Case No: **FD25F00003**

IN THE HIGH COURT OF JUSTICE
FAMILY DIVISION

NCN: [2026] EWHC 317 (Fam)

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 16 February 2026

Before:
Mrs Justice Morgan:

AA AND OTHERS

Applicants

- and -

(1) THE HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY (HFEA)

(2) THE FERTILITY CLINICS

(3) THE SECRETARY OF STATE FOR HEALTH AND SOCIAL CARE (SSHSC)

Interested Parties

- -

Ms Emma Sutton KC and Ms Imogen Goold (instructed by LDMH Partners) for the **15 Applicants**
Mr Ravi Mehta and Mr Femi Adekoya (instructed by the HFEA's legal department) for the **HFEA**
Mr Jeremy Hyam KC and Ms Emma-Louise Fenelon (instructed by the Government Legal Department) for the Third Respondent, the **SSHSC**
No attendance or representation on behalf of the Second Respondents, the Fertility Clinics

Hearing dates: 27, 28, 29 October 2025

- -

Approved Judgment

This judgment was handed down remotely at 2pm on 16 February 2026 by circulation to the parties or their representatives by e-mail and by release to the National Archives.

.....

This judgment was delivered in public but a transparency order is in force. The judge has given leave for this version of the judgment to be published on condition that (irrespective of what is contained in the judgment) in any published version of the judgment the anonymity of the parties must be strictly preserved. All persons, including representatives of the media and legal bloggers, must ensure that this condition is strictly complied with. Failure to do so may be a contempt of court.

Mrs Justice Morgan:

1. Fifteen applications are made to the court for declarations that it is lawful for gametes or embryos to continue to be stored and to be used in circumstances where in each of the fifteen cases written consent to storage has expired and was not renewed within the timeframes provided by legislation for renewal of such consent.

2. The applicants are all patients whose embryos or gametes are stored at one of a number of Fertility Clinics. Those clinics are: Clinic 1, Clinic 2, Clinic 3, Clinic 4, and Clinic 5. The clinics are joined as interested parties. None have participated in this hearing. Written evidence has been filed by the clinics. Also joined as interested parties are The Human Fertilisation and Embryology Authority ('HFEA') and the Secretary of State for Health and Social Care ('SSHSC'). Each has attended and been represented at this hearing. The HFEA has filed evidence from its Chief Executive, Peter Thompson, the SSHSC has filed evidence from the Director of NHS Safety and Investigations Division in the DHSC

3. The applicants have been represented at this hearing by Ms Sutton KC and Ms Goold; the HFEA by Mr Mehta and Mr Adekoya, and the SSHSC by Mr Hyam KC and Ms Fenelon.

4. The applications for declaratory relief are made on the basis of the European Convention of Human Rights ('ECHR') given effect by the Human Rights Act 1998 ('HRA 1998'). The applications fall outwith the scheme of the Human Fertilisation and Embryology Act 1990, the Human Fertilisation and Embryology Act 2008 and as amended by the Health and Care Act 2022 (respectively 'HFEA 1990', 'HFEA 2008', and 'HCA 2022'). It has been convenient to hear the applications together since the issue which arises in each of them – whether, and if so how, consent to continued storage and future use of gametes and embryos may be given and renewed within the relevant legislative scheme and the permissibility or otherwise outside that scheme considered by the court under s 3 (1) HRA 1998 as a route to relief - is applicable to all fifteen cases. It nonetheless is important to remember that in determining the applications for relief it is the individual circumstances of those involved in each of the fifteen cases which fall to be considered. That it is convenient to do so at one hearing, primarily because of how the circumstances came to be discovered, and the necessity

for applications arose, should not lead to the inadvertent impression that this is an application brought, to use the words of Leading Counsel, Ms Sutton as '*some sort of 'test case''.* It has been made explicitly clear that it is not.

5. Much of that which follows is concerned with an examination of legal and technical aspects of the applications which occupied the court and counsel during argument and submissions. The approach rightly taken by Ms Sutton in presenting the applicants' cases was not to rehearse the detail of the intensely personal and intimate experiences in their lives which had led each of them to fertility treatment, the ways in which those experiences had, for each of them, impacted upon the most private aspects of their life, how hopes had been raised only to be dashed, and now the exquisitely painful experience of finding themselves before the court, with the possibility remaining to them of genetic parenthood but knowing that the strict provisions of legislation may mean that possibility is illusory. Each of those making applications has set out those experiences in witness statements in support of their application and I have read them carefully. Each spoke of the individual pain, distress and anxiety which they had lived through to this point. Many accounts had a quality of yearning and longing, some of desperation. I hold in my mind all that I have read and been told about those aspects. I hold in my mind also, the many and strong exhortations emerging from the authorities where similar issues have fallen to be determined, reminding those making the determinations that sympathy for the situation of those involved cannot be allowed to offer itself as a substitute for a proper application of the relevant law.

6. Ms Fenelon concluding her able submissions on behalf of the SSHSC, perhaps reflecting that tension described above, emphasised that the position taken by the SSHSC is not one borne of cruelty and of course it is not. For those whose lives are so closely affected by the applications however, this court process is likely to have been felt to be cruel. It must be understood that where opportunities develop, made possible by scientific progress which barely a generation previously could only have been imagined, the strictness of the legislative framework surrounding those opportunities is a necessary and important protection from unregulated consequences which are not tolerable to society.

7. It has been of very great assistance to receive from counsel detailed written arguments developed and amplified by skilled oral submissions from both leading and junior

counsel. The Court's gratitude is recorded for that assistance and for the very significant amount of work which lay behind it in these unusual and difficult cases.

8. The precipitating events that led to this hearing were these. On 23rd December 2024 an emergency application was made to Cusworth J as the urgent out of hours judge in Christmas High Court vacation for injunctive relief in circumstances where a number of fertility clinics would otherwise be required by 31st December 2024 (for reasons examined later in this judgment) to remove from storage and destroy embryos and gametes which were being stored. By his order an interim declaration as to lawful storage was made. Following the making of that order the position has been preserved that none of the embryos or gametes which are the subject of the applications have been destroyed, but neither can any of them be used. A series of case management hearings followed at which the interested parties were joined and directions including for evidence were made.

The Relevant Legal Framework

9. There is, unsurprisingly, no dispute between the parties as to the relevant legal framework – though as will be necessary to consider later, there is as to the question of how it should be applied.

10. The relevant provision of the ECHR is Article 8 which provides:

"1. Everyone has the right to respect for his private and family life, his home and his correspondence.
2. There shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others."

11. Section 3(1) HRA1998 provides:

"Interpretation of legislation (1) So far as it is possible to do so, primary legislation and subordinate legislation must be read and given effect in a way which is compatible with the Convention rights."
Section 6(1) HRA states that:
"Acts of public authorities.
(1) It is unlawful for a public authority to act in a way which is incompatible with a Convention right."

12. As to the legislative framework regulating the use of gametes and embryos there is also consensus. The key provisions, the operation of which have resulted in the position here, are these.

13. Donation storage and use of gametes and of embryos is regulated by the Human Fertilisation and Embryology Act 1990 ('HFEA 1990') as amended by secondary legislation, the Human Fertilisation and Embryology Act 2008 ('HFEA 2008') and the Health and Care Act 2022 ('HCA 2022'). The legislation is supplemented by the HFEA Code of Practice (issued pursuant to section 25 of HFEA 1990) and associated Guidance. In 2020 the societal and health circumstances arising from the Covid Pandemic led to the *Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) (Coronavirus) Regulations 2020. ('Coronavirus Regulations 2020')*

14. The regulatory effect of those provisions in combination may conveniently be summarised as follows. A person's gametes must not be kept in storage unless there is an effective consent by that person to their storage and they are stored in accordance with that consent (*HFEA1990 Schedule 3, Para 8(1)*). An embryo, the creation of which was brought about in vitro, must not be kept in storage unless there is an effective consent, by each relevant person in relation to the embryo, to the storage of the embryo and the embryo is stored in accordance with those consents. (*HFEA 1990 Schedule 3, Para 8 (2)*)

15. Until the coming into effect of the HCA 2022, the upper limit of time for which embryos or gametes might be stored was 10 years. This was subject to some limited exceptions. For the purposes of this case, the relevant exceptions were introduced by the Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009/1582 ('the 2009 Regulations') which, for those patients who were prematurely infertile (or likely to become so) provided an upper limit of 55 years provided that the premature infertility or likely infertility was supported by a Medical Practitioners Statement ('MPS'), to be renewed every 10 years. The other relevant variation in respect of extension is to be found in the *Human Fertilisation and Embryology* (*Statutory Storage Period for Embryos and Gametes) (Coronavirus) Regulations 2020* which permitted those whose gametes or embryos were already in

storage on 1st July 2020 to extend further the storage period by an additional 2 years (i.e. providing a maximum of 12 years). Those regulations were later repealed in 2022.

16. When the HCA 2022 was enacted it had the effect of extending the period for which gametes and embryos may be stored from 10 years to 55 years in all cases and extinguished the differences in time permitted between those instances where there was premature infertility and those where there was not. The 55 year time limit still required consent, and that consent required renewal every ten years. Detailed provisions govern the process for renewing consent, the circumstances in which consent is deemed to have been withdrawn, and the consequences of withdrawal of consent.

The Process for the Renewal of Consent

17. Paragraph 11A of Schedule 3 to the HFEA 1990 provides for the renewal of consent to storage in relation to gametes as follows:

(2) The person keeping the gametes in storage ("K") must, in each consent period, request P to renew consent to storage of the gametes within the renewal period.
For the meaning of "consent period" and "renewal period", see paragraph 11B.
(3) A request under sub-paragraph (2) must be given in writing before the start of the renewal period.
(6) P renews consent by informing K in writing that P consents to the storage of the gametes.
…
(7) If P's consent is not renewed under sub-paragraph (6) before the end of the consent period, K must, as soon as possible after the end of that period, give a notice to P stating that if P does not renew consent before the end of the renewal period, the gametes will be removed from storage and disposed of.

18. Paragraph 11B of Schedule 3 to the HFEA1990 defines the 'consent period' and the 'renewal period' in relation to gametes (Paragraph 11A) as follows:

(1) For the purposes of paragraph 11A, each of the following is a "consent period"—
(a) the period of 10 years beginning with the relevant day, and
(b) each successive period of 10 years.
(2) In sub-paragraph (1)(a) "relevant day" means—
(a) the day on which the gametes are first placed in storage, or
(b) in a case where sub-paragraph (3) or (5) applies, the day on which P gives consent to the storage of the gametes.
…
(6) In paragraph 11A "the renewal period", in relation to a consent period, means the period which—
(a) begins 12 months before the end of the consent period, and
(b) ends 6 months after the end of the consent period.

19. Paragraph 11C of Schedule 3 to the HFEA1990 provides in relation to embryos:

(2) The person keeping the embryo in storage ("K") must, in each consent period, request P to renew consent to storage of the embryo within the renewal period.
For the meaning of "consent period" and "renewal period", see paragraph 11D.
(3) A request under sub-paragraph (2) must be given in writing before the start of the renewal period.
...
(7) If P's consent is not renewed under sub-paragraph (6) before the end of the consent period, K must, as soon as possible after the end of that period, give a notice to P stating that if P does not renew consent before the end of the renewal period, the embryo will be removed from storage and disposed of.

20. Paragraph 11D of Schedule 3 to the HFEA 1990 defines the 'consent period' and the 'renewal period' in relation to embryos (Paragraph 11C) as follows:

(1) For the purposes of paragraph 11C, each of the following is a "consent period"—
(a) the period of 10 years beginning with the day on which the embryo is first placed in storage, and
(b) each successive period of 10 years.
(2) In paragraph 11C "the renewal period", in relation to a consent period, means the period which—
(a) begins 12 months before the end of the consent period, and
(b) ends 6 months after the end of the consent period.

21. The effect of the Renewal Period in relation to embryos is that the statute provides a six-month period – referred to in argument at this hearing as a 'grace period' or a 'cooling off period' following the end of the consent period. There is no such period in relation to gametes.

22. The legislation thus requires clinics to send a statutory notice to patients before the start of the Renewal Period (i.e. more than 12 months before the end of the Consent Period), notifying patients of the possibility of renewing their consent to storage. Renewal of consent must be in writing and must follow the offer of counselling. If patients do not renew their consent before the end of the Consent Period, clinics *must* send a further statutory notice to patients, notifying them that if they do not renew their consent before the end of the Renewal Period, their consent will be deemed to have been withdrawn and their material will be removed from storage. The relevant provisions follow.

Withdrawal and Deemed Withdrawal of Consent

23. Paragraph 11A of Schedule 3 to the HFEA 1990 details the effect if consent is not renewed by the end of the Renewal period in relation to gametes:

(8) P's consent to the storage of the gametes is to be taken as having been withdrawn at the end of a renewal period that relates to a consent period if—
(a) K has complied with the requirements of sub-paragraphs (2) and (7) in relation to that consent period, and
(b) P's consent is not renewed under sub-paragraph (6) before the end of the renewal period. But this is subject to sub-paragraphs (9) and (10).
(9) If, in a case referred to in sub-paragraph (8)(a) and (b), P dies before the end of the renewal period—
(a) P's consent is not to be taken as withdrawn under sub-paragraph (8), but
(b) if at the end of the period of 10 years beginning with the day on which P died there is still effective consent from P to the storage, P's consent is to be taken as withdrawn at that time.
(10) If, in a case referred to in sub-paragraph (8)(a) and (b), before the end of the renewal period P is certified as lacking capacity to renew consent—
(a) P's consent is not to be taken as withdrawn under sub-paragraph (8), but
(b) if at the end of the period of 10 years beginning with the day on which P was so certified there is still effective consent from P to the storage, P's consent is to be taken as withdrawn at that time."

24. Paragraph 11C of Schedule 3 to the HFEA 1990 details the effect if consent is *not* renewed by the end of the Renewal period in relation to embryos:

(8) P's consent to the storage of the embryo is to be taken as having been withdrawn at the end of a renewal period that relates to a consent period if—
(a) K has complied with the requirements of sub-paragraphs (2) and (7) in relation to that consent period, and
(b) P's consent is not renewed under sub-paragraph (6) before the end of the renewal period. But this is subject to sub-paragraphs (9) and (10).
(9) If, in a case referred to in sub-paragraph (8)(a) and (b), P dies before the end of the renewal period—
(a) P's consent is not to be taken as withdrawn under sub-paragraph (8), but
(b) if at the end of the period of 10 years beginning with the day on which P died there is still effective consent from P to the storage, P's consent is to be taken as withdrawn at that time.
(10) If, in a case referred to in sub-paragraph (8)(a) and (b), before the end of the renewal period P is certified as lacking capacity to renew consent—
(a)P's consent is not to be taken as withdrawn under sub-paragraph (8), but
(b) if at the end of the period of 10 years beginning with the day on which P was so certified there is still effective consent from P to the storage, P's consent is to be taken as withdrawn at that time."

25. The effect of Paragraphs 11A(8) (gametes) and 11C(8) (embryos) is therefore to set out conditions for the withdrawal of consent.

26. The patient's consent to storage will be *deemed* to have been withdrawn at the end of the Renewal Period *if the clinic has written to the patient* and asked them to provide consent to continued storage and the patient has not responded.

27. Where patients do not renew their consent to storage before the end of the Renewal Period, the end of the Renewal Period will be treated as the date of withdrawal of consent.

28. Expressed as it is, conditionally, i.e. '*if*' the clinic has complied with its obligations of notification, the provision deeming withdrawal of consent plainly had in contemplation when drafted, the prospect that there might be a failure of compliance by the clinic. It is curious that the legislation is silent on what may be done if the clinic fails to comply with sub-paragraphs (2) and (7). The impact of a failure to notify the patient (which is the factual circumstance in at least some of the applications before this court) of the need to renew consent is therefore unclear. This is discussed below at [91].

Effect of Withdrawal of Consent

29. Withdrawal (including deemed withdrawal) of consent has the effect of imposing obligations on the clinics storing gametes and embryos.

30. Paragraph 8 provides:

> *(1) A person's gametes must not be kept in storage unless there is an effective consent by that person to their storage and they are stored in accordance with the consent.*
> *(2) An embryo the creation of which was brought about in vitro must not be kept in storage unless there is an effective consent, by each relevant person in relation to the embryo, to the storage of the embryo and the embryo is stored in accordance with those consents. It is unlawful for a clinic to store gametes or embryos without valid consent.*
> [emphasis added]

31. Once consent is deemed to have been withdrawn, HFEA 1990 requires the gametes/embryos to be removed from storage and destroyed. Where consent has been deemed to be withdrawn, Paragraph 11A is silent on *when* this must occur in relation to gametes. As to embryos, paragraph 11C(14) provides that:

(14) Storage of the embryo remains lawful until—
(a) the end of the period of 6 months beginning with the day on which P's consent is taken as withdrawn under this paragraph, or
(b) if, before the end of that period, K receives a notice from each person notified under sub-paragraph (13) stating that the person consents to the disposal of the embryo, the time at which the last of those notices was received.

32. Thus the effect of these provisions differs for gametes and embryos. For gametes, storage once withdrawal of consent has occurred is unlawful, which suggests removal should be immediate. For embryos, there is a 6-month period during which storage remains lawful although not seemingly obligatory.

