.

<u>Welfare of the child</u>

**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. For consistency, the definition of "significant harm" should be modeled on that contained in the Children Act 1989.

There should also be a requirement to take account of the well-being of the child and any children affected. Where patients are contemplating the use of donated gametes, this would involve clinics being required to provide non-medical services which prepare patients for forming a family through donor conception and for meeting the identity needs of a donor-conceived child.

**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).

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| Given ambiguity regarding the welfare of the child and the fact that child welfare does not sit wholly within the medical domain in professional terms, we consider that if this is left to "good clinical practice" and to the judgement of individual clinicians, there will be unacceptably wide variations in definitions and practice. Subject to our recommendation in 13 above, we consider that there remains a strong case for guidance and regulation by the appropriate regulatory body to minimise the occurrence of such discrepancies and to ensure acceptable standards. |

**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).

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| 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).

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| 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).

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| 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. |

<u>The use and storage of gametes and embryos</u>

**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).

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| 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).

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| 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).

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| We agree fully with this proposal, subject to the safeguards regarding subsequent **usage** in 21 below. Careful consideration needs to be taken of the position of legal minors to ensure that any change accords with legislation relating to legal minors in the four UK nations. |

**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).

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| 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).

We agree fully with this proposal for the reasons outlined in the consultation document. We note that the government does not propose to change the law regarding the need for the consent of both parties whose gametes were used to create the embryo for the use of that embryo. Notwithstanding the difficult personal circumstances and distress that withdrawal of consent by one party only may have on the remaining party, we do not support any change in legislation regarding the consent that is necessary for the use of embryos.

**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 – see ?? below).

**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).

See response to 23 above

**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).

We agree with the principle that those seeking medical treatment should be provided with information about that treatment.

Individuals and couples considering assisted conception procedures are potentially vulnerable, because of the likely psycho-social distress to which they have been subject as a result of their involuntary childlessness, the invasiveness and likely expense of treatment and the still limited likelihood of treatment success. They need to have as much accurate information as possible both about the procedures and the potential implications of pursuing such procedures before embarking on treatment, during treatment and after treatment. 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. We consider that information about the implications of treatment should be provided by the independent counsellor.

**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 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.

Prior to implementation of the Human Fertilisation and Embryology Act 1990, infertility counselling as a specialist area of counselling practice barely existed. Its development in the subsequent 15 years has, in our view, been largely driven by the Act's requirement to make available such counselling. 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.

While technology and clinical competence have developed significantly since implementation of the Human Fertilisation and Embryology Act, there is no evidence that these have resulted in people with fertility difficulties contemplating invasive assisted conception procedures, undergoing such procedures and coping with treatment failure becoming any less exposed to psycho-social distress. Indeed, the increased treatment options available to individuals and couples, the continuing high levels of treatment failure and of multiple pregnancy when treatment is successful may well make deciding on a particular course of action and its implications more difficult for them.

We consider the need for competent counselling to be made routinely available to be at least as strong now as it was in 1990. Therefore, we do not consider that the statutory obligation on licensed centres to offer a suitable opportunity to receive counselling should be diluted in any way.

**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.

**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).

Parliament should establish the broad parameters within which donors should be compensated. While in principle we would welcome greater parliamentary involvement in the oversight of assisted conception in general, unless Parliament is able to establish a means by which it can keep the level of compensation under regular review, this is something that, in practice, is probably best undertaken by the regulator.

**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.

<u>Reproductive choices: screening and selection</u>

**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).

Legislation should outline the relevant criteria, which should be consistent with our proposals for safeguarding the welfare of the child outlined in 13 above.

**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).

See 31 above.

**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).

Yes.

**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).

No – see reply at 33 above

**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).

Our recommendation at 13 above concerning the need to consider the likelihood of significant harm to any child should also apply to the regulation of PGD, e.g. PGD may be permitted if the treatment centre has taken all reasonable steps to satisfy itself 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. See also our response at 31 above.

We would also emphasise the need for implications counselling to be made available when PGD is being considered.

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

We consider that techniques such as sperm sorting should be brought within regulatory control for similar reasons to those outlined in 38 below. We consider that the law should provide equally for sperm and eggs undergoing processes intended to result in the creation of embryos – whether fertilisation or other non-fertilisation processes. See also our response to 6 above.

**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).

We do not believe that there is a sound case for permitting sex selection on any social grounds. Sex selection for social reasons is unlikely to result in a major

imbalance overall in sex ratios at birth in a country such as the UK. However, we are aware of the sex ratio imbalances in countries such as China and India, the role that modern sex selection techniques play in perpetuating such imbalances, the disadvantages to which girls and women continue to be subjected and the serious demographic consequences that both countries are now facing.

Permitting sex selection on social grounds – including for "family balancing" - promotes the view that the use of such techniques is acceptable. In recognition of its global rather than purely domestic responsibilities, the UK should make an explicit statement that it is not.

**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).

We do not believe that there should be a power to relax the ban through regulations as the level of ethical and social concerns surrounding these developments require Parliamentary involvement. In addition, "safety and efficacy" should not be restricted to matters of physical safety but should also take account of our proposals regarding the welfare of future children.

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).

We agree with this proposal but would favour the removal of the reference to intention to marry as a criterion for information release (see also 40 below).

**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 (e.g. young people in Scotland who are subject to a Parental Order are able to access their birth records at the age of 16). While we accept that applying a minimum age is administratively simpler to apply, we prefer the application of a "Gillick-competence" requirement in this case; however, if this is not considered acceptable, we would agree to such information being made available uniformly from the age of 16. We note that any change in respect of donor conception may have implications for disclosure of birth origins information in respect of parental

orders and adoption. Any reference to intention to marry as a criterion for accessing information should be removed (see also 41 below)

**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).

See our responses to 42 and 43 above.

