British Fertility Society

response to the

Department of Health

public consultation on

Review of the Human Fertilisation and Embryology Act

November 2005

This document represents the British Fertility Society (BFS) response to the Department of Health's Review of the Human Fertilisation and Embryology Act.

The British Fertility Society is a multi-disciplinary organization representing professionals with an interest in reproductive medicine. The objectives of the society are:

- To promote high quality practice in the provision of fertility treatment.
- To provide a common forum for members of various disciplines having an interest in the science and treatment of infertility.
- To promote high quality scientific and clinical research in the causes and treatment of infertility.
- To provide professional leadership in the provision and regulation of infertility services.
- To promote the increase of NHS funding for and equity of access to fertility treatments.

The provision of assisted conception is an important part of the workload of BFS members and as such the society has an interest in policy developments in this area.

To respond to this consultation, BFS membership were circulated by email and asked to send in their replies using the standard proforms. This response represents the majority view of those who replied and was compiled by Alison Murdoch on behalf of the Executive Committee.

It is submitted by the Honorary Secretary whose contact details are:

Dr. Allan Pacey
c/o British Fertility Society Secretariat
22 Apex Court
Woodlands
Bradley Stoke
BS32 4JT

bfs@bioscientifica.com

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).

The BFS agrees with this view

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).

The BFS is disappointed that the Government has not recognised the problems that of the Human Fertilisation and Embryology Authority but agrees that, assuming that these issues are addressed, the principal of an independent statutory authority should continue.

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).

The BFS agrees that the role of regulation and policy making must be independent and accountable.

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).

The BFS supports the view that embryos outside the body should be subject to regulation. It recognises the differing views on the definition of an embryo and suggests that this be reviewed. It supports that view that different consideration must be given to cells that are grown for research and those that are grown for the purpose of reproduction.

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).

The government needs to be aware that the rapidly changing technology and science in this field require sufficient flexibility in regulations to enable the new successful treatments to be implemented without delay. The BFS agrees that

only accepted forms of embryos should be used in treatment, and other forms require consideration by Parliament (see 7 below).

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).

If the definition of an embryo is 'after first cleavage' (see 4), this is acceptable: procedures not intending to result in cleavage should remain outside regulation by the HFEA.

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).

It is the majority view of the BFS that primary legislation is not necessary to ensure good clinical practice. The BFS expects that existing clinical governance regulations and the regulations under the EU Tissues and Cells directive will mean that there is no requirement for additional regulation on this issue.

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).

It is the current BFS majority view that regulation should be limited to technical and safety issues and that this should be possible to achieve through the EU Tissues and Cells Directive rather than additional UK legislation.

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).

It is the BFS view that there are significant safety issues surrounding the use of fresh sperm that has not been held in quarantine. Such services should be brought into line with those currently regulated by the HFEA.

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).

The BFS view is that this is an issue which must be set by the Professional bodies and funders. It can be enforced by the regulatory body.

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).

It is the BFS view that the regulator should have no powers in relation to the costs of assisted reproduction.

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).

These should be allowed but do not need any additional approval/licensing from the regulator authority. The authority should accept the practices approved by other regulators.

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).

It is the BFS view that treatments providers will continue to take account of the welfare of the child in accordance with all the other principals of clinical governance to which they are subject. The BFS is happy with the outcome of the recent HFEA consultation exercise on the Welfare of the Child. However, it is mindful that infertile couples consider this aspect of the HFE Act to be potentially discriminatory.

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).

It is the BFS view that this should be a multidisciplinary team decision, with responsibility not resting only with the clinician.

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).

No.

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.

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).

The need for a father should be removed and replaced with "the need for high quality parenting".

<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).

Yes, except with respect to consent for use of surplus gametes in training and audit. This should not require specific consent, consistent with the Human Tissue Act.

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).

Yes

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).

Yes – consent for storage should be taken at the time of removal.

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).

Yes

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).

It is the BFS view that the current system – where both parties have to consent to storage or use – remains appropriate.

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).

For use in clinical treatment the BFS view is that there should continue to be a set statutory maximum storage period for gamete and embryos. Without a time limit, many couples would be left with no closure to their treatment. For use of stored gametes and embryos in research projects, the BFS view is that there should not be a set maximum storage period. The current limit means that because many couples donate gametes and embryos close to the statutory storage period, that they cannot be used in research, and are wasted, because there is not enough time to do so.

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).

Yes. Except for storage for research, as (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).

It is the BFS view that this is required by good medical practice guidelines so should be provided irrespective of additional legislation.

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.

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).

Similar regulations should apply to ART as for other medical treatments. However, it is the BFS view that it should be available to those using donated gametes (see 28).

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).

The BFS supports this view.

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).

This should be subject to constant review given the rapidly changing practice of donations. Any system must take account to the need for this flexibility.

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).

The BFS has responded previously on this matter during HFEA SEED review (February 2005) and members are equally split between those who feel that there should be no payment and those who felt that some level of payment should be permitted. The BFS remains concerned about the current supply of donors in UK clinics.

<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).

The strong view of the BFS has been that it is for the profession societies to set out the general criteria for screening and selection. The regulator can ensure that clinics maintain these standards but they must not be responsible for the setting of the standards.

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).