33. The *HFEA Clinic Practical Guide on Legal Changes to Storage Limits and Guidance* ('The HFEA Clinic Guide') supports this interpretation of the provisions. For gametes, it states: *"In the case of gametes, centres will be legally required to remove the gametes from storage and dispose of them at the end of the renewal period."*

34. Section 3 of the HFEA Clinic Guide addresses the requirements for storage consent. Section 3.2.9 covers "*Action to be taken if consent to storage of embryos has not been renewed before the end of the renewal period*". It states:

"if after the renewal period has ended (six months after the end of the consent period) the centre has not received either a renewal of consent or a withdrawal of consent, centres are required to take all reasonable steps to give a further 'Notification to each person whose eggs or sperm were used to create embryo(s) that consent to storage has been withdrawn' (NWC) to each person whose gametes were used to bring about the creation of the embryo.

In these circumstances the continued storage of the embryos will remain lawful for a further period of six months from the end of the renewal period which is up to 12 months after the end of the consent period.

If, before the end of the additional six-month period, the centre receives written notification of withdrawal of consent to storage of the embryo from each person notified then the embryo should be removed from storage when the last of those notices is received."

35. Therefore, with regard to embryos, during this 6-month period, clinics are required (by the Guidance) to take all reasonable steps to give notice of the withdrawal of consent to the patient(s) in relation to embryos. This period is referred to in the Explanatory Notes to the 2022 Act at para [1211] as a 'Cooling Off Period'. As has been seen no such similar provision is made in relation to gametes in the statute - yet the explanatory notes state at [1211] under the heading Renewal of consent to storage of gametes:

Paragraph 7(4) inserts new paragraphs 11A to 11D into Schedule 3 to the 1990 Act. The new paragraphs 11A and 11B specify the requirement for 10-year review periods and consent renewals as a condition to continue the storage of gametes up to the maximum of 55 years. These new requirements will need to be complied with as a condition of any storage licence granted under the 1990 Act by facilities storing gametes.
Paragraph 11A applies the renewal requirements to people who are storing their gametes for the purposes of their treatment alone or with a partner, including for the purposes of surrogacy arrangements. The facility storing the gametes must attempt to contact the person storing their gametes 1 year in advance of expiry of any 10-year storage period and request that consent for ongoing storage is renewed. If the person whose gametes are in storage does not renew their consent, then their consent may be taken as withdrawn after certain requirements have been met. The facility must then attempt to contact the person storing their gametes on or around the date of expiry to tell them that their storage period has come to an end. If the gamete provider does not provide renewed consent, the facility must dispose of the gametes 6 months following the expiry of consent to store. This is effectively a "cooling off" period to allow for disposal.
…
The renewal of consent requirements set out in paragraph 11A do not apply to donated gametes stored for the treatment of others.

36. As to *Renewal of consent to storage of embryos* which is set out at paragraph 1216 of the Explanatory notes to the HCA 2022 states as follows:

Paragraph 11C (Renewal of consent to storage of embryos) applies to people who are storing their embryos, created in vitro, for the purposes of their treatment or that of a partner, including for the purposes of surrogacy arrangements. This paragraph applies in the same way as paragraph 11A, subject to the exception that both gamete providers must provide consent to storage, and the facility storing the material must contact both persons whose gametes have been used to produce the embryo, in order to renew consent, unless one set of gametes is provided by a third-party donor. If either of the gamete providers fail to renew their consent before the 6 months after the consent expires, subject to certain requirements, consent for storage will be taken as withdrawn and the facility must dispose of the embryo(s) following another 6 months cooling off period.

37. The HFEA 1990 does not include any specific provisions in relation to what may or may not be done during the Cooling Off period. The HCA 2022 is similarly silent.

38. The HFEA Guidance covers the Cooling Off Period in relation to embryos where *one* gamete provider has actively withdrawn consent to storage where the embryo is not in storage for the treatment of that gamete provider alone (Section 3.7). Section 3.7 is couched in terms of provision of time for written consent to destruction during the cooling off period. No mention is made of renewal of consent during the cooling off period:

"3.7 Cooling Off Period

The law still allows an embryo to be stored when a centre receives signed written notification of withdrawal of consent from one gamete provider where the embryo is not in storage for the treatment of that gamete provider alone. In such circumstances, the centre must, as soon as possible after receiving the signed notice, give notice to each interested person. The continued storage of the embryos will be lawful for a period of 12 months from the date that the centre received the signed notice of withdrawal of consent unless the centre receives written signed consent to the destruction of the embryo from each person notified of the withdrawal. This 12-month 'cooling off' period must not extend beyond the end of the period for which valid consent exists."

39. Section 10 of the HFEA Guidance includes: "*Further Guidance on Consent and Calculation of Storage Periods*", noting at Section 10.6 that these provisions should be interpreted as meaning that "*During this six-month period embryos cannot be used in treatment and consent to storage can no longer be renewed".* That advice is contained in the last paragraph of the section set out below:

"As explained in section 3.6 above the amendments to the Act relating to renewal of consent to storage provide some modifications as to when consent to storage will be treated as withdrawn.

Where patients do not renew their consent to storage before the end of the renewal period, the end of the renewal period will be treated as the date of withdrawal of consent.
When gamete providers have failed to respond to statutory notices RNE and NDE to

indicate whether they wish to renew or withdraw their consent to storage of their embryos, centres must then send a further statutory notice NWC. This notice is only required in these circumstances when one or both gamete providers have failed to respond to previous notices. If one gamete provider actively withdraws consent to storage of their embryos on the RE, then centres are not required to send the NWC and instead should follow their current processes for contacting and informing the other gamete provider of the withdrawal of consent to storage of the embryos created with their gametes. The 'cooling off' period will not apply in these circumstances because there is no longer effective consent in place.

In relation to embryos in storage for treatment purposes, paragraph 11C (14) provides that storage will remain lawful for a period of six months after consent is treated as withdrawn under paragraph 11C (8) (i.e., the end of the renewal period). This must be read in conjunction with 11C (13) which requires centres, when consent is taken as withdrawn, to take all reasonable steps to give notice of the fact that consent has been taken as withdrawn to each person whose gametes were used to bring about the creation of the embryo. This additional period will come to an end before the full 6 months has elapsed if the centre receives consent to the disposal of the embryos from each person notified. There is no comparable provision for gametes.

"During this six-month period embryos cannot be used in treatment and consent to storage can no longer be renewed. Centres should consider the specific circumstances of the patients in deciding whether they continue to store the embryos lawfully until the end of the six-month period, or whether to remove the embryos from storage before the end of the six-month period without receiving consent to disposal of the embryos from each person notified under 11C(13). Considerations could include whether there is a risk of legal challenge." [emphasis added]

There is no similar Cooling Off Period in respect of gametes and therefore no corresponding Guidance.

40. The effect of this guidance is to interpret the new regulations as prohibiting patients both from using their embryos during the Cooling Off Period and from renewing their consent to storage. That is the position of those making applications here.

Transitional Arrangements for Renewal of Consent

41. For those whose embryos or gametes were already stored under the existing provisions, the HCA 2022 sets out transitional arrangements where consent to storage would expire during the Transitional Period identified as 1st July 2022 – 30th June 2024. The arrangements appear in Schedule 17 to the HCA 2022.

42. Part 2 of Schedule 17 sets out these arrangements as follows:

Renewals falling due in the transitional period

17. (1) This paragraph applies in relation to the storage of gametes under a pre-commencement gamete storage licence in a case where—

(a) paragraph 11A of Schedule 3 to the 1990 Act applies in relation to the storage, and (b) for the purposes of that paragraph, the first consent period (see paragraph 11B(1)(a) of that Schedule) ends in the transitional period.

2. Where this paragraph applies, paragraph 11A of Schedule 3 to the 1990 Act has effect in relation to that first consent period as if—

(a) for sub-paragraphs (2) and (3) there were substituted—

(2) The person keeping the gametes in storage ("K") must request P to renew consent to storage of the gametes before 1 July 2024.

(3) A request under sub-paragraph (2) must—

(a) be given in writing before 1 July 2023;

(b) state that if P does not renew consent before 1 July 2024, the gametes will be removed from storage and disposed of.";

(b) in sub-paragraph (5)(b), for "the start of the renewal period which relates to that consent period" there were substituted "1 July 2023";

(c) sub-paragraph (7) were omitted;

(d) for sub-paragraph (8) there were substituted—

"(8) P's consent to the storage of the gametes is to be taken as having been withdrawn at the beginning of 1 July 2024 if—

(a) K has complied with sub-paragraph (2), and

(b) P's consent is not renewed under sub-paragraph (6) before 1 July 2024.

But this is subject to sub-paragraphs (9) and (10).";

(e) in sub-paragraphs (9) and (10), references to the end of the renewal period were to 1 July 2024.

18 (1) This paragraph applies in relation to the storage of an embryo under a pre-commencement embryo storage licence in a case where—

(a) paragraph 11C of Schedule 3 to the 1990 Act applies in relation to the storage, and (b) for the purposes of that paragraph, the first consent period (see paragraph 11D(1)(a) of that Schedule) ends in the transitional period.

(2) Where this paragraph applies, paragraph 11C of Schedule 3 to the 1990 Act has effect in relation to that first consent period as if—

(a) for sub-paragraphs (2) and (3) there were substituted—

"(2) The person keeping the embryo in storage ("K") must request P to renew consent to storage of the embryo before 1 July 2024.

(3) A request under sub-paragraph (2) must—

(a) be given in writing before 1 July 2023;

(b) state that if P does not renew consent before 1 July 2024, the embryo will be removed from storage and disposed of.";

(b) in sub-paragraph (5)(b), for "the start of the renewal period which relates to that consent period" there were substituted "1 July 2023";

(c) sub-paragraph (7) were omitted;

(d) for sub-paragraph (8) there were substituted—

"(8) P's consent to the storage of the embryo is to be taken as having been withdrawn at the beginning of 1 July 2024 if—

(a) K has complied with sub-paragraph (2), and

(b) P's consent is not renewed under sub-paragraph (6) before 1 July 2024.

But this is subject to sub-paragraphs (9) and (10).";

(e) in sub-paragraphs (9) and (10), references to the end of the renewal period were to 1 July 2024.

43. Clinics were required to write to patients affected by the Transitional Arrangements by 30th June 2023 and request that they renew their consent to storage before the end of the transitional renewal period, namely before 1st July 2024.

44. Since HFEA 1990 requires gametes and embryos to be removed from storage once consent has been, or is deemed to be, withdrawn, the effect of these provisions in the Transitional Period was therefore that if consent had not been renewed or given by 30th June 2024:

i) gametes should have been removed from storage on 1st July 2024; and

ii) embryos should have been removed from storage by 1st January 2025.

iii) These consequences were outlined in the HFEA Guidance.

For gametes:
"centres were legally required to remove the gametes from storage and dispose of them after the end of the Transitional Period (i.e., on 1 July 2024) if consent is not renewed by that date."
For embryos:
"centres were required to take all reasonable steps to give notice of the withdrawal to each person whose gametes were used to bring about the creation of the embryo. In these circumstances, if consent is not renewed by 30 June 2024 the continued storage of the embryos will remain lawful until 31 December 2024 unless, before that date, written notification of withdrawal of consent to storage of the embryo is received from each person notified. Centres will be legally required to remove the embryos from

storage by 31 December 2024 unless written notification of withdrawal of consent to storage of the embryo is received from each gamete provider, in which case the embryos should be removed from storage sooner. It is not possible to renew consent to storage after 30 June 2024."

45. The effect of the Transitional Arrangements was that:

i) All patients whose consent would expire between 1st July 2022 and 30th June 2024 were afforded the opportunity to renew their consent to storage (within the Transitional Renewal period);

ii) All affected patients should have been notified of the opportunity to renew their consent (and thereby extend their storage) by 1st July 2023; and

iii) Those patients who failed to renew their consent by 30th June 2024 were no longer able either to renew consent to storage, or to use their gametes or embryos.

iv) From 1st July 2024, clinics were required to write to patients and inform them that their consent to storage of their gametes and/or embryos was deemed to have been withdrawn and that they could no longer use or renew storage of them.

46. There are a number of authorities both domestic and before the European Court of Human Rights, in which the operation of the legislative scheme and the HRA 1998 have been considered, and on which counsel placed reliance in the course of argument as relevant to these applications. There was little if any disagreement as to which authorities are likely to be of relevance and assistance to the decisions to be made here though there was some difference, as emerged in oral argument as to the extent of that. A point of distinction on which Mr Mehta for the HFEA placed particular emphasis in his submissions is that in the applications before this court, it is not a posthumous situation which falls to be considered. That sets it apart from much of that which is at the heart, factually, of *Jennings v HFEA 2022 EWHC 1619 (Fam)*; *G v HFEA; [2024] EWHC 2453* and *EF v HFEA [2024] 3004 (Fam),* where the court did not have the opportunity to know from the deceased as to their wishes in respect of consent and so was considering whether on the evidence consent was appropriately to be inferred and declaratory relief granted.

47. Mr Hyam on behalf of the SSHSC has referred the Court to the way in which the regulation of IVF treatment has developed in the United Kingdom. His more detailed submissions are considered below. As an overarching position he submits, and I agree, that the Court should have regard to the very careful and considered way in which by a process of inquiry, review, consultation and debate, the broad spectrum of differing views were taken into account, balanced and resulted in a legislative regime both fit for purpose and acceptable to the public. Questions of morality and legality and how those two concepts sit beside each other and coexist, have required careful and sensitive consideration throughout the development of the law. The roots of what we see today, he reminds me, lie in the Committee of Inquiry chaired by Mary (later Baroness) Warnock, the need for such inquiry having been brought about by the birth of the first child via IVF in 1978. It is hard, from this distance, perhaps to appreciate the magnitude of the scientific and societal change which that birth represented.

48. As to the approach to be taken to s 3 (1) HRA 1998 the court must take an approach consistent with *Ghaidan v Godin-Mendoza [2004] 2 AC 557* [26] - [33] and per Lord Nicholls, cannot adopt a meaning '*inconsistent with a fundamental feature of legislation*'. Any meaning brought in via s3 must be '*compatible with the underlying thrust of the legislation being construed*' and in determining what that meaning is. Further explanation is to be found in Lord Rodger's judgment and his characterisation at [121] that the meaning implied must '*go with the grain of the legislation*'. During argument Mr Mehta suggested for the HFEA that a difficulty arises here because the applicants are not asking to read down words because there are no words to be interpreted, it would be necessary to read in. Whilst by the time of final oral submissions this technical aspect of argument was not pursued for the HFEA, in consideration of that issue, I consider that aspect in more detail from [102] below.

Submissions

49. On behalf of the applicants Ms Sutton submits that for a range of reasons, written consent in respect of the 15 applicants was not lawfully renewed in respect of schedule 3 of the HFEA 1990 Act as amended by Schedule 17 of the HCA 2022 before the end of the relevant renewal periods. The applicants submit that this was due to a mistake –

whether that was error by the clinic, or a combination of clinic and patient errors. There are, submits Ms Sutton also what she calls a '*suite of mitigating circumstances*' within which context the errors fall to be considered when the Court comes to examine the individual circumstances of each applicant. Significantly, submits Ms Sutton, the statutory framework is silent as to how errors such as those which feature in the applications before this court should be addressed. All applicants wish for their embryos to remain in storage.

50. As a starting point, Ms Sutton and Ms Goold submit that the applicants' Article 8 rights are engaged - the new arrangements for the renewal of consent to storage and use of embryos set out by the HCA 2022 have the effect of preventing renewal of consent to storage and use regardless of the circumstances that have led to the failure to renew before the end of the renewal period. In consequence there is an interference with the Article 8 rights of each patient to use or store embryos to start a family. In this respect Ms Sutton relies on the fact that the Strasbourg Court has interpreted the notion of private life as including the right to become a parent in the genetic sense (*Evans v United Kingdom* (2008) 43 EHRR 21 at paragraph [72]). Ms Sutton accepts that the requirement for consent (and hence the provision of clear and certain rules to ensure it has been obtained) was also recognised in *Evans v United Kingdom* (2008) 43 EHRR 21 as a legitimate aim, and that clear consent requirements and brightly drawn lines provide clarity both to patients and to clinics as to what can be done with gametes and embryos, and are in line with one of the fundamental principles of the HFEA regulatory scheme, which is to protect and promote patient autonomy. However, she submits situations necessarily arise in which a patient has not provided consent at the time or in the form required by the regulatory framework. In such cases, the Courts have recognised not only the need for clarity and certainty, but also that there will be circumstances in which flexibility is required to do justice to the patient and to ensure their autonomous wishes are respected and protected. Ms Sutton relies for support for her submission as to this, on a number of authorities over the last decade in which domestic Courts have had to consider whether in the absence of consent as required by statute it may be inferred from the evidence and surrounding circumstances. See *X and Y* [2015] EWFC 13; *Jennings v HFEA* [2022] EWHC 1619; *EF and HFEA* [2024] EWHC 3004; *G and HFEA* [2024] EWHC 2453. In all of those cases, she submits the Court has been faced with circumstances in which it has had to consider not only

whether to read down or read in consent (as she moves on to submit that the court should here) but has on each occasion had to do so from a position of having to infer consent from the available information and evidence since in all instances the application arose in relation to posthumous consent. In each of the applications before this Court the applicants are alive and clearly asking the court to take account of their individual circumstances. This she submits, makes matters more straightforward since there is no question as to intent when the Court comes to consider consent. In this she is supported by Mr Mehta who takes the same position for the HFEA.