Use of the term “natural” in this question is unfortunate, since it invites comparison with “non natural”; “non-donor-conceived” would be a preferred term.

Not only “Non-donor-conceived” children of donors, but also “non-donor-conceived” children of recipients, should be entitled to receive the same non-identifying information as donors (42) and should be able to access identifying information so long as the express consent of the person whose identity is sought is obtained.

**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).

While parents cannot be directly compelled to tell their donor-conceived children about the nature of their conception, every effort should be made to encourage parents of donor-conceived children to tell their children about their conception, both before proceeding with treatment (including through providing preparation for parenthood through donor conception services) and at the different stages in their child’s development. More effort should be put into preparing people for becoming parents of donor conceived children and providing information about relevant support groups.

One way of encouraging parental disclosure would be to annotate birth records in a way analogous to adoption and parental order registration. 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. 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 decision about medical intervention and treatment.

The majority of our members support the annotation of birth records on the grounds that the birth record should not endorse a biological untruth and that knowing that the information is recorded somewhere in official documentation may help prevent deceit and secrecy. However, this is not a unanimous view; in particular, the Donor Conception Network is opposed to this in principle.

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. 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).

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| 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).

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| 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).

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| We agree fully with this proposal. |

<u>Surrogacy</u>

**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).

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| 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).

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| As indicated at 50 above, we are wary of using the Brazier report as an adequate basis for any proposed legislative change without further analysis of changing practices regarding surrogacy during the last 7 years. In the absence of such a review, our comments must remain impressionistic, although they draw on considerable experience within PROGAR of dealing with Parental Order applications.<br><br>The Brazier report noted wider community support for surrogacy than previously; however, it is likely that there remain substantial public concerns about it. Although we believe that there are no compelling reasons for banning surrogacy completely, the current legislation allows many loopholes. |

We agree that payments to surrogate mothers should be expressly limited to actual expenses occasioned by the pregnancy, and that what constitutes expenses should be defined in law

We are concerned that the recommendation of the Brazier report that payments to surrogates other than expenses should result in ineligibility for parental orders does not fully consider the implications for the welfare of the child concerned. We recognise that legislation needs to include sanctions for non-compliance, but breaches of rules are potentially more complicated where a child is involved. Sanctions should therefore be designed so as not to impact adversely on the welfare of any child(ren) concerned.

We agree that all agencies involved in surrogacy arrangements should operate only on a non-profit-making basis, and should have to be registered with the Department of Health.

We agree that a binding code of practice setting out minimum standards for surrogacy arrangements should be drawn up by the UK Health Departments, the HFEA and other interested bodies (covering matters such as the age of the surrogate). Arrangements will need to be made for inspection of agencies and ensuring their compliance with the law/regulations.

Grounds for the making of a parental order should be amended to mirror those pertaining to adoption. In particular, the law should enable an application for parental order to be made (subject to the order continuing to be in the child's best interests) in the rare event of the death of one of the commissioning parents either before an application for the order has been made or the order has been granted. There is also a need for amendment to the grounds on which Parental Orders are made to take account of civil partnerships and of unmarried heterosexual couples (see below).

All parental order applications should be heard in County Courts in England and Wales (and their equivalents in Scotland and Northern Ireland).

We are concerned about the continuing lack of clarity and understanding among some staff in licensed treatment centres about adoption and surrogacy and the resultant incorrect information that is passed to patients.

**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

<u>Status and legal parenthood</u>

**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).

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| 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. |

**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).

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| 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).

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| Yes in respect of both questions. |

**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).

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

<u>Research</u>

**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).

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| We agree fully with this proposal. |

**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).

In principle such decisions should remain with Parliament but should include greater reference to child and family welfare, social and ethical dimensions than hitherto, and not simply reflect the polarised views of the medical/scientific and the 'right to life' lobbies.

**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).

See our response to 58 above.

**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).

See our response to 58 above.

**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).

See our response to 58 above.

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

See our response to 58 above.

**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 fully 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).

All regulatory requirements will need to compliant with the EU Tissue Directive.

**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).

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| See our response to 58 above. |

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).

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| We agree fully with this proposal. However we also believe that it is essential that the body includes members with professional expertise in child and family welfare and academic expertise in the social sciences to reflect the fact that its activities extend beyond medicine and science. |

**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).

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| We agree in principle with the various elements of this proposal, although we have some concerns that the proposed funding arrangements – as with the HFEA at the present time – place the regulator and the centres it regulates in a potentially ambiguous relationship. We would not wish to see this impair the effectiveness of the regulatory process. |

**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).

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| We agree fully with this proposal. |

**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).

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| We agree fully with this proposal. |

**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).

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| The regulator should be required to take account of relevant professional bodies' contributions not only for "technical standards for assisted reproduction and embryo research" but also for social and ethical practice. |

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

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| In response to breaches of regulations, the regulator should continue to have available sanctions of:<br>• revoking a centre's licence<br>• varying a centre's licence<br>• imposing licence conditions on a centre<br>• making binding directions on licence holders. |

**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).

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| We note that, since this is a **maximum** penalty, courts will be able to apply a lesser sentence in the event of a conviction, dependent on the specific factors in each case.<br><br>In principle, sanctions should reflect the seriousness with which breaches are viewed by society. |

<u>Miscellaneous</u>

**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).

We have regularly voiced concerns about the operation of the HFEA regulatory system and have been pleased to note some improvements over the years while still highlighting areas that continue to need attention. In particular, there has been, in our view, a less-than-robust approach to the inspection of counselling services and to psycho-social issues involved in the provision of assisted conception services. There is still considerable room for improvement in achieving standardised inspection practices, and good enough levels of inspector training.

**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**