These decisions should be the result of discussions between patients and those given the responsibility for their care. Ultimately this must be a decision made by the patient. Any regulations must be consistent with those applying to post-implantation diagnosis.

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).

The BFS has argued strongly the standards must be set by the professional bodies and not the regulator. The role of the regulator is to ensure standards are maintained.

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).

The BFS has argued strongly the standards must be set by the professional bodies and not the regulator. The role of the regulator is to ensure standards are maintained.

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).

It is the BFS view that this should be permitted but needs to be carefully regulated. It should only be allowed in cases where PGD is also required to avoid genetic disease, i.e. where the biopsy of cells from the embryo is performed at least partially for the benefit of that embryo rather than for the benefit of a third party alone. PGD for tissue typing alone should not be allowed because of the lack of evidence of long term effects on development. This is a good demonstration of the DH's interpretation of the precautionary principle, as it is not possible to demonstrate harm in this case and yet the potential harm cannot be ignored.

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

It is the BFS view that the standards on screening and selection should be set by the professional bodies based on clinical and laboratory evidence available. However, the EU Directive will ensure that these standards are being met through the through regulation by the responsible body.

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).

The members of the BFS who responded to this question were divided on the point. There are those who believe that there is little point in trying to regulate sex selection by assisted conception procedures when it can be achieve by other

means (e.g. termination). Whereas there are other members who strongly believe that it should be banned for non-medical reasons where there is a danger of the child being treated as a commodity.

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).

It is the BFS view that caution is still needed in relation to treatment but research must be permitted.

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).

The BFS is in agreement with this.

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).

The BFS is in agreement with this.

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).

The BFS is in agreement with this but would like to point out that it would be more accurate to check this DNA testing.

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).

It is the BFS view that there is no need to specify the non-identifying information which could be provided. No information other than that in the medical records is available and this should all be made available.

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).

The BFS is of the view that this would not be acceptable.

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).

The BFS is of the view that this would not be acceptable.

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).

It is the BFS view that this is the personal choice of the parents and any legal regulations to require them to tell children about their origins would not be enforceable. However, the BFS is of the view that a culture of openness should be encouraged.

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).

It is the BFS view that such data should be collected and published. The regulators should ensure that clinics give potential patients accurate information about their services and outcome.

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).

It is the BFS view that there is no current evidence to support an unspecified and untargeted collected of further data beyond the current dataset. However, if it were more accessible to researchers then a case for an expanded dataset could be made as long as it was achieved without a further burden on clinics. In the future this could be possible more clinics have their own computerised databases and therefore electronic reporting would make any future expansion of the dataset relatively simple.

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).

Yes, local databases will be required under the EU regulations to permit ongoing audit of each unit. As outlined in 47, this could be used to expand the central database.

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).

The BFS is in agreement with this.

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).

It is the BFS view that no changes are needed.

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).

It is the BFS view that no changes are needed.

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).

It is the BFS view that no changes are needed.

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).

The Act should ensure that the legal definitions relating to parental responsibility following conception after ART is consistent with spontaneous conception whether or not they were married.

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).

The BFS has no view on this point.

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).

The BFS has no view on this point.

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).

It is the BFS view that both partners agreeing to treatment leading to conception should have their commitment and responsibilities recognised in law.

<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).

The BFS is in agreement with this.

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).

The BFS is in agreement with this. The Government need to be aware that this might result in requests to move to treatment if the research is successful.

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).

The BFS is in agreement with 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).

The BFS is of the view that the law needs to be made clear as to what is meant by genetic structure and whether this includes both nuclear and mitochondrial DNA. In principle the BFS supports the view that the genetic structure of the

nucleus should not be altered for reproductive purposes unless previous research has provided evidence to support clinical use. We support the proposal that it should be allowed for research purposes.

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).

It is the BFS view that this should not be prohibited by law. Any research will be subject to appropriate ethic and scientific review by other bodies before it could be approved.

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

It is the BFS view that the current arrangements are satisfactory.

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).

The BFS view is that there are already substantial bodies overseeing clinical research that have national consistency in their process (COREC). This includes both ethical and scientific review. National consistency has not been a significant problem in other areas of research and MREC procedures have been instituted to resolve those which mainly related to minor issues in multicentre studies. There may need to be national review of projects to ensure compliance with the current legal framework, but there is no need to duplicate the COREC process.

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).

The BFS is of the view that no additional regulatory requirements are needed other than the review by the institutional research ethics committee.

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).

It is the BFS view that this is essential if the promise of embryonic stem cell therapies is to be achieved.

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).

The BFS has no view on this point and feels that parliament should make this decision.

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).

The BFS has no view on this point and feels that parliament should make this decision.

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).

It is the BFS view that policy-making and regulation are 2 separate functions. It is not appropriate that the same body is responsible for both.

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).

The BFS has no view on this point and feels that parliament should make this decision.

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).

It is the BFS view that standards must be set by the professional bodies.

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

It is the BFS view that criminal sanctions are not appropriate for technical violations of licensed procedures.

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).

It is the BFS view that criminal penalties should only be used against those who knowingly carry out procedures covered by regulations without a licence. The maximum penalty should only apply if there is evidence of serious harm as a consequence.

<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).

The BFS has no view on this point.

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.

The BFS has no further views