51. Ms Sutton submits that the court should interpret HFEA 1990 to allow each applicant to be permitted to renew their consent. Although she suggested in opening that there is agreement between the parties that relief should be given in 9 applications in which the errors which resulted in the failure to renew in line with the process were undisputedly errors by the clinics, the SSHSC, in submissions (see later in this judgment) put his approach in a way which was subtly but importantly different from agreement. It is that approach I have taken. As to the other 6 applications it was the common ground of all that each of their individual circumstances require very careful consideration by the Court. On the basis of submissions by Ms Goold the Court was invited to find that all 15 cases are instances of a failure to renew because of clinical error or alternatively that it doesn't matter who makes the error.

52. For the applicants before this Court, Ms Sutton submits that it is helpful to consider by analogy the way in which Mrs Justice Theis in Jennings approached the inherent tension between the certainty and clarity which, as the SSHSC urges on this court are key legislative aims, and flexibility. Expressed at [101]in these terms: *"....Consent is a critical issue within the statutory scheme but what is important is to consider the role and purpose of consent in the statutory scheme, which is to ensure that gametes and embryos are used in accordance with the relevant person's wishes. The reference to written consent is an evidential rule with the obvious benefits of certainty but it is not inviolable where the circumstances may require the Court to intervene."*

53. In developing that submission, Ms Sutton acknowledged that the President had subsequently, when determining an issue of posthumous consent in *G v HFEA* although approving the approach taken by Theis J in *Jennings* revisited that passage articulating some disquiet at the prospect that it might be misconstrued saying at [75] - [76]:

75 Fourthly, it is necessary to offer clarification of the words of Theis J in Jennings where she described the requirement of written consent in the HFEA 1990 as "an evidential rule with the obvious benefits of certainty but it is not inviolable where the circumstances may require the court to intervene".

76 The provisions which stipulate the manner and form in which valid consent is to be given under the HFEA 1990 are contained in Schedule 3 (set out at para 19 above). HFEA 1990, section 12(1)(c) requires that every licence issued to authorise treatment, storage or research under the Act must comply with Schedule 3, which, in turn, requires that it "must be in writing", be signed and it must state what is to be done with the gametes or embryo. Insofar as the term "evidential rule" may suggest that these provisions are anything other than strict and essential requirements of the statutory scheme, such a suggestion is not sustainable. Further, it would be an error to read Theis J's reference to the "rule" being "not inviolable" as holding that it is open to a clinic, the HFEA or a court within the statutory scheme to waive the requirement for effective consent that complies with the specific terms of Schedule 3. The key parts of the judgment in Jennings read as a whole demonstrate that Theis J did not make her decision within the statutory scheme by demoting the status of the Schedule 3 requirements to that of rules which may be waived in any case. As her judgment shows, Theis J determined Mr Jennings' application by holding that his ECHR article 8 rights had been significantly interfered with and that the court was required by HRA 1998 to read down the relevant provisions of HFEA 1990, Schedule 3 in order to dispense with the requirement for written and signed consent. It is in that sense, namely that the statutory provisions will be vulnerable to being read down where it is necessary for the court to do so under the HRA 1998, that the Schedule 3 requirements were "not inviolable" in Jennings; the "circumstances" which "require[d] the court to intervene" were those which made it necessary for the court to act under HRA 1998, section 3(1).

In this case submits Ms Sutton there is no scope for any misunderstanding, the applications for relief here are each brought pursuant to HRA 1998 s 3 (1)

54. Ms Sutton submits that here, in exercising its function, and discretionary powers, the HFEA must consider the applicants' Convention rights. The more so where the legislator has given the HFEA discretion without express guidance as to its exercise (*L v HFEA [2008] EWHC 2149 (Fam) at paragraph 135*). Given that the applicants' Article 8 rights are (as all agree) engaged and are to be applied by this Court, the focus of the applicants' submission moves onto the question of whether there is an interference with those rights and if so, the nature and proportionality of the interference.

55. Absent relief granted by this Court the interference in the Article 8 right of each of the applicants will prevent them using their stored gametes or embryos to become, or have the opportunity to become, parents in the genetic sense.

56. As to the issue of proportionality, Ms Sutton submits that the interference by the prohibition on the renewal of consent following the end of the renewal period constitutes a significant interference with their Article 8 rights. In consideration of whether it is not only significant but also necessary and proportionate in pursuit of a legitimate aim she invites the Court's attention to the words of Lord Nicholls in *Ghaidan v Godin-Mendoza* [2004] 2 AC 557 at paragraphs 26 – 33. The Court cannot adopt a meaning *'inconsistent with a fundamental feature of legislation'*. Consequently, any meaning brought in via section 3 must, he stated, *'be compatible with the underlying thrust of the legislation being construed'*. In determining what this meaning is, Lord Rodger explained at paragraph 121, that the implied meaning must *'go with the grain of the legislation'*.

57. The core submission made for the applicants is that to read in to permit the relief sought here does not adopt a meaning which is inconsistent with a fundamental feature of legislation since the underlying thrust of the legislation is to protect patient autonomy and give effect to informed consent without which no use may be made of gametes and embryos and at the heart of each application is a wish to renew consent so that gametes and embryos may be used. In each instance that will of course be dependent on whether the individual circumstances permit the reading in of consent. But it goes with,

rather than against the grain of the legislation where the fundamental feature or principle of the legislative scheme regulating infertility is the protection and promotion of the autonomy of patients in relation to their reproductive goals as protected by Article 8.

58. The requirement for consent (and hence the provision of clear and certain rules to ensure it has been obtained) has been recognised as a legitimate aim multiple times by the courts including by the Strasbourg Court in *Evans v United Kingdom* (2008) 43 EHRR 21. The applicants submit that while *Evans* was concerned with whether use could be made of an embryo *without* the consent of *one* party, the decision recognised the fundamental commitment within the legislative scheme to the protection and promotion of individual autonomous wishes.

59. Ms Goold made submissions on what might be regarded as a mistake in the context of renewal of consent, suggested that all of those involved infertility treatment were to be regarded as vulnerable, and placed reliance on Theis J in *X and Y* and earlier Hale LJ in *Mrs U.* I consider in more detail these submissions later. Whilst I accept to a degree that the recognition of the need for a humane and sympathetic approach to those affected by infertility emerges from the judgment of Hale LJ (as she then was) in *Mrs U v Centre for Reproductive Medicine [2002] EWCA Civ 565*, it is important not to lose sight of the context within which she made that observation namely that sympathy must not overbear the respect for the scheme:

'The new scientific techniques which have developed since the birth of the first IVF baby in 1978 open up the possibility of creating human life in ways and circumstances quite different from anything experienced before then. These possibilities bring with them huge practical and ethical difficulties. These have to be balanced against the strength and depth of the feelings of people who desperately long for the children which only these techniques can give them, as well as the natural desire of clinicians and scientists to use their skills to fulfil those wishes. Parliament has devised a legislative scheme and a statutory authority for regulating assisted reproduction in a way which tries to strike a fair balance between the various interests and concerns. Centres, the HFEA and the courts have to respect that scheme, however great their sympathy for the plight of particular individuals caught up in it.'

There is resonance in that warning with the much more recent consideration by the President of the Family Division in *G v HFEA* and his caution against the '*free for all*' to the same effect.

60. Since Article 8 rights are not absolute Ms Sutton accepts that interference may be justified if shown to be necessary and proportionate to the pursuit of a legitimate aim including the protection of health or morals or for the protection of the rights and freedoms of others. Against that backdrop she submits that the four-stage proportionality test requires the court to consider: (i) is the legislative objective sufficiently important to justify limiting a fundamental right? (ii) are the measures which have been designed to meet it rationally connected to it? (iii) are they no more than are necessary to accomplish it? (iv) do they strike a fair balance between the rights of the individual and the interests of the community? As to the fourth stage of the assessment Ms Sutton submits that it requires there to be proportionality between the effects of legislative measures on countervailing rights or interests and the objective that is sought to be achieved: see *R (Quila) v Secretary of State for the Home Department* [2011] UKSC 45; at [44]-[45] (per Lord Wilson).

61. It is the issue of a fair balance which the applicants submit is critical in the applications under consideration here. They do not suggest that the HFEA is wrong when it makes clear in its Code of Practice and Guidance that it considers it vital that the consent requirements in relation to the use and storage of gametes and embryos are clear and certain. Ms Sutton accepts also that this was a stated aim of the HCA 2022 (para. 243, Explanatory Notes). Clear consent requirements and brightly drawn lines are in line with one of the fundamental principles of the regulatory scheme, which is to protect and promote patient autonomy. This is a legitimate and important aim with which the applicants do not disagree. It is clearly right, submits Ms Sutton, that to ensure this aim is met, patients do not enjoy unfettered rights to reproductive freedom. Furthermore, for the most part, the legislative scheme's aim to achieve certainty does serve the more fundamental aim of the scheme, which is to protect patient autonomy.

62. The stringent consent requirements within the HFEA Acts, Code of Practice and Guidance are also rationally connected to that aim and are no more than is necessary to achieve it. However, submits Ms Sutton those measures, in entirely prohibiting, the

renewal of consent outside the renewal period, do not strike a fair balance between that aim and the interests of the applicants.

63. Turning to the aim of certainty, that, she submits, must be understood against the fact that the requirement for consent as the cornerstone of HFEA 1990 has not in appropriate circumstances, prevented the Courts from finding that effective consent need not be in writing. In this respect Ms Sutton submits that the Court has accepted previously that there are circumstances in which it will dispense with the necessity for written consent: see Theis J in *Jennings* and in *EF v HFEA*

64. Ms Sutton submits that the legislative aim which underpins the requirements in relation to the strict requirements for consent is to ensure that there is respect for the autonomy of the individuals concerned, that the wishes of gamete providers are given effect and that there is no use or storage without their consent. In this regard she does not dissent from the well-recognised characterisation of consent as a cornerstone of the legislation. Neither did she take any issue with the written submissions of the SSHSC demonstrating the way in which consent had been at the heart of the legislative framework as it developed.

65. Mr Mehta adopts the position for the HFEA that in respect of all the applications before the Court it does not oppose the granting of declaratory relief in any of the fifteen applications. The HFEA neither in the evidence filed for these proceedings nor in argument expressed any anxiety that to allow the applications here would either undermine the legislative scheme (of which it is the regulator) or open the floodgates to numerous other applications. In submissions he addressed first the issue of the caselaw on the principle of consent and examined the way in which the importance of consent runs through the authorities, taking as his starting point the judgment of Hale LJ in *Mrs U v Centre for Reproductive Medicine* at [24] "*The whole scheme of the 1990 Act lays great emphasis upon consent.... Parliament has devised a legislative scheme and a statutory authority for regulating assisted reproduction in a way which tries to strike a fair balance between the various interests and concerns. Centres, the HFEA and the courts have to respect that scheme however great their sympathy for the plight of the particular individuals caught up in it.*".

He examined in detail the decisions in *Evans* ; *Jennings* and *G v HFEA* . For sake of brevity I do not replicate that detail here and I accept the submission for the HFEA that running through all the authorities once can see both the importance of consent and what Mr Mehta submitted was the meaning or underlying aim of consent - personal autonomy. It is that he submits that is the hallmark of the legislation.

66. There are a number of domestic authorities to which Mr Mehta invited the court's attention. First by reference to *Evans* he considered the issue of live disagreement rather than posthumous consent and then from three cases which are concerned with the issue of consent arising posthumously: *Mrs U; Jennings* and *EF* , where the Court is faced with inferring intent and consent. Having considered those authorities in detail Mr Mehta made what he said is the fundamental submission of the HFEA that none of the issues relevant to those cases arise in these proceedings. Here the relevant people are before the court and they are consenting. I took him to mean by that that they are wishing to renew their consent. Whatever the reason for it, the material is still in storage and in those circumstances, he submits that the legislative focus on consent means that the Court could be supportive of the outcome sought. The HFEA does not adopt the sort of granular analysis by the applicants of '*factual wrinkles*' or '*linguistic difficulties*' rather it seeks to focus on the living consent being manifested which is quite different from the other decided cases. I had some difficulty with that submission which seemed to me to suggest that the Court should not consider the individual circumstances of each case but should deal with the applications in a broad-brush way. Mr Mehta made clear that this was not what he had intended to say. The questions arising are, he submits: how procedurally do you consider these cases? and how do you resolve the relief? In an important respect he aligned himself with the position of the SSHSC, in that to be drawn into making decisions by categories of error would be undesirable.

67. An important consideration when the Court comes to consider the applications is that the scheme imposes obligations on the clinics, as providers of services, as seen from the terms in which the provisions of the HFEA 1990 and the HCA 2022 are couched. The scheme does not impose obligations on the patients. That submits Mr Mehta is important when the court considers the individual facts of each case and the balance to be struck in each case. It is a relevant factor that the Act does not seek to impose duties on patients.

68. As to the relief sought by the applicants here, the HFEA is clear that there is no opposition raised to it but submits that the applicants must identify the impediment and interference on which they make their claim since he submits one does not reach the proportionality test under the HRA 1998, if not first satisfied that there is interference and what it is. He further submits in relation to relief that it is not open to the court to infer consent where there is already (expired) consent and there are applicants wishing to give it. It is he submits '*not appropriate to cast around for additional information when in reality you already have the specific thing you are looking fo*r'. I did not take that submission as suggesting that the Court should not examine the detailed factual circumstances of the applications to determine whether in those individual circumstances relief should be granted.

69. On behalf of the SSHSC Mr Hyam and Ms Fenelon submit that individualised determination by the Court of each case is essential. Whilst it may be the case that those undergoing the process of IVF are or may be vulnerable, on behalf of the SSHSC it was submitted that the point made by junior counsel for the applicants in submission as to that characteristic of vulnerability as a matter of generality attaching to those undergoing IVF treatment should be relied on by the Court only if found by the Court to be so in the particular and individual case under consideration. Both in written submissions and orally, the SSHSC articulated the concern strongly held that a broad declaration – as distinct from any relief which the Court may find appropriate being tailored to individual circumstance – carries with it a real risk that it would be interpreted by clinics as meaning that a clinic could never be sure of what constitutes reasonable or sufficient efforts to secure consent. Having regard to the consequences of improper destruction which include, as illustrated by *Yearmouth v North Bristol NHS Trust [2010] 1 QB 1* the prospect of facing an action for damages. Not knowing when a clinic may be liable may lead some clinics not to take the risk and to continue to store resulting in indefinite storage.

70. Mr Hyam and Ms Fenelon submit that there is potential for the legislation to be undermined. In their written submissions, amplified orally, they examined in detail the way in which Parliament has, following on from significant inquiry review consultation and debate sought to balance and respect a broad spectrum of views such that the resulting legislative regime is and remains fit for purpose and publicly acceptable. They

submit that it is possible to trace through from the earliest stages of that process, a Committee of Inquiry, (Warnock), through to the enactment of the HCA 2022 how avoiding the prospect of indefinite storage of embryos and gametes (regarded as unacceptable from the earliest consultation) has featured prominently alongside the objective of ensuring there is effective and informed consent to any storage.

71. By reference to a close examination of the development of the legislation Mr Hyam submits that the legislation in this area has always been, and remains, highly sensitive involving a conflict between ethical and moral considerations inherent in the concept of the beginning of human life and a plurality of views on the subject. That translates for Article 8 purposes into meaning that it is an area where Parliament has a wide margin of discretion (see *Evans v United Kingdom [2007] ECHR 264 at [59] ; Parillo v Italy 46740/11 (2016) 62EHRR 8*).

72. It has always been understood, they submit, again since the time of the Warnock Report that gamete providers should be recognised as having rights to the use and disposal of embryos but also that such rights are not unfettered and are subject to limitation by Parliament. By way of example of such limitation the SSHSC points to *Yearmouth v North Bristol NHS Trust [2010] 1 QB 1 at [42]* (a case involving use and disposal of sperm rather than embryos).

73. As to consent, Mr Hyam and Ms Fenelon submit that the legislation has throughout recognised the importance of consent characterised as a '*cornerstone*' of the legislative framework. Consent must be both informed (hence the emphasis on counselling both at the outset and on renewal) and effective. They further submit that to be effective it must be both up to date and applicable – reflected in the need for renewals of consent for which there is a clear renewal process. Also, that it is significant that there is a distinction between the rights and obligations of the patient and the storage facility within the period of effective consent and the period outside it. Within the period the principle is that the patient's wishes are paramount whilst outside the period there is a requirement that the embryos or gametes must be removed from storage and disposed of (allowing for where the legislation provides for a 'cooling off' period).

74. In submissions drawing together the strands of the legislation they submit it provides the following clear rationale and purpose:

i) Clarity, certainty and public acceptability

ii) Avoidance of indefinite storage or storage beyond lawfully prescribed storage periods

iii) Avoidance of storage or use without effective and informed consent in place

iv) Facilitating greater reproductive choice but only within a tightly controlled regime (a facet of public acceptability)

v) Avoidance of arbitrariness and inconsistency achieved by having strict rules that permit of no exceptions since the possibility of mistakes or difficult cases are legislatively mitigated in a reasonable and proportionate way by the statutorily prescribed 'cooling off' period, the renewal period(which extends beyond the end of effective consent, the transitional period between 1st July 2022 to 30th June 2024 and (in the case of embryos) the further cooling off period of 6 months after the deemed withdrawal of consent after the expiry of the renewal period.

75. As to the applications before this Court, Mr Hyam and Ms Fenelon submit that it is for the applicant on the facts of each individual case to convince the Court that a reading in of an implied discretion for the Court is required to prevent a breach of Article 8 and that to do otherwise would frustrate the intent of Parliament. Support they submit is to be found for that in the approach taken by the President in *G v HFEA [2024] EWHC 2453* at para [70]-[72]

70 Before turning to an evaluation of the evidence of N giving informed consent in the present case, it is necessary to emphasise a number of matters.

71 First, the HFEA 1990 is a general measure which is applicable to one and all in like manner with no facility for the evaluation of the individual merits of circumstances which may fall outside its strict requirements and no role for administrative or judicial discretion. In the words of Lord Bingham in Quintavalle, "[Parliament] opted for a strict regime of control. No activity within this field was left unregulated. There was to be no free for all". The ECtHR has established that general measures of this nature can be compatible with the ECHR (Animal Defenders para 106) and in Evans accepted that the HFEA 1990 is one such.

72 A principal consequence of a general measure is that there will be some hard cases, where the individual merits of a claim to access the scheme generate sympathy, yet access must be refused due to a failure to comply with its strict requirements. The role of decision-makers in such circumstances was described in unambiguous terms by Hale LJ in the case of U at paras 24,29:

"24. Centres, the HFEA and the courts have to respect that scheme, however great their sympathy for the plight of particular individuals caught by it."

"29. There is a natural human temptation to try to bend the law so as to give her what she wants and what she truly believes her husband would have wanted. But we have to resist it."

76. They further submit that when this Court considers whether it is appropriate to read in such a discretion, it is important to hold in mind that when the legislation was renewed in 2008 (and again in 2022) it had been open to Parliament to 'water down' or loosen its strict requirements but it did not. It chose to maintain the structure keeping the centre point as consent and that whilst in the light of scientific developments Parliament extended the time limits it did so whilst maintaining the strict requirement for consent renewal and a clear process for the same. See the words of the President at [73]

"*73 Second, when reviewing the 1990 Act in 2008, Parliament maintained its rigid structure, at the centre of which is the requirement for informed consent, recorded and signed in the stipulated form. The domestic courts have upheld the strictness of the scheme. Judicial interpretation of it's clear terms has been limited in England and Wales to the case of R (M) where the Court of Appeal clarified that, for effective consent, an individual need only be given "such relevant information as is proper" (in the words of Schedule 3) rather than "all" relevant information, and that what information was "proper" might change with the circumstances and over time. The scheme itself has, for over three decades, been operated by clinics, the HFEA and, where required, by the courts by strict application of its clear requirements. Any judicial determinations which have held that circumstances outside the terms of the HFEA 1990 scheme are lawful have not been made under that Act but under the HRA 1998 by applying the ECHR"*

77. In common with the other parties to these applications, Mr Hyam accepts that the applicants' Article 8 rights are engaged. The Grand Chamber in *Evans* held that the right to respect for the decision to become a parent in the genetic sense falls within the scope of Article 8 and these applications are brought squarely on an Article 8 basis. He does not accept that an interference automatically follows . Rather the SSHSC submits that the Court must go through the well-established 4 stage proportionality test recapitulated by Theis J in Jennings at para [47]

"The four-stage proportionality test is well established: (i) is the legislative objective sufficiently important to justify limiting a fundamental right? (ii) are the measures which have been designed to meet it rationally connected to it? (iii) are they no more than are necessary to accomplish it? (iv) do they strike a fair balance between the rights of the individual and the interests of the community? The fourth stage of the assessment requires there to be proportionality between the effects of legislative measures on countervailing rights or interests and the objective that is achieved: R. (on the application of Aguilar Quila) v Secretary of State for the Home Department [2011] UKSC 45; [2012] 1 A.C. 621 at paragraphs 44-45 (per Lord Wilson)."

78. When the court comes to its consideration of those 4 stages the SSHSC having regard to the detailed examination of the way in which the legislative framework developed, invites it to hold in mind *Parillo v. Italy*: *"It falls to the Court to examine carefully the arguments taken into consideration during the legislative process and leading to the choices that have been made by the legislature and to determine whether a fair balance has been struck between the competing interests of the State and those directly affected by those legislative choices..."* submitting that the question of a fair balance lies at the heart of the case(s) before this Court. As to this, the applicants' submissions also identify the question of fair balance as critical.

79. Whether the legislative objective is sufficiently important to justify the limitation of a fundamental right, is readily answered in the affirmative submit Mr Hyam and Ms Fenelon the aims including clarity and certainty as to finite storage by effective and informed consent and public acceptability. In respect of avoidance of arbitrariness and inconsistency it is significant submits the SSHSC that the possibility of mistakes is, to a limited degree, already 'baked in' to the legislation, in a proportionate way. The 18-month renewal period, which includes 6-months cooling-off period and the transitional

provisions within the changed legislation is in itself an acknowledgement of the difficulties and possibility of mistakes and a reasonable way to address that. The legislation as it stands is the fair balance struck. The primary submission on the point for the SSHSC is that in the hard cases that inevitably result, access to the scheme must be refused where there has been a failure to comply with the strict scheme and its requirements.

80. There can be no question says the SSHSC but that the measures designed to meet the legislative objective are rationally connected to it – as to which no other party disagrees. Neither, submit Counsel for the SSHSC are the measures any more than necessary to accomplish the objective.

81. The provisions, they submit draw an important and clear distinction between the rights and wishes of patients during the currency of effective consent, and those rights and wishes when (by the operation of the relevant statutory provisions) there is no effective consent in place, and continued storage after the period of effective consent is rendered unlawful. At that point there is an obligation on clinics to dispose of gametes or embryos. This division between paramountcy of the patients' wishes during effective consent and obligation on clinics to dispose outside any period of consent is an entirely justifiable 'bright line' and in the submission of the SSHSC both preserves and protects the importance of consent as a cornerstone of the HFEA 1990. It is neither arbitrary nor impermissible for the State to have a rule requiring the destruction of embryos or gametes by allowing them to be removed from storage and disposed of and in their oral submissions Counsel drew attention to *Mrs U v Centre for Reproductive Medicine [2002] 259* at para [25] in relation to the justification for the storage of sperm.

"25. In this context, none of the case law on undue influence in other contexts is particularly helpful. This is not like deciding upon the validity or enforcement of a will, gift or other transaction, which may have been procured by the undue influence of the person who will benefit from it. The Centre did not stand to benefit from the withdrawal of consent. Nor, as Mr Moon on behalf of the Centre points out, is it like deciding upon the lawfulness of medical treatment. There are other justifications for performing life-saving medical treatment apart from the possession of an effective consent. There is no other justification for continuing to store human sperm." [emphasis added]

82. Not only is the existence of a rule requiring destruction of gametes and embryos consistent with that, but also submits the SSHSC, it is an indication of a compromise made by Parliament. The fact that so called 'hard cases' are, submit counsel, already mitigated by the cooling off period and the Transitional Provisions, supports the view that the measures are no more than is necessary. In circumstances where the legislation requires the clinics to notify, the effect of allowing six months after the strict deadline gives an opportunity to apply to the court for declaratory relief. In making that submission, Counsel properly accepted that to the extent that provided an element of what had been called '*baked in*' mitigation, it applied only to embryos and not to gametes since there is no 6-month cooling off or grace period so far as gametes are concerned.

83. Encapsulating the detailed written submissions on the fourth strand of striking a fair balance between the rights of the individual and the interests of the community, Ms Fenelon submits that the starting point is that, in each of these cases, the gametes and embryos were required to be removed from storage and disposed of, so the question is whether, in light of the evidence in each of the applications, the facts are sufficiently compelling for the court to conclude that, in the individual circumstances, a read down is justified to render the case compatible with convention rights.

84. Should the Court make any of the declarations sought, the SSHSC urges it not to do so in a way which suggests a general extension widely applicable and invites close attention to the way in which the President addressed this aspect at paragraph [74] of *G v HFEA*:

"*74 This leads on to the third matter that requires emphasis which is the need to maintain a firm distinction between those cases within the scheme, which do not rely on the ECHR, and those outside of it which must rely on the ECHR if they are to succeed. There is a clear danger of conflating these two separate categories and reading across judicial decisions which have been taken outside the scheme as if they were taken as part of the statutory regime. The list of points drawn from the authorities by Ms Fottrell (set out at para 38) demonstrates the danger of conflating, or failing to acknowledge, these two distinct routes to treatment. Insofar as, in previous reported cases, courts have taken the specific courses adumbrated in the five points in that list they have done so outside the HFEA 1990 scheme and have done so in the*

circumstances of a particular individual whose article 8 rights have, on the facts of a specific case, been engaged to the extent that the court has used its power under the HRA 1998 to read down, or otherwise relax, the strict provisions in HFEA 1990, Schedule 3. There is a danger in constructing such lists if it is suggested that they represent a general and accepted extension of the court's jurisdiction for all cases, when they are no more than examples of specific approaches that a court has been prepared to take when evaluating and then, if justified, acting upon the need to avoid a breach of an individual's rights under the ECHR in that case."

85. Drawing together their detailed written submissions and their oral amplification, Mr Hyman and Ms Fenelon on behalf of the SSHSC submit that there is no opposition – should it be determined by the Court, on its own assessment of the facts, that it is right to grant it - to the declaratory relief sought by those applicants in respect of whom the clinics required to notify them of the need for renewed consent had not done so – the 'clinic failure' cases. In those cases, have been prevented from giving effective consent or renewal of consent by failure of the clinics to operate the primary legislation effectively. The SSHSC recognises the disadvantage that a failure to operate the statutory regime properly will have caused to patients. In those circumstances, an enhanced weight is given to their wishes so far as they are ascertainable.

86. Whilst the SSHSC submits the court must be satisfied on the individual facts of each application that a declaration is justified, those instances which are not 'clinic failure' cases, are ones in which, having regard to the potential for the legislation to be undermined, it is not necessarily accepted that there is disadvantage caused to the donors. The Court must ascertain the nature and effect of the interference in each given case and Counsel submit that whilst each case will be fact specific there is assistance to be drawn from the approach taken by Mrs Justice Theis in *EF –v HFEA [2024] EWHC 3004 at [90]*

"*In my judgment, there is no dispute that the requirement that consent be in writing pursues a legitimate aim, the issue is whether that aim is sufficiently weighty to justify the very significant interference with EF's Art 8 rights, making due allowance for the margin of appreciation. The requirement of consent is the cornerstone of the HFEA 1990 which reflects the importance of personal autonomy and giving effect to an individual's wishes. The evidence establishes that AB would have wanted EF to be able*

to use the embryo with a surrogate in the event of her death, which seeks to support rather than undermine the importance of consent and personal autonomy which, in turn, promotes the fundamental objective of the legislative scheme. AB was unable to record her consent to this treatment as she was not given the opportunity to do so through no fault of her own. The insistence on written consent would, in the particular circumstances of this case defeat rather than promote this objective of the legislative scheme. In circumstances where the interference with EF's Art 8 rights would be significant, final and lifelong there are no countervailing factors to justify the interference as, in the circumstances, permitting the application would not undermine a fundamental objective of the statutory scheme. I accept Ms Richards' submission that 'to fail to respect compelling evidence of a donor's wish, in circumstances where she was not given an opportunity to record that wish in writing as a result of (a) the lack of clarity in the HFEA's pro forma forms and (b) the failure of the [Clinic] to provide her with relevant information, would constitute a disproportionate interference with [EF's] rights under Article 8'"

87. As to the applications before this court, save in strong individual circumstances, the SSHSC submits that the objectives of the scheme mean that there are strong countervailing factors and that insistence on the strict wording would promote rather than defeat those objectives. Furthermore here where there are a cohort of applicants in distinction to the surviving husband who was the applicant in *EF* the risk of floodgates is real and must be given weight. The SSHSC did not make submissions as to the respective merits of any of the individual applications, though as indicated earlier, did not oppose (subject to the Court's own evaluation of them) relief in those nine instances where the reason for non-renewal lay with a failure of the clinic. That position was not on the basis of creating a class of applicants, but a reflection of the view taken by the SSHSC of the evidence of the fact specific circumstances in each.

Discussion and Decision

88. It has been necessary to set out the legislative Scheme of the HFEA and procedures for the renewals of consent at very considerable length.

89. It is a strict scheme permitting of no exceptions. If there is to be relief, it can only be outside the scheme by reading in provisions to allow renewed consent. The SSHSC

has demonstrated very effectively that running through the development of the legislation has been the restriction and limit to the way in which embryos and or gametes may be stored and used. The unbending nature of the HFEA legislation provides the protection and certainty that Parliament intended. I agree that it is a powerful indicator that when as recently as the HCA 2022 Parliament might have had the opportunity to take the view that societal changes in the years following the birth of the first baby by IVF – now in her late forties – meant that a less rigid and restrictive approach is required, and should be reflected in the HCA 2022, it did not. The spectre of what the President described as a '*free for all*' is one against which the tight regulations guard and protect. It is, however, in my judgment, important to hold in mind that the protection is not directed at certainty and clarity alone or as freestanding concepts but at those concepts as they are allied to and underpin a regime of effective and informed consent to promote autonomy. To put it another way the rigidity of the scheme is not rigidity for its own sake.

90. In Schedule 3 to the HFEA 1990 by:

11A(8) P's consent to the storage of the gametes is to be taken as having been withdrawn at the end of a renewal period that relates to a consent period if—

(a) K has complied with the requirements of sub-paragraphs (2) and (7) in relation to that consent period, and

(b) P's consent is not renewed under sub-paragraph (6) before the end of the renewal period.

[emphasis added]

there is contemplated the possibility that a clinic might not send (as required) the notice or relevant documentation for renewal. Were that not so, there would be no '*if*'. Yet there is silence as to what are to be the consequences - or the means to address the consequences - of the failure of the clinic to comply. The SSHSC at this hearing has taken as a primary position that it should not be inferred from the Parliamentary draftsman's silence that a discretion to permit renewal of consent outside the legislative regime was intended by Parliament but that it may properly be inferred that Parliament intended that rules permitting of no exception were considered justified by reference to

the principle of legal certainty and avoidance of arbitrariness. The logical extension of that is that in circumstances where, hypothetically, someone storing gametes or embryos is not sent within the time required or at all, the required notices and reminders for renewal of their consent, as the clinic keeping their material is obliged to do, time passes, the clinic does not notice its failure, but the patient realises that they have not been asked for any renewed consent and so makes contact to check when is the need to renew. The clinic only then realises it is months past the last moment for renewal. I have found it helpful to consider that hypothetical example against the context, of a scheme, the cornerstone of which is, as acknowledged in multiple authorities, informed consent,

91. The legislation does not provide any mechanism for dealing with situations in which mitigating circumstances arise which may be entirely outwith a patient's control and prevent them from renewing their consent when they would have wished to do so. Both the HFEA1990 and the HCA 2022 are silent as to whether the possibility of renewal of consent to storage, within the Cooling Off period for embryos although it is not silent as to earlier destruction. Yet if destruction is inevitable, it is hard to see what can have been the intention of Parliament in including a cooling off period.

92. In a different factual situation, the late Sir James Munby, then President, in *A and Others (HFEA 2008) [2015] EWHC 2602* was faced with a situation in which the wrong or incomplete forms recording consent had been used. In those circumstances he posed the rhetorical question at [59] "*Can Parliament really have intended [the use of the wrong form] to be fatal? Surely not. So surely, what one is looking for is compliance with the substance, not slavish adherence to a form. Is parenthood to be denied by the triumph of form over substance? In my judgment not*." In like form here, it is surely consent that is important, not consent by an immutable date. I find it hard to conclude that Parliament intended the possibility of parenthood should be removed by the ticking of a clock, not in the cliched phrase, the ticking of the biological clock, but by the ticking of the clock beyond midnight of the day when existing consent expires whatever might be the circumstances.

93. The approach taken by Mrs Justice Theis in Jennings where the basis on which she determined it was right to read down the relevant provisions of HFEA 1990, Schedule 3, pursuant to HRA 1998, section 3, in order to dispense with the requirement for

written and signed consent (in the different factual situation of posthumous consideration) was "*in the limited situation where a person is denied a fair and reasonable opportunity in their lifetime to provide consent for the posthumous use of their embryos*". In the hypothetical example above at [90] the operation of the scheme would mean that there had been a denial of a fair and reasonable (or any) opportunity during the renewal period to renew consent. It is a situation not far removed from the factual circumstances of some of the individual applications here that I will come on to consider later in this judgment.

94. Where the Act deals with the consequences of deemed withdrawal of consent in relation to embryos at 11C(14) Storage of the embryo remains lawful until—

(a) the end of the period of 6 months beginning with the day on which P's consent is taken as withdrawn under this paragraph, or

(b) if, before the end of that period, K receives a notice from each person notified under sub-paragraph (13) stating that the person consents to the disposal of the embryo, the time at which the last of those notices was received. [emphasis added]

It is hard to see what can be the purpose of that cooling off period, other than, by inference, to provide the opportunity to seek relief outside the legislative regime. As can be seen, in so far as it is addressed (both here and in the explanatory notes to the Act) it is couched in terms of contemplating, where no renewal of consent has been received, the prospect of destruction without waiting the full 6 months. There is silence as to any possibility of renewal within that period. So to the extent that as it is put by the SSHSC protection is '*baked in*' to the legislation, at least in respect of embryos (there being no 6 months cooling off in respect of gametes) I do not see that that is so, save that during that 6 month period there is the opportunity to make an application to the Court for relief. Relief which of necessity falls outside the legislative scheme. It is noteworthy that, whilst appearing in the *HFEA Clinic Guidance* though not in the statute, one of the matters to which clinics are specifically invited to give consideration to before destroying embryos within that 6-month period is what is expressed as the '*risk of legal challenge*' .

95. I have had at this hearing the very significant benefit of the intensely detailed examination of the legislative framework and its history. It is inevitable that in a field

where scientific and medical advances are near constant, the legislation and its drafting will not take account of all possible situations which may arise as to consent to use and storage. The issue of renewal of consent which arises in the circumstances of these cases is however simply not addressed in the legislation. There is nothing in the legislative history to which I have been taken which suggests that circumstances of the sort which are the focus of these applications were ever considered by Parliament.

96. I am satisfied that the Article 8 rights of each of the applicants in this case are engaged. In each case their opportunity to become a parent in the genetic sense has been interfered with as a result of the fact that they are not now able to renew consent, regardless of the reasons that led to consent not having been renewed within the timeframes prescribed by legislation. Absent a solution within the scheme, a reading in of an implied opportunity to renew consent is required (if appropriate on the individual facts of each of the applications when coming on to consider proportionalit***y***) to prevent a breach of Article 8. I have listened carefully to the arguments advanced on behalf of the SSHSC and I agree that a broad reading would, or at least would have the potential to, frustrate the intention of Parliament. I agree that as well as informed consent, so too is certainty a critical issue within the statutory scheme, so to run the risk of giving the impression to potential future applicants that if one could bring oneself within a certain category of circumstance then in effect relief would near automatically follow would be wrong. A broad reading might carry with it the further unintended risk that although an Article 8 extension outside the scheme it might be interpreted as undermining the strict requirements of the scheme. As to this I have held in my mind the President's consideration of the application in *G v HFEA* in which he drew attention to:

"*...the need to maintain a firm distinction between those cases within the scheme, which do not rely on the ECHR, and those outside of it which must rely on the ECHR if they are to succeed. There is a clear danger of conflating these two separate categories and reading across judicial decisions which have been taken outside the scheme as if they were taken as part of the statutory regime. The list of points drawn from the authorities by Ms Fottrell (set out at para 38) demonstrates the danger of conflating, or failing to acknowledge, these two distinct routes to treatment. Insofar as, in previous reported cases, courts have taken the specific courses adumbrated in the five points in that list they have done so outside the HFEA 1990 scheme and have done so in the*

circumstances of a particular individual whose article 8 rights have, on the facts of a specific case, been engaged to the extent that the court has used its power under the HRA 1998 to read down, or otherwise relax, the strict provisions in HFEA 1990, Schedule 3. There is a danger in constructing such lists if it is suggested that they represent a general and accepted extension of the court's jurisdiction for all cases, when they are no more than examples of specific approaches that a court has been prepared to take when evaluating and then, if justified, acting upon the need to avoid a breach of an individual's rights under the ECHR in that case"

97. Within this context I have reflected on the submissions made by Ms Goold for the applicants that the court should, in the context of an error leading to non-renewal by the expiry of the relevant period, take what she called a '*broad understanding of error'* taking account of the fact that the Regulatory framework was already very complicated and had been made more so by the changes brought it by the HCA 2022. There is a responsibility on the clinics she submitted to use different steps to communicate if the patient did not respond and to '*provide in short a safety net'.* To the extent that there were errors they should be regarded as clinic errors even if as she put it '*superficially*' they appeared to be errors made by the patient – such as not reading a communication. Furthermore, what she described as the '*context in which patients are interacting with the legislation'* meaning that they were already overborne by dealing with their infertility and so to the extent that mistakes were made they lay with the clinic. Asked what might be an error which should *not* be regarded as clinic error, given the extent to which her submissions encompassed, as it seemed, all failures within a broad bracket of errors attributable to clinics, – the example given was of a patient throwing away or simply not reading a letter.

98. Reliance was placed on the observations of Theis J in *X and Y* at paragraph [2] *This case highlights the important responsibility imposed on licensed clinics that provide fertility treatment, to ensure they comply with all aspects of the relevant statutory provisions and guidance. The somewhat labyrinthine provisions of the relevant statutes, supporting guidance and code must be strictly adhered to by those implementing its provisions on the ground. Particular care is required, as this responsibility is often undertaken in the context of providing treatment to people who have been through a di–cult emotional period in their lives; frequently following a*

number of failed attempts to conceive. Their focus, understandably, is often on the treatment rather than the precise legal formalities of what they are embarking on'

99. I did not ultimately find that seeking to define what is or is not an error in the renewal process ultimately helped me in reaching decisions. Still less an approach that essentially invited a category of vulnerability into which patients would all fall. It seemed to me that in this part of the case, the applicants came close to moving away from the position outlined by Ms Sutton that they put their cases on the basis that, should the Court come to the conclusion that relief could properly be granted, it should consider whether in each case, the individual circumstances of that case made it appropriate. Having since the hearing reflected on the important aspects at [96] above of the President's judgment in *G v HFEA*, I regard it as another instance of an approach which raises the risks outlined by the President in *G* and one which could properly be regarded as potentially undermining of the scheme.

100. In considering whether the circumstances of any of the cases before me are ones in which it is possible and appropriate to consider granting relief by reading in an opportunity to renew consent, it is important to consider whether to do that would be permissible. If it is not, then the issue which has arisen is not one for a court but for Parliament to address by legislative change. Whatever one's sympathy might be, even for positions such as the hypothetical one posed at [90] above, if reading in or down were to be an affront to the legislation, or as it has been put went against the grain it would be impermissible to do so.

101. There was some disagreement in the course of argument between the HFEA who had taken the position that there could be no reading down where the legislation was silent and as a result there were no words which would be the subject of any interpretation. Albeit that this argument was not revisited in closing submissions for the HFEA, I agree with Ms Sutton that a careful reading of the authorities does not support that approach. I accept her submission that it is unnecessary in the light of the authorities to draw any artificial distinction between 'reading down' or 'reading in'. I have found it helpful to consider that in the light of *Ghaidan*, Notably at [29] (Lord Nicholls) "*The House read words into section 41 of the Youth Justice and Criminal Evidence Act 1999 so as to make that section compliant with an accused's right to a fair trial under article 6. The House did so even though the statutory language was not ambiguous*'. I agree with and

accept Ms Sutton's submission that there is no need to identify the specific words being interpreted. This case, these applications, concern the absence of words. It is about *reading in* to avoid a violation of Article 8. The authorities show that the Court must not take an overly technical approach where the human rights of individuals are concerned, see Lord Steyn at [41] of *Ghaidan*: "*Nowhere in our legal system is a literalistic approach more inappropriate than when considering whether a breach of a Convention right may be removed by interpretation under section 3. Section 3 requires a broad approach concentrating amongst other things, in a purposive way on the importance of the fundamental right involved*".

102. Ms Sutton relies on the Supreme Court's explicit endorsement of the approach taken in *Ghadain* in *Gilham v Ministry of Justice* [2019] UKSC 44 at [39]: "*In Ghadian [...] it was also established that what is possible [in section 3] goes well beyond the normal canons of literal and purposive statutory construction [...] Lord Nicholls of Birkenhead referred to the unusual and far-reaching character of the obligation: para 30. He also emphasised that it did not depend critically on the particular form of words used as to the concept: para 31. Lord Rodger too said that to attach decisive importance to the precise adjustments required to the language of the particular provision would reduce the exercise to a game: para 123. The limits were that it was not possible to go against the grain of the legislation in question (para121) or to interpret it inconsistently with some fundamental feature of the legislation*."

103. I am satisfied that in appropriate circumstances it is possible to read in an opportunity to give renewed consent where it has not been renewed within the time allowed by statute. Whether it is appropriate to do so will be dependent on the circumstances which have resulted in that non-renewal. Consent is at the heart of the issues here, just as it has run through the authorities in which courts have had to consider consent in the context of the legislative framework which all Counsel have reminded the Court has it as its cornerstone. I do not accept – and nor does anyone, not even the SSHSC argue - that the *only* aims of the legislation are those of certainty and restriction. The aim of the detailed and complex legislation which has developed alongside the scientific and medical progress necessitating it, has been to protect the autonomy afforded by that consent, to ensure that those whose gametes and embryos can now be stored outside the human body are in a position that only with consent can use be made

of them. The other important aims of certainty and restriction impose obligations on those who keep gametes and embryos as part of so ensuring. I am satisfied that in principle to read in, an opportunity to renew consent does not therefore go against the grain but with it, but that this is dependent on the particular circumstances of the case in which the court is invited to consider it, not simply as a blanket approach. I have considered whether having reached the conclusion that it would be right to go on to identify that there are categories of case or circumstance in which such relief should be available and categories where is should not. I have, however, drawn back from that approach. I recognise that there may be cases in which there is a similarity to the particular circumstances which bring them to the court, and that those circumstances may be especially compelling, but that is, as I see it a matter of the strength and persuasiveness of the evidence in each particular case rather than a reason to create artificially a category within which to place applications. That the relief may be available does not mean that it is on all occasions to be granted. I accept Mr Hyam's point that the Court should hold in mind that a broad and general approach may give rise to the potential for a floodgates situation.

104. Returning to the circumstances of the applications with which I am concerned here, against the backdrop of the conclusion I have reached I will turn now separately to consider each of the fifteen applications.

The Fifteen Applications For Declaratory Relief Before This Court.

105. Having arrived at the conclusion that if the individual factual circumstances of an application for relief warrant it, it is appropriate to read in , in order to prevent a breach of Article 8 rights engaged, the Court must move on to apply that reasoning to the particular circumstances of the applications made. At the close of submissions, there was some debate between Counsel as to the formulation of the question to be applied as the court moved on to consider whether relief should be granted. Having heard arguments, I have preferred and will apply the formulation: *' was the applicant by reason of the particular facts and matters raised unable to renew their consent because he or she was not given a fair and reasonable opportunity to do so in accordance with the legislation'*. It will be necessary for me to consider that question separately in respect of each application.

106. In each application I take the facts from the witness statements filed by the applicants – which have not been the subject of challenge by anyone and from the evidence (similarly unchallenged) filed on behalf of the clinics concerned. It is unnecessary to rehearse all of the detail of that evidence, but it will be necessary to set out some of it, and in cases where the circumstances are more nuanced and less clear cut, rather more.

AA and BB

107. AA and BB make an application for declaratory relief in relation to stored embryos. The HFEA does not oppose the declarations sought. The SSHSC does not oppose the declarations sought if the court is satisfied that declarations should be made in the particular circumstances of this application. Six healthy and viable embryos remain in storage following fertility treatment by which two children were born. Both AA and BB signed consent forms on 1st January 2009 consenting to storage for 5 years. Embryos were frozen on 7th March 2009. This consent was renewed on 7th June 2013 for further 10 years. The expiry date was listed as 6th June 2023.

108. An MPS confirming AA's infertility (at the time a requirement for extended storage time that AA and BB were permitted before the changes brought in by the HCA 2022) was completed, but the clinic did not ensure it was dated. The MPS was in fact undated which meant it was invalid. AA was unable to comment on the MPS deficiency, and the evidence filed for the clinic does not address it.

109. On 30th June 2023, the clinic sent an email to the couple's individual email addresses, informing them of the regulations introduced on 1st July 2022 regarding storage. Consent had already expired by the time it was sent. The e mails attached the HFEA RNE(TP) Notice, patient information, and a pro forma HFEA RE (TP) *'Renewal of consent to storage of your embryos for treatment'* form, also noting (incorrectly) that the embryos have been in storage for 10 years and that the storage period would end on 6th March 2019. No consent form to be signed by the partner was attached.

110. On 4th April 2024, AA emailed the clinic her completed HFEA RE (TP) *'Renewal of consent to storage of your embryos for treatment'* form, asking them to confirm everything was correct and if any action still needed to be taken by the couple. The clinic confirmed receipt and an update of their file without noting that a renewal form

still needed to be completed by BB. AA and BB explain that this led them to believe that nothing further was required from them. [emphasis added]

111. The couple also renewed their storage payments by direct debit in April 2024 and this was accepted by the clinic . In this case as in several, the applicants in part rely upon the fact of their continued payment of storage charges as indicative of their intentions and consent. Mr Hyam submitted that the Court should be careful not to elide the issues of payment for continued storage and consent to continued storage, since the former cannot be proxy for the latter. I accept that submission, but it does not follow that there is no evidential worth to the continued payment of storage fees. It is less important, as I see it, to the question of intention in circumstances where this Court is not in the same position as for example *Re G v HFEA* and *Jennings* and having to infer what might have been the intention posthumously. It does however in some instances have relevance to my assessment of whether there has been opportunity to renew in accordance with the legislation if clinics are accepting payments for continued storage where there has been no renewal of consent.

112. Taking all of those matters together and considering the opportunity which was given to renew consent: A Notice was issued but included the wrong expiry date and was sent together with the renewal form to AA only on 30th June 2023 (after consent had expired). AA signed this form and named BB. AA asked if she needed to do anything else when she sent the forms back and was told that she did not. This catalogue of errors by the clinic was completely outside the control of AA and BB, and it is notable that the clinic, on receiving only one consent form back (from AA), was not alerted by that or even at the stage when AA asked whether further forms needed to be completed she was not informed that BB's form was missing

113. The clinic concerned accepts those failings and that AA and BB were not contacted as per its protocol prior to the end of the renewal period. In addition to which there is no record that AA and BB were informed that they could extend storage to 12 years in accordance with the 2020 Coronavirus Regulations, notwithstanding that the embryos were still in storage on 1st July 2020. AA and BB explain in their evidence that they want to have the opportunity to use their remaining embryos. It is undisputed that on the evidence filed, were this or another clinic to accept the couple for fresh treatment - which owing to AA's age many may not - to create on a new cycle, further embryos,

the prospects of success are not high. I accept also that they have already high-quality embryos in storage which they each strongly wish to use to complete their family and that those embryos are their chance of future genetic parenthood.

114. On the basis of the particular facts of AA and BB's case, it cannot be said that they were given a fair and reasonable opportunity – or in my judgment any opportunity – to renew their consent in accordance with the legislation.

115. I am satisfied that AA and BB's application for relief should be granted. The interference with their Article 8 Rights is significant, final and lifelong.

116. In considering whether there are countervailing factors, on the particular facts of this case I am satisfied that to permit their application and by s 3 HRA 1998 to read in an opportunity under the 1990 Act to renew consent to the continued storage and use of their remaining 6 embryos would not undermine the objectives of the statutory scheme.

117. In the individual circumstances of their application it is in my judgment appropriate pursuant to s3 HRA 1998 to read in an opportunity under the HFEA 1990 to consent to continued storage and use of their remaining embryos.

CC and DD

118. CC and DD make an application for declaratory relief in relation to stored embryos. The HFEA does not oppose the declarations sought. The SSHSC does not oppose the declarations sought if the court is satisfied that declarations should be made in the particular circumstances of this application. Three healthy and viable embryos are kept in storage following fertility treatment which led to the birth of a child in 2021. CC and DD signed consent forms consenting to storage for 2 years . In their evidence to this court, they explain that they knew that they would want to use another embryo to have a second child 2 years later and linked their consent to that. CC's form was signed on 28th March 2020. DD's form was signed on 30th March 2020. Their embryos were frozen and stored on 28th and 29th July 2020.

119. Although when CC and DD first completed their consent forms to freeze the three embryos, they opted for a period of time less than 10 years (the previous statutory storage limit), at the point of cryobanking the embryos and entering the expiry date of

the storage consents on the clinic's internal patient management system, the default setting on the system of the statutory limit of 10 years was not adjusted by the embryologist to the reflect the period of consent in this case. The expiry date for the consent of CC and DD should have been 27th and 28th July 2022, dates which fell within the transitional period. The effect of the expiry date being incorrectly set to a date ten years after storage was that the system in place at the clinic did not prompt staff to contact CC and DD to seek renewal of consents to storage at the correct time. Had that system operated correctly, this couple would have been given the opportunity to renew consent to extend the storage period at 2 years from storage in July 2022.

120. In this case, the clinic identified the error on 18th September 2024 during an internal quality audit. Before the error had been identified, CC and DD had already made contact, in August 2023, with the clinic about using another embryo and had attended an appointment in November 2023 to discuss embryo transfer, which they then intended to have towards the end of 2024. All of that contact, unappreciated by the applicants and undiscovered by the clinic, was during a period when consent had already expired. In November 2024, the clinic informed the applicants CC and DD, that they would not be able to use the 3 embryos because consent had expired. In this case the applicants had continued to pay storage fees annually, but the fact that the default storage setting had not been changed meant that the continued receipt of payments did not alert the clinic to the error.

121. CC and DD had been unable to conceive naturally for many years before starting their family with the birth of their first child. They had always intended that they would use their stored embryos, in the hope of having another child, and to do so with an eye to the age difference between their children (should they be successful). They had taken the preliminary steps to embark on having a second child when the clinic discovered its error.

122. In the particular circumstances of CC and DD's case, it cannot be said that they were given a fair and reasonable opportunity to renew their consent in accordance with the legislation.

123. I am satisfied that the interference with CC and DD's Article 8 rights is significant, final and lifelong. I am satisfied also that there are no countervailing factors and on the

individual facts of this case that to permit their application and by s3 HRA1998 to read in an opportunity under the HFEA1990 to consent to the storage and use of their remaining 3 embryos would not undermine the objectives of the statutory scheme. It is accordingly determined that CC and DD's application for relief should be granted.

EE

124. EE makes an application for declaratory relief in relation to sixteen stored eggs. The HFEA does not oppose the declarations sought. The SSHSC does not oppose the declarations sought if the court is satisfied that declarations should be made in the particular circumstances of this application. In late 2008 or early 2009, following a long history of gynaecological difficulties, EE was diagnosed with low ovarian reserve. She was given medical advice which led her in her early thirties to preserve her fertility through egg vitrification. EE signed a consent form on 21st May 2009 consenting to storage for 10 years. EE's eggs were frozen on 2nd June 2009. EE signed a consent form on 6th July 2018 to extend storage for a further 10 years. This would have given an expiry date of 1st June 2029 though in some of the clinic documents it was recorded as 2028. These storage periods were (as the clinic was aware) by reason of her premature infertility.

125. Between 2019 and June 2024, EE signed internal clinic *'Stored Eggs Intention'* forms and paid annual storage fees and understood that all was in order so far as the continued storage of her eggs was concerned. However on 30th December 2024, the clinic contacted EE to inform her that there was an issue with the MPS confirming her premature infertility and that the clinic did not have the relevant completed HFEA consent forms for storage to continue.

126. The issue was not that the clinic was unaware of her premature infertility, but that on examination of the MPS in support for storage limit purposes, the MPS was invalid. On 6th September 2018, Dr A, Consultant Gynaecologist, completed a HFEA MPS, certifying that EE was/or was likely to become prematurely infertile but indicated that this was due to her age - which is not a valid ground for extended storage. EE's unchallenged evidence is that she does not recall ever seeing this MPS form, and furthermore that she has never had an appointment with Dr A.

127. EE recalled (and informed the clinic) that it was another consultant, Dr B, who had confirmed her premature infertility. The clinic has subsequently obtained medical evidence that supports (on the basis of tests taken in October 2016) that EE was likely to become prematurely infertile. In light of this information, the MPS has been revised confirming her likely premature infertility on the basis of her reduced ovarian reserve. However, the HFEA has confirmed that such an amendment would not validate retrospectively the MPS. To meet the requirements under the 2009 Regulations (paragraph 4), an MPS which was amended in August 2025 does not satisfy the requirement for having a valid MPS within the relevant period (i.e. between 2nd June 2009 and 1st June 2019). This notwithstanding that the condition which would have justified an MPS was present in 2016.

128. On the evidence it is apparent that the clinic did not appear to require an MPS or to explain to EE that one was required when the extension was obtained in 2018. Neither did the clinic contact the patient's GP to confirm premature infertility before extending storage. It follows from that, that EE's consent to the extension in 2018, was not effective consent and was invalid (with the effect that the expiry date would have been 6th July 2018.)

129. EE's individual circumstances are such that recognising early issues with fertility meant that if she wanted to have the opportunity of genetic parenthood at a later point in her life she would have to preserve her fertility, she took steps to do so. She took those steps because she had always known that she wanted to become a mother (in the genetic sense) at some future point. That remains her wish and her reproductive health means that if she is not permitted to use the eggs which she stored for that purpose, genetic motherhood will be lost to her.

130. I am satisfied that in the EE's individual circumstances she was not given a fair and reasonable opportunity to renew her consent to storage of her eggs in accordance with the legislation. The interference with EE's Article 8 rights is significant, final and lifelong. There are in her case no countervailing factors. To grant her application for relief and by s 3 HRA 1998 to read in an opportunity under the HFEA1990 to consent to the storage and use of the eggs which remain in storage would not, I am satisfied, undermine the objectives of the scheme. In those circumstances, EE's application for relief will be granted.

FF and GG

131. FF and DG make an application for declaratory relief in relation to stored embryos. The HFEA does not oppose the declarations sought. The SSHSC does not oppose the declarations sought if the court is satisfied that declarations should be made in the particular circumstances of this application. FF signed a consent form (naming GG) on 3rd September 2009 consenting to storage for 10 years. FF and GG signed further consent forms on 1st August 2011 consenting to storage for 10 years. Their embryos were frozen and stored on 5th April 2011. The expiry date following from that would be 4th April 2021.

132. In March 2021 the clinic informed FF and GG that although the ten-year period to which they had consented would otherwise expire in April 2021, the 2020 Covid Regulations meant that they could extend the storage period for 2 years. FF and GG confirmed intent to extend on 14th April 2021 and requested forms. The expiry date recorded by clinic was 3rd April 2023. That expiry date was one which fell within the Transitional Period. on 1st April 2022, the Clinics sent FF and GG the HFEA RNE(TP) Notice informing them that the consent period would end on 3rd April 2023 and information provided for the purposes of informed consent. On 27th June 2023 the clinic sent by e mail the HFEA RNE(TP) Notice, patient information and pro forma HFEA RE (TP) '*Renewal of consent to storage of your embryos for treatment*'. GG and FF did not complete or return these forms. There was in place at the clinic a review protocol where forms were not returned, such that patients were to be contacted a third time within the period during which they were still able to renew, but that protocol failed on this occasion. The clinic accepts that, for reasons which are not clear, the third contact was not made with FF and GG when they did not complete and return forms.

133. The particular circumstances of this case make the fact that FF and GG did not return completed forms hard to reconcile with the fact that since 2009 – so for some 14 years – they had assiduously completed and renewed consent. FF's evidence is that she has no recollections of the forms being sent to her on this occasion and that she along with GG had on every other occasion completed and returned the form. Although the clinic had not received completed consent forms, it accepted, and was not alerted by, the direct debit storage payment in May 2024 covering a period past the expiration of the storage period i.e. to May 2025. Seemingly, the payment did not trigger the clinic renewal

records as the financial aspect was managed by a different department in the clinic. In October 2024, the clinic contacted FF and GG by telephone to inform them that since consent had not been renewed to extend storage, the embryos could no longer be stored or used. Acknowledging that its own protocol for contact with patients to renew consent for storage of embryos which would otherwise expire had not been effective in this case, the clinic suggested to FF and GG that an application should be made to the Court for declaratory relief and that it should be made at the clinic's expense. Although in her witness statement FF recalls the clinic staff suggested in the telephone call that FF and GG should make an application funded by the clinic, it is noteworthy that in the clinics own record of that first contact on the point, the clinic's suggestion was that it should both make and fund any application for declaratory relief. Although it is obvious why that was not the course taken, it is telling evidence when the Court comes to consider whether FF and GG had an opportunity to renew their consent in accordance with the legislation.

134. FF and GG had intended continued storage of their embryos so as to have the option of expanding their family as genetic parents of another child. FF will be 58 later this year. The stored embryos represent their only remaining opportunity. The couple are clear that they wish their material to be available to them.

135. Having considered carefully the individual circumstances and history of FF and GG, and notably in their case the established history of completing consents when required taken together with the clinic's acknowledgment of its failure to give effect to its own procedures to follow up the consent renewal forms, I am satisfied that it cannot properly be said that FF and GG were given a fair and reasonable opportunity to renew their consent in accordance with the legislation. I am further satisfied that the interference with FF and GG's Article 8 rights is significant, final and lifelong. There are in the limited circumstances of their application no countervailing factors such that to allow their application and by s3 HRA 1998 to read in an opportunity under the HFEA 1990 to consent to the storage and use of the stored embryos would not undermine the objectives of the statutory scheme. The application for relief made by FF and GG will be granted.

HH and II

136. HH and II make an application for declaratory relief in respect of stored embryos. The HFEA does not oppose the declarations sought. The SSHSC does not oppose the declarations sought if the court is satisfied that declarations should be made in the particular circumstances of this application. Following fertility treatment in 2007, as a result of which twins were born in 2008, seven healthy embryos remained. HH and II signed forms on 28th October 2007 consenting to storage for five years. Their embryos were frozen and stored on 4 December 2007. Both signed further consent forms on 27th (HH) and 29th (II) October 2012 consenting to storage for a further 5 years. The initial expiry date was 6th December 2012 and became 6tn December 2017 after a second set of consent forms was signed. An MPS was completed and HH signed a consent form to extend consent to 15 years. This would have made the expiry date 6th December 2022: however, on that occasion of renewal II did not sign a consent form to extend until this date. There is no record that HH and II were notified that they could extend the storage period pursuant to the Coronavirus Regulations 2020 even though their embryos were in storage on 1st July 2020.

137. It seems that the clinic did not notice that II had not also completed the necessary consent form and continued to store the embryos. Since II's missing consent form was not noticed, it appeared that there was valid consent to extended storage to 6th December 2022, That is a date which falls withing the Transitional period. On 22nd December 2022, the clinic sent a transitional period renewal notice. HH responded on 2nd February 2023 that the couple wished to renew and requested the necessary forms. The HFEA forms were not sent, and HH and II did not complete the consent renewal forms. There was no further prompt from the clinic to return the completed forms even though the clinic was in touch with HH and II on 4th and 23rd April 2023 to request the payment of fees for storage (to which II and HH responded and paid on 9th May 2023). It is accepted that during the contact in requesting and acknowledging payment of fees, there was no mention of consent renewal. In its written evidence the point is made on behalf of the clinic that it has since changed its system such that outstanding consent issues will be picked up when contact is made about payment of fees. The clinic in this case accepts also that its own protocol to remind them before the end of the renewal period did not take effect and so HH and II were not reminded to complete the necessary forms to renew consent. It further accepts that the earlier missing consent form from II had not been noticed or followed up by the clinic.

138. In October 2024, the clinic notified HH and II that consent to storage had expired. In an e mail on 8th October 2024, following up on the telephone notification an employee of the clinic wrote *' I explained due to an administrative error on our side and as we did not follow up on the process of contacting you, if you did want to renew then we would need to apply to the courts to allow you to use the embryos. This is because the consent to storage has expired'.*

139. HH wishes to preserve her embryos. She describes in her evidence that it is not simply the opportunity of genetic parenthood that the stored embryos offer but the wider emotional and psychological significance the knowledge of the stored embryos holds for the couple. II's evidence in the trial bundle does not address the detail of his views as to this aspect but he explicitly aligns himself with all that HH has said.

140. The unchallenged factual circumstances of HH and II's application indicates clearly that they were not given a fair and reasonable opportunity to renew their consent in accordance with the legislation. The clinic's acknowledgement of, and apology for, the failures both immediately upon discovery in correspondence with HH and II and in its evidence for these proceedings underscores that. The interference with HH and II's article 8 rights is significant, final and lifelong. I am satisfied that in the individual circumstances of their application there are no countervailing factors such that to allow their application and by s3 HRA1998 to read in an opportunity under the HFEA 1990 to consent to the storage and use of the stored embryos would not undermine the objectives or go against the grain of the statutory scheme

141. The application for relief made by HH and II will be granted.

JJ and KK

142. JJ and KK apply for declaratory relief in relation to stored embryos. Neither the HFEA nor the SSHSC oppose the declarations sought if the court is satisfied that declarations should be made in the particular circumstances of this application. In 2019, following IVF 54treatment they had an embryo transfer and in 2020 their child was born. JJ and KK signed *pro forma* HFEA consent forms on 24 June 2019 consenting to storage of embryos for 5 years which was the period indicated on the forms signed. Their three remaining embryos were frozen and stored on 9th and 10th September 2019. The expiry date was therefore 8th and 9th September 2024. At the time (before the coming into

effect of the HCA 2022) the storage limit was 10 years but JJ and KK gave consent for five.

143. Although JJ and KK had selected a five year storage period, the clinic had its system set to the ten year maximum as the default period and did not adjust this setting for JJ and KK's consent to a lesser period. This led to an incorrectly entered expiry date of 8th and 9th September 2029. As a consequence of this error the clinic system did not generate an alert for renewal of consent. On 11th September 2024 the clinic, during an internal audit, identified that the consent which had been for five years had expired – the day before for the later frozen embryo - and that there was no valid consent in place. The detrimental effect of the disconnect between the limb of the clinic dealing with storage fee payment and the limb dealing with consent is illustrated starkly on the facts of this case. On 4th September 2024, that is 5 days prior to one expiry date, six days prior to the other, the latest confirmation of payment for storage was made. Had there been in place a system which, on renewing payment, checked the status of consent, it would be at least capable, provided the check included cross-checking the forms signed against the (incorrect) entries on the clinic system, of detecting that consent was imminently to expire. As it turned out, it was the audit that revealed consent had expired 24 and 48 hours previously. There is in JJ and KK's case an additional failure by the clinic since despite qualifying since their embryos were in storage on 1st July 2020, there is no record that they were ever notified of the opportunity by the Covid Regulations 2020 to extend the storage period by 2 years.

144. In September 2024 (on another account 1st October 2024) – it is not clear on the evidence whether that was shortly before or shortly after consent had expired – KK telephoned the clinic to discuss a further embryo transfer. On 5th November 2024 JJ and KK were sent a letter from the clinic informing them that consent had expired and the embryos could no longer be used. The terms of the letter are unambiguous as to the failings on the part of the clinic.

145. I am satisfied that the factual situation of JJ and KK's application means that they were not given a fair and reasonable opportunity – or any opportunity – to renew their consent in accordance with the legislation. The embryos had passed their lawful consent period before the issue was identified. I accept the evidence that this couple had always intended to enlarge their family with a second child once their circumstances permitted.

Their history of difficulties with natural conception which led them to IVF means that in reality they have no other prospect of genetic parenthood. They have been clear that it remains their wish to use their stored embryos as soon as possible.

146. The individual circumstances which underpin JJ and KK's application lead to the clear conclusion that the interference with their Article 8 rights is significant final and lifelong. I do not, having regard to the particular facts of their case find that there are countervailing factors which mean that to allow their application would go against the grain of the legislation or undermine the objectives of the statutory scheme.

147. JJ and KK's application for relief will be granted.

LL and MM

148. LL and MM apply for declaratory relief in relation to stored embryos. The HFEA does not oppose the declarations sought. The SSHSC does not oppose the declarations sought if the court is satisfied that declarations should be made in the particular circumstances of this application. In 2011, LL was diagnosed with cervical cancer. The recommended treatment was that she undergo a hysterectomy, together with chemotherapy, radiotherapy and brachytherapy. The proposed treatment carried with it the impossibility of LL being able to conceive and bear a child herself. Before commencing treatment for the cancer, she was referred to a clinic for an egg collection to give the opportunity of creating embryos to be used in later life with a surrogate. MM and LL were at the time of the diagnosis in a relationship which had moved to cohabitation quite recently. The advice in 2011, LL recalls, was that what she understood as the 'chances' were better if the eggs were fertilised to create embryos and then frozen rather than frozen unfertilised. LL and MM decided to create and store embryos. On 23 December 2011, LL completed a *pro forma* HFEA WT form, consenting to the storage of embryos for 10 years. MM completed a HFEA MT form, consenting to the storage of embryos for 10 years. 24 healthy embryos were created and stored on 10th and 12th January 2012, resulting in initial storage expiry dates of 9th and 11th January 2022.

149. On 24 October 2019, LL and MM completed *pro forma* HFEA WSG and MSG forms respectively, consenting to the storage of their embryos for 10 years. They completed the same forms again in 2020.

150. On 30 December 2021, LL and MM a *pro forma* HFEA ES form, consenting to extending the storage period to 10 and 12 January 2023. This expiry date was incorrectly set by the clinic system not to January 2023 but to a date of 10 years in the future i.e by adjusting the expiry date by ten years added to the initial period of storage whereas the patient consent form had given consent to one year added to the initial period of storage. As a result of that error the clinic's system did not generate an alert to prompt staff to ask LL and MM to renew their consent prior to the expiry of the storage period, resulting in the storage period expiring before the oversight was identified.

151. An additional aspect of this case which worked to LL's and MM's disadvantage is that although it is evident that LL would have been eligible for extended storage of 55 years in 2011 when by reason of her cancer treatment she would become prematurely infertile (hence the decision to store eggs/embryos), there is no evidence that this was discussed with her or offered as an option. Neither is there any record that these applicants, whose embryos were in storage on 1st July 2020, were given notice of the possibility of extending their storage period by reason of the Coronavirus Regulations 2020

152. Throughout the time that the embryos remained in storage (there remain 14) LL and MM continued to pay fees for storage. On 22nd December 2023, after the expiry of consent (in January 2023) on the face of the document sent requesting payment of storage fees, appears *'According to your current consent form the embryo(s) can remain in storage until 04-01-32'*. Whilst the obligations of the legislative scheme fall on the clinics not on the patients, the inclusion of this date provides not only evidence that the clinic was failing in discharging that obligation but is also an indication that there was nothing to alert LL and MM to the fact that their embryos were anything other than safely stored.

153. The clinic contacted LL and MM on 6th December 2024 by telephone to inform them that the storage consents had expired and absent an application to court the remaining embryos could not be used.

154. LL (and MM with LL) has no prospect of genetic parenthood if she is not able to use these stored embryos. LL delayed starting cancer treatment specifically to ensure that she preserved the possibility of becoming a mother, in the genetic sense, in the future.

In her evidence she has expressed the impact on her of feeling she may have done so for nothing. She and MM very much want their embryos to remain in storage so that they may have the opportunity to start a family.

155. I am satisfied that facts underpinning the application made by LL and MM demonstrate clearly that they were not given a fair and reasonable opportunity to renew consent to storage of her eggs in accordance with the legislation. The interference with LL and MM's Article 8 rights is significant, final and lifelong. There are here no countervailing factors. To grant the application for relief and pursuant to s 3 HRA 1998 to read in an opportunity under the HFEA1990 to consent to the storage and use of the embryos which remain in storage would neither go against the grain of the legislation at the heart of which is informed consent nor undermine the objectives of the scheme. In those circumstances the application made by LL and MM for relief will be granted.

NN and OO

156. NN and OO apply for declaratory relief in respect of stored embryos. The HFEA does not oppose the declarations sought. The SSHSC does not oppose the declarations sought if the court is satisfied that declarations should be made in the particular circumstances of this application. This case concerns frozen embryos created with anonymous donor eggs in Spain. Following several unsuccessful IVF cycles with NN's own eggs, upon medical advice she and her husband (OO) undertook successful treatment in Spain in 2005 using donor eggs and a child was born prematurely by elective caesarean section in 2006. That election was needed because during the pregnancy, NN was diagnosed with breast cancer and required treatment. She underwent treatment following birth, which included the removal of her ovaries. The patients' remaining four embryos were transferred to the United Kingdom from Spain on 15th October 2013, an application having been made to the HFEA for permission to import frozen embryos. The expiry date for storage of those imported embryos was 14th October 2023, but this was not entered on the clinic system. That expiry date means that it falls within the Transitional Provisions.

157. Mr Mehta on behalf of the HFEA made what he called a point of clarification as to this case. The normal position, he submitted, where there is a third party donor who has provided a gamete is that material provided by cannot be stored or used beyond the

expiry of the donor's consent. However, here the gamete was provided in Spain where anonymous donation leads to an irrevocable consent, and the donor was never identified. For those two reasons he submitted the issue of third party consent is not relevant. That clarification does not affect the position on the relief sought by these applicants, which as indicated the HFEA does not oppose.

158. On 30th June 2023, the clinic emailed NN and OO, making reference to changes in legislation regarding storage of embryos and gametes and indicating that information about those changes was attached and that consent forms would follow later. In fact the email attached the wrong information (regarding the transportation of the embryos and gametes). NN on 2nd July 2023, informed the clinic that the wrong attachment had been sent, but received no reply.

159. NN and OO continued to pay for storage by direct debit. The clinic continued to accept payment (until the cancellation of the direct debit by the clinic in April 2025) after the storage consents had expired but did not have any system in place which alerted the clinic when accepting payment that the consent had expired.

160. On 24th September 2024 (confirmed by e mail the following day) the clinic informed NN and OO that during an audit it had been discovered by the clinic that consents had expired in October 2023 and that they could no longer be used. The content of the email sent by the clinic both acknowledges the failure of the clinic to make contact to renew consent and offers legal representation at the clinic's expense.

161. As a consequence of the fact that NN and OO's expiry date was not included on the clinic's system, no HFEA RNE(TP) Notices for renewal were sent to them and the clinic's protocol to remind patients to renew did not take effect. Although it is a feature of this case that despite falling outside the protocol the clinic did in the email attaching the wrong information explicitly indicate that consent forms would follow and so this situation was not one solely reliant on automatically generated consent reminders.

162. In combination these mistakes and errors mean that NN and OO were therefore not asked to sign the required consent forms before the end of the renewal period. The disadvantage to them is compounded by the fact that in two other respects they had not been given the opportunity of extended storage. First, there is no record that they were informed when importing the embryos in 2013 that NN's premature fertility by reason

of her cancer treatment made them eligible (under the legislation then operating) for storage extended to 55 years. Second, there is no evidence that they were informed of the extension to storage periods in accordance with the 2020 Coronavirus Regulations, since the embryos were in storage on 1 July 2020.

163. NN and OO would like the opportunity to have another child. They have known, since the NN's diagnosis and treatment for cancer during her pregnancy in 2005 that any child they might have would be by the surrogacy route and that is what they would intend now. They wish to have the opportunity to use their stored embryos.

164. Having examined the particular circumstances of this application, I am satisfied that NN and OO were not given a fair and reasonable opportunity to renew consent to the storage of their embryos in accordance with the legislation. The interference with their Article 8 rights is significant, final and life long. In the narrow circumstances of their application there are no countervailing factors sufficient such that relief should not be granted. I am satisfied that to grant the application for relief and by s 3 HRA to read in an opportunity under the HFEA1990 to consent to the storage and use of the four embryos which remain in storage would not go against the grain of the legislation neither would it undermine the objectives of the scheme which include, as discussed elsewhere, protection and respect for informed consent.

PP and QQ

165. PP and QQ apply for declaratory relief in relation to frozen embryos. The HFEA does not oppose the declarations sought. The SSHSC does not oppose the declarations sought if the court is satisfied that declarations should be made in the particular circumstances of this application. In 2020, PP underwent two procedures for egg collection. In anticipation of the first in January 2020 consent to storage forms were completed. As it turned out, the embryos created as a result of that egg collection were not of sufficient quality for storage and later in the year another procedure was undertaken from which embryos of sufficient quality were created. These are the embryos which are the subject of this application. They were stored on 29th November 2020.

166. When PP completed the pro forma HFEA form on 5th January 2020, she consented to a 10 year storage period. QQ, completing his pro forma form on 15th January consented to a 3 year period. When the forms were returned to the clinic, the discrepancy was

drawn to PP's attention with the information that it would mean a storage period of 3 years. On 16th January 2020, PP made contact with the clinic agreeing to a 3 year rather than a ten year storage.

167. Against that background the expiry date for consent for the embryos stored on 29th November 2020 was 28th November 2023. That is a date falling within the Transitional Period. In fact, however the clinic incorrectly recorded the storage period as ten years with the result that consent was recorded as expiring in November 2010. As a consequence of that no reminder was generated in anticipation of the November 2023 expiry date

168. The error was discovered by an audit carried out by the clinic and on 31st January 2025, PP and QQ were sent a letter confirming an earlier telephone notification that the consent to storage had expired for the embryos in storage and they could no longer be used. Within that letter the clinic informed PP and QQ that they could each by completing consent forms (which were enclosed with the letter) retrospectively and prospectively consent to storage. The author of the letter asked PP and QQ to opt for '*at least 5 years*' but advised them that they could select '*up to 10 years'* consent and concluded the letter with '*please complete these forms as a matter of urgency to allow us to continue storing your embryos*' [emphasis added] . It is surprising that that was said. It was not correct and there had already been application for, and interim declarations made on an emergency basis, in December 2024.

169. In this case PP and QQ wish to use their embryos. They have had three transfers which were not ultimately successful. On two subsequent occasions when they have been intending to embark on the process of embryo transfer – once in January 2022 and once in January 2024, - they discovered unexpectedly that they had conceived naturally. It is their wish to be able to use their stored embryos and to expand their family of two children.

170. On the facts of this case I am satisfied that PP and QQ were not given a fair and reasonable opportunity to renew their consent. The incorrect date entered on the system following on from the discrepancy in their selected dates meant that they were not sent renewal forms or reminders as they should have been in readiness for an expiry date of November 2023. The interference with PP and QQ's Article 8 rights is significant, final

and lifelong. There are no countervailing factors to the relief in their case. I am satisfied also that to grant the application for relief does not go against the grain of the legislation and does not undermine the objectives of the scheme. In those circumstances relief will be granted.

RR and SS

171. RR and SS make application for declaratory relief in respect of stored embryos. The HFEA does not oppose the declarations sought. The SSHSC takes no position on this case but invites the Court to scrutinise the particular factual circumstances of the case with care so as to determine whether relief should be granted.

172. In early May 2014, RR was diagnosed with advanced cancer and was recommended to undergo chemotherapy. There was a one-month window for egg recovery and storage due to the risks associated with delaying chemotherapy. SS and RR created and froze embryos prior to RR commencing chemotherapy. On 14th May 2014, RR and SS both signed pro forma HFEA consent forms consenting to storage for 10 years. The clinic did not discuss or provide the patients with the option to store their embryos for 55 years on the basis of RR's premature infertility, notwithstanding that under the legislation then in force RR's cancer diagnosis and treatment would have made her eligible. On 21st May 2014, the embryos were frozen. The expiry date based on the consent was therefore 20th May 2024. This fell within the Transitional Period. The applicants were not informed, in 2020, that they could have extended to 12 years under the Coronavirus Regulations 2020.

173. This is not a case in which the applicants had ongoing contact with the clinic to pay annual storage fees as, on 12 June 2014 and 26 June 2014, RR and SS had paid the storage fees for the full 10 years upfront. In their evidence both applicants make clear that their intention was for the embryos to remain in storage for the maximum period of time which they understood to be possible, and since they knew this, they paid in advance.

174. On 16 May 2023, the clinic issued a HFEA RNE(TP) Notice dated 16 May 2023 to the applicants, containing notice that if the embryos had been first kept in storage prior to 1st July 2022 and the consent period for their storage ends between 1st July 2022 and 1st July 2024, then consent to storage must be renewed before 1st July 2024. The

accompanying e mail contained the information (in bold type face) that if not renewed, consent would be taken as withdrawn and the clinic would be legally required to dispose of the embryos. It also alerted RR and SS to the need to log on to the clinic portal to renew consent forms and offered the option of attending the clinic in person to complete consents if preferred. RR's evidence is that she does not recall this email but acknowledges that it set out the need to renew consent, how to do that, and the consequences of not doing it.

175. On 21 March 2024 and 25 April 2024, the clinic sent RR messages on the online Patient Portal with information that the ten years paid storage period for embryos would come to an end on 21 May 2024, and that in order to continue with storage, payment must be made before then. In submissions to this Court it is said on behalf of RR and SS that it is unclear whether those messages were read and it is not addressed by RR in her evidence.

176. On 16 May 2024, RR telephoned the clinic to pay for continued storage. In her witness statement, RR's evidence includes this: "I s*pecifically remember the phone call, as I had wanted to make sure that our embryos would remain in storage. This was very important to both [SS] and myself. On calling up the clinic to make the payment over the phone, I was informed that I could also make the payment online. However, I informed the clinic staff member that I was worried that I might do something wrong and would prefer to make the payment over the phone with someone. Given that I was so anxious in making sure everything was ok with the stored embryos, I specifically asked whether I needed to do anything else. The response given was 'No, don't worry. The payment has gone through. I've put a note on the Portal that you have paid for a year. You don't need to worry.'"*

177. Neither the clinic nor RR suggest that she was informed about the need to renew consent during that phone call. There were no further communications from the clinic to these applicants until 5th September 2024 when the clinic sent an email to RR and SS saying they had not received the relevant consent form, and consent could no longer be renewed.

178. RR and SS each set out in their evidence the ways in which they are both deeply affected by the possibility of not being able to use the embryos. The fact that the news of the

expiry of consent coincided with RR reaching the milestone of 10-year remission of cancer and the couple turning their hopes to starting a family has exacerbated the emotional impact described. The treatment means that there is no possibility of genetic parenthood for RR (and for SS with RR) if they are not permitted to use the embryos stored.

179. It has been necessary to reflect very carefully about the evidence which RR gives about paying for renewed storage on 16th May 2024. It is apparent from the way she expresses herself in the passage set out above that the question of continued storage was understood by her to be contingent on the payment of storage fees. I have to consider that, holding in mind as do so the submission made (as a matter of general principle not specifically as to the merits of this case) that payment of storage fees cannot stand as proxy for consent in this, a strict scheme. I accept that. As I examine the particular facts of this case, and what the evidence tells me about the opportunity to renew consent, the communications with the clinic are an important component of that. Within the body of the letter sent by registered post to SS on 16 May 2023, which is concerned with renewal of payment, appears this *'Please remember that if you would like to continue storing you must keep up to date with your payments : contact us for advice on our payment options and/or setting up a monthly direct debit. If we do not receive payment, we will remove your embryos from storage even if your consent remains valid.* [Emphasis added] . This clinic (and other clinics in other applications) makes the point that the departments dealing with consent to storage renewal and the with payment of fees for storage are different. That is said to explain, for example, the absence of any reminder or discussion of the need to renew consent during the conversation about payment on 16th May 2024. So it is, to my mind likely to import confusion to draw so explicitly a link between effective consent to storage and payment in this passage of the letter of 16th May 2023. That is part of the context in which I evaluate the evidence about the circumstances here.

180. Ms Sutton for the applicants does not rely solely on that aspect of the evidence, but in reliance on it she submits that the clear but false reassurance that RR did not need to take any further action, strongly mitigates in favour of relief. In developing that submission, she went on to say that, as a lay person it is not unreasonable to take a reassurance provided by an employee in a specialist clinic. I have not found that latter

part of the submission helpful in considering this case since it carries with it the risk of thinking in too wide a way, rather than focussing on the narrow individual circumstances of this application. Whether it is or is not unreasonable to do so, will be fact specific from case to case. I have confined myself to the significance of the reassurance within the context of these narrow circumstances. The failure of the clinic to give the option to store for 55 years – and thus to renew consent within the mechanism of that time frame and the failure to inform RR and SS of the possibility of extended storage pursuant to the Coronavirus Regulations both have relevance to the question of whether and to what extent the applicants were given a fair and reasonable opportunity to renew consent within the legislation.

181. Whilst I had some reservations as to whether it could properly be said, as RR and SS contend, that they had not been given a fair and reasonable opportunity to renew their consent to storage, reflecting on the whole picture after a very careful examination of the matters raised, I find that those reservations have receded. Taken together the elision here of the issues of consent to storage and payment for storage; the failure to offer extended storage for premature infertility or per the Coronavirus Regulations 2020; and the absence of further reminder that consent expiry was fast approaching on balance satisfies me that RR and SS were not given such opportunity. I am further satisfied that the interference with their Article 8 Rights would be significant, final and lifelong.

182. In consideration of countervailing factors to justify the interference, I do not find that there are such factors here. I have paused to consider very carefully whether granting the declaratory relief in this application would go against the grain of the legislation or would run the risk of undermining the objectives of the scheme. The HFEA as the state regulator of fertility treatment does not oppose the declaratory relief sought by RR, SS or indeed any other applicant in these proceedings. It is therefore submitted that the Court should take reassurance from the fact that the HFEA does not take a position aligning itself with the concerns expressed on behalf of the SSHSC. I hold in my mind however Mr Hyman's submission (as an overarching point, rather than to adopt a position in any of the individual cases) as to the risk of undermining the certainty of the scheme. That may be, for example, by seemingly requiring of clinics more than is required of them by statute in renewal of consent- perhaps in the number of ways in which they might be expected to make contact or send reminders. The thin end of a

wedge which might lead to litigation risk averse clinics storing indefinitely in a climate of reduced certainty. I am satisfied that in the narrow and particular circumstances of these applicants, to grant the declarations sought does not risk undermining the certainty of the legislation. The declaratory relief sought by RR and SS is granted.

TT and UU

183. TT and UU apply for declaratory relief in relation to stored embryos. The HFEA does not oppose the declarations sought. The SSHSC takes no position on this case but invites the Court to scrutinise the particular factual circumstances of the case with care so as to determine whether relief should be granted.

184. On 15th October 2012, TT completed the HFEA consent form. On 16th October 2012, UU completed the HFEA consent form. The following month, in November 2012, two of the three embryos created during treatment were stored (the third having been transferred and leading ultimately to the birth of the parties' child). The expiry date based on their consent was therefore November 2022. This fell within the Transitional Period. The applicants were not informed that they could have extended to 12 years under the Coronavirus Regulations.

185. The applicants paid storage fees regularly by Standing Order. UU's evidence is that *"The clinic consistently contacted me via telephone whenever there was an issue with payment or when a payment was missed. They were persistent and diligent in chasing these payments, sometimes calling multiple times until the issue was resolved. At no point during these calls or other communications was I informed that a storage related consent form needed to be renewed. I did not receive any letters by post or follow-up phone calls indicating that there was a serious issue relating to consent."*

186. On 1 June 2022, an HFEA (RNE) TP notice was sent to the couple. The consent period for storage however is incorrectly recorded and is shown as ending on 2nd November 2023, rather than the correct date i.e. 2nd November 2022. It was not therefore a valid statutory notice. On 27 June 2023, the clinic emailed TT and UU to inform them that there were new regulations in place (2022 Regulations). This communication was also unsatisfactory since although, unlike the 1st June 2022 notice, it contained the correct day for expiry of consent, it was sent 8 months after that expiry and so to the extent that it invited signature of forms for renewal of consent it could have no effect.

187. The clinic acknowledges both in its evidence to this court and in correspondence with the applicants at the time, that it failed to follow its internal protocol to contact the applicants before the renewal period. On 6th December 2024, the Head of Quality at the clinic recorded in file notes of contact with UU and TT: *"I confirmed that we have owned our mistakes and will be reporting it to HFEA."*. Noteworthy also is the fact that amongst the options which in correspondence with TT and UU it is acknowledged they may wish to consider (alongside legal action for declaratory relief facilitated by the clinic) is the making of a formal complaint against the clinic.

188. The evidence of the clinic correspondence with, and notices to, UU and TT, taken together with the clinic's candid acknowledgement of failure, demonstrates that these applicants were not given a fair and reasonable opportunity to renew consent in accordance with the legislation.

189. I accept the applicants' evidence that had they had the opportunity they would unhesitatingly have given written consent. The applicants wish to have the opportunity to use the two embryos which remain in storage. The interference with their Article 8 rights in this case would be significant, final and lifelong. There are in the circumstances of TT and UU's application no countervailing factors to justify the interference.

190. I am satisfied also that to permit their application on the particular facts of this case would not undermine the scheme as it is boundaried and limited to these facts. Accordingly, the declaratory relief sought by TT and UU will be granted.

VV and WW

191. VV and WW make application for declaratory relief in relation to one stored Embryo. The HFEA does not oppose the declarations 6767sought. The SSHSC takes no position on this case but invites the Court to scrutinise the particular factual circumstances of the case with care so as to determine whether relief should be granted.

192. These applicants have a very long history of fertility treatment having been unable to conceive naturally. They had one successful treatment in 2005 resulting in the live birth of their only child but between 2004 and 2020 multiple other attempts were unsuccessful. There were two embryos remaining in storage from those created and stored in 2013 (see below) but only one is suitable for transfer.

193. On 30th May 2013, VV and WW signed the HFEA consent forms for 3 years of storage. On 19th and 20th August 2013, the frozen embryos were stored. The original expiry date was therefore 18th and 19th August 2016. On 1 July 2016, further consent forms were signed extending the storage to 10 years. The effect of this is that the storage expiry date would fall in 2023. Both in the skeleton argument for this court and in submissions the applicants assert that the expiry date is June 2023 and that the date fell within the Transitional Period. Having examined the forms exhibited which the applicants signed on 1st July 2016, I would expect the expiry date, following renewal to be 18th and 19th August 2023.

194. The applicants, whose embryos were already in storage on the relevant date, 1st July 2020, were not sent information that they could have extended to 12 years under the Coronavirus Regulations.

195. In May 2021, VV had a telephone review with a doctor at the clinic the focus of which was the prospect of transfer using the two remaining embryos and the need to identify whether both or were suitable for transfer. There was no discussion in this call about the approaching expiry of consent to storage or the date of that expiry and that absent consent the embryos would be destroyed. Neither was VV informed of the option of extending storage for two years under the Coronavirus Regulations 2020 or of the need for associated written consent for that extension.

196. On 31 January 2022, VV and WW completed Welfare of the Child forms required by the clinic. These forms are not concerned with consent to storage or its renewal but nonetheless provide relevant evidence for the evaluation of the circumstances of this application since in completing those forms VV and WW indicated that their address had changed and gave the new address. Ms Sutton submits therefore that as of 31 January 2022, the clinic was on notice of the family's new address. The clinic's evidence for this hearing accepts that it had the Welfare of the Child forms and that those forms did include a different address. As to the effect of it however, the author of the clinic evidence says this:

"The WOC forms were completed on [the clinic's] electronic consent platform, known as Engaged MD or EMD. When patients and their partners are registered with EMD by [the clinic] we do not share their address or telephone contact details and so these

details are not prefilled but are added by the person completing the assessment. When a patient seeks to change their contact details [the clinic] would issue a change of details form to capture all relevant changes and ensure that they are updated on their systems. Unfortunately, using the WOC form to alert [the clinic] to a change of address is not a usual or an acknowledged mechanism for updating contact details and staff reviewing the WOC forms would not check/ cross reference the address against the patient's demographic data on file"

197. On 12 May 2023, letters were sent to VV and WW about the new regulations (2022 Regulations), and advising them of the fact that they must renew their consent by the end of the Transition Period on 30 June 2024. Those letters were sent to VV and WW's previous address. Of itself and despite the clinic's approach to cross-referencing between its departments updated address information (see above) that may not have mattered since the clinic operated a policy of sending important documentation by recorded delivery. There was however no follow up, as seen from the clinic evidence on this aspect: *"As such, the letter dated 12 May 2023 was sent to the address that [the clinic] had on its records, and as re-confirmed on 5 January 2022, namely Springwood Avenue. All letters sent in the post by [the clinic] are sent recorded delivery, however unfortunately at that time it was not the administrators' practice to retain printouts from the franking machine as evidence of the letters being sent by recorded delivery."* [emphasis added]

198. It is hard to reconcile that approach with the decision to use recorded delivery. Recorded delivery would require a signature. As it happens, VV and WW still owned (though did not occupy) the previous address. Their evidence is that no letter was received.

199. On 23 April 2024, an email was sent by the clinic to VV, reminding her to renew consent by the end of the Transition Period on 30 June 2024. The email forms part of the documentary evidence before this court. VV explains that it did not arrive in the form seen in the documentary evidence but that the email shows simply 'please log in' directing to the "portal" used by the clinic for patient communication. VV accepts that she received and saw the e mail 'please log in'. She did not.

200. On 13 September 2024, VV received a further email. This time although it was again a clinic portal message, the content was copied into the body of the e mail. VV's evidence

is that it mentioned the need to renew consents. The clinic's evidence is that what was issued on 13th September was the statutory notice of withdrawal of consent. The effect of receiving the email was that VV immediately made contact with the clinic. It is accepted and recorded on the clinic system that she was advised by the clinic that the stored embryos could be used up until the 31st December 2024. That incorrect advice was recorded on the clinic's system. The advice that the embryos could still be used (as distinct from stored) until 31 December 2024 does not have any evidential value as I assess the particular circumstances in which consent was not renewed. It has some relevance as I assess the communications between the clinic and these applicants so as to determine whether there was a fair and reasonable opportunity to renew in accordance with the legislation.

201. On 20 September 2024, the clinic called VV and said that her consent was considered withdrawn and nothing further could be done.

202. In her evidence VV outlines a series of difficult personal circumstances that she says had an impact on her during the time when the consent was not renewed. I have been very careful as to what account I take of those aspects of her evidence in relation to the particular decisions falling to be made here. Elsewhere in this judgment I have made reference to the cautions against allowing sympathy for sad, even tragic, personal circumstances to divert the court from its function. See by way of recent example the President of the Family Division in refusing the application in *G v HFEA* . Applications of the sort under consideration in these 15 cases are made, almost by definition, by people who find themselves in anguished situations. What I understand the President to be conveying essentially is not that Courts must be hard of heart in determining applications made, but that Courts must do so with the head not the heart.

203. I have considered very carefully that it was known in this case that the portal was used by the clinic for communications, VV knew in April 2024 there was a message on the portal, knew she had been asked to log in and yet did not do so. When considering what the clinic did, in respect of its obligations that evidence carries weight as to whether VV (and WW) were given a fair and reasonable opportunity. Having the opportunity is not the same thing as taking it. To be balanced against that however is that this clinic did use also other means of communication. Letters were sent recorded delivery. I have already considered how in this case in combination the use of an outdated address, a

system that did not cross reference addresses and a failure of follow up and retention where recorded delivery was used made that communication ineffective. The evidence of VV that on another occasion (in relation to expired contact) an email was sent with the important information displayed in the body of the email -which can only have been so it was immediately obvious -is not challenged. It had the effect of immediate contact. On a very careful examination of the circumstances of this case I am on balance satisfied that the VV and WW were not given a fair and reasonable opportunity to renew their consent to the storage in accordance with the legislation

204. Here the applicants wish to consent to their sole embryo being stored and used. It is their last hope of another child. The interference with VV and WW's Article 8 rights is significant, final and lifelong. There are no weighty countervailing factors to justify such interference. I am satisfied that to permit VV and WW's application on the discrete facts will not undermine the legislation. Accordingly, the application they make for declaratory relief will be granted.

XX

205. XX applies for declaratory relief in relation to storage of gametes. The HFEA does not oppose the declarations sought. The SSHSC takes no position on this case but invites the Court to scrutinise the particular factual circumstances of the case with care so as to determine whether relief should be granted.

206. XX was diagnosed with high grade lymphoma and referred for gamete cryopreservation prior to treatment with chemotherapy. In March 2014, gametes were stored. Despite the fact that the internal referral form specified that this was an oncology referral, the clinic did not discuss or provide XX with the option to store the gametes for 55 years on the basis of his premature infertility, notwithstanding his eligibility as a consequence of his cancer diagnosis. Unaware that he was eligible for the 55–year period, when on 24th March 2014, XX completed the HFEA consent form, he ticked the "10 year" box. The expiry date for consent was therefore 25th and 27th March 2024. The clinic also failed to inform XX when the 2020 Coronavirus Regulations permitted it, that he could extend storage from 10 to 12 years.

207. An important factual aspect of this case is that XX, was living and working at in the UK on a military base of another nation at the time of his diagnosis. For many of the

intervening years he has lived between the other nation and the UK travelling back and forth between the two. XX changed address from time to time and there are recordings on the clinic system of these changes.

208. There was regular communication – which included frequent telephone communication – between the clinic and XX, but this communication was only in relation to payment of storage fees. XX's evidence is that he was never sent a notice or informed about the need to renew consent. He highlights as a key instance when there was an opportunity to inform him, but he was not told, 16th May 2023, when he paid storage fees over the phone.

209. On 12th April 2023 the clinic prepared to be sent to XX the relevant HFEA RNG(TP) to renew consent. It shows entered on it XX's old address on the HFEA statutory notice to renew consent. The clinic's evidence for this hearing is that the notice was not sent. The author of the clinic's evidence expresses it in this way:

"I can confirm that this letter was not sent by the Administrative Team as they wished to confirm that they had the correct details prior to sending confidential information. This is in keeping with the enhanced confidentiality requirements we impose to ensure we are compliant with the HFEA Code of Practice".

What is surprising is that in this instance, it is not that the clinic had an address, was unaware it had changed, and so sent out the notice to an address not appreciating it would, or might, not reach its intended recipient. Here the clinic did not send the notice because it did not regard itself as having an up-to-date address. Elsewhere in the clinic records – those relating to storage payment – there is evidence that for the most recent invoice payment, change of address was noted as there appear handwritten amendments to an invoice. The clinic evidence is that their records were updated with XX's new address on the afternoon of 16th May 2023. It is a reasonable inference to draw, and I draw it that this update will have been as a result of information given during the telephone call to pay the storage charges made the same day.

210. Within the body of the witness statement filed by the Chief Executive of the HFEA as evidence on behalf of the regulatory body in these proceedings, surprise is expressed at the position of the clinic in this application that it was unable to send a notice in respect of renewal when the same clinic is able to make contact for storage fees:

I note that there are some Claimants (for example, ... XX) in whose case the clinic was able to contact the patient in order to secure payment for ongoing storage, but not for the purpose of securing consent to ongoing storage. In such circumstances it is hard to see how clinics could justify having made reasonable efforts, but failed to contact a patient to discuss storage consent in cases where they have been able to reach the patient to take payment. [emphasis added].

That rhetorical question, posed as it is by the CEO of the regulatory body, is heavily relied on by XX as support for his application

211. As to other contact made with XX, the clinic states that in the period May 2023 to June 2024 it contacted XX three times by email. The first of those e mails (16th May 2023) is marked private and confidential and asks for confirmation of name date of birth and address. It indicates that there is documentation to be reviewed about stored samples but makes no reference to consent or urgency. The second e mail (19th March 2024) has 'URGENT' in the strapline and in the body of the e mail reads *'we have some consent documentation regarding your stored samples which requires your urgent attention'*. The third (24th June 2024) has 'URGENT' in the strapline; it starts with *I have some urgent documentation for you to review regarding your stored samples which are nearing their expiry* and further on *please note that if we do not hear from you by 30th June 2024* ***your consent will expire and we will be legally obliged to remove your sample from storage*** [original emphasis]

212. On behalf of XX it was submitted orally that he had not appreciated the urgency of the e mails. How that might be is readily appreciable as to the first, less so as to the second but irreconcilable with the terms of the third. His evidence in fact about that e mail is that he did not read it immediately. He is not explicit as to when he did read that email but from the context of his statement where he indicates i) that the 19th March 2023 email was not read until after he was notified there was a problem with his consent and ii) that the first time he appreciated that there was an issue with his consent was in a call from the clinic on 15 August 2024 I understand it to be after the event. The reading or appreciating the urgency of the 24th June email had to be seen in the light of the expiry date here of 25th and 27th March 2024

213. An interesting feature of the telephone call from the clinic on 15th August is that it was made in response to XX's own call the day before for the purpose of paying a storage fee. Within the context elsewhere of a separation of the fees side of the clinic business, and the consent to storage side (see for example the 16th May 2023 phone call), it is notable that where the clinic wishes to contact a patient to give information that consent is now treated as withdrawn there is seemingly no difficulty doing that in the context of a call for the purpose of payment of fees. This throws into yet sharper relief the observations of the CEO of the HFEA in his evidence referred to earlier.

214. In this application the question of whether there has been a fair and reasonable opportunity is particularly nuanced. Were it the case here that only the communication by post that fell to be considered it would be much more straightforward. It is my clear view that XX was not given the necessary opportunity by that route or to put it another way the clinic did not discharge the obligations on it. It is especially striking that the separation of storage consent and payment for storage functions creates a lack of joined up thinking. A stark example emerges from the fact that on 12th April 2023 the clinic is unable to send a renewal notice because it does not have an address, yet its own systems do not seem to permit it to realise that little more than a month later (and crucially within the time) it does then have an updated address on the system and to send the statutory notice to that address. Balanced against that however is the question of the email correspondence. Reflecting on the emails that were sent by the clinic, I reminded myself of the exchange with Ms Goold in her submissions as to errors when, in response to question, she gave as that which could be seen as the responsibility of a patient, just throwing away or not reading at all a letter. XX's approach to the emails is very close to the digital equivalent. It raises for me the question how far along the spectrum of what constitutes being given a fair and reasonable opportunity is it right to travel before arriving at receiving an urgent e mail and simply not troubling oneself to read it. At one stage it was submitted for him that he is someone who was more used to, more comfortable with, speaking on the phone. I did not find that submission helped me.

215. I have come close to determining in relation to this application that XX was given a fair and reasonable opportunity to renew his consent to storage in accordance with the legislation but have drawn back from that since I have concluded that the following

aspects balanced against the e mail communications favour a contrary conclusion: the clinic, was aware of XX's new address within the time frame within which he could renew but did not send the statutory notice to it; at the point when the clinic wanted to alert XX to the fact that consent had expired and it would no longer lawfully store his gametes it did use a telephone call to contact him, yet did not when it received no response to e mails for example that sent on 19th March 2024; at the very outset in circumstances where he was storing gametes at all because of cancer related premature infertility, XX was not given relevant information about extended storage options.

216. XX who continues to consent to gametes being stored wishes to preserve the possibility of becoming a parent in the genetic sense. His cancer and the treatment required to overcome it means that such a possibility only remains to him if permitted to use and so continue to store for use these gametes. I am satisfied that the interference with his Article 8 rights is significant final and lifelong. I accept and agree with the submission that there are no countervailing factors sufficient to justify the significant interference. On the foregoing careful examination of the particular facts I am satisfied that to permit his application for relief will not undermine the fundamental objective of the legislation.

YY and ZZ

217. YY and ZZ make application for declaratory relief in relation to the storage of embryos. The HFEA does not oppose the declarations sought. The SSHSC takes no position on this case but invites the Court to scrutinise the particular factual circumstances of the case with care so as to determine whether relief should be granted.

218. The factual circumstances of this case are very unusual. In 2014, the applicants underwent treatment for IVF. YY, at an earlier time having, as she thought at the time, had a completed family with a previous partner had had a laparoscopic procedure to her fallopian tubes. When in her subsequent relationship with ZZ the couple wished to have a child together, they decided on medical advice that IVF would be preferable to an attempt to reverse the procedure.

219. In readiness for treatment YY and ZZ filled out HFEA consent forms on 11th March 2014. Those forms form part of the evidence at this hearing. There are two sets of forms completed and dated the same day. One set is completed with YY and ZZ each ticking the box 'no' to consent to storage of the embryos. One set is completed with both YY

and ZZ ticking both the *'no*' and the *'yes'* boxes for consent to storage of embryos, with in each case what appears to be a scribbling out and initialling next to the 'no' box. Although that would seem to indicate ambiguity, the evidence makes clear that is not so. As appears in YYs witness statement in April 2014, one embryo was unsuccessfully transferred and the couple was offered the option to freeze the remaining embryos, but they decided against doing so and instructed that the embryos should be destroyed. ZZ's evidence is that *'we did not intend to leave any embryos stored'*. YY's evidence is that she clearly remembers completing forms confirming that they did not consent to storage which reflected their intention. YY does not recall circumstances when the double ticked form was completed but to the extent that it records anything other than a refusal of consent to storage, she thinks it may have been *'signed under a misapprehension'*.In submissions made on behalf of YY and ZZ Ms Sutton invites the court, as between the two different sets of consent forms to prefer the ones which said '*no*'. She submits also that any confusion arising from the two sets of forms should have been checked by the clinic at the time.

220. I accept the submission that on all of the evidence I have, the Consent forms indicating *'no'* to storage are to be preferred and reflect YY and ZZ's refusal of consent to storage.

221. On 8th April 2014, the embryos were, in fact, contrary to the consent forms and unknown to the applicants placed in storage. The clinic recorded a storage expiry date of 8th April 2024. Although if there is no consent, on the basis of the forms to be preferred that date is without real meaning. Since the storage of the embryo(s) without consent was not lawful, there was no consent to expire or renew.

222. In 2015 YY and ZZ were contacted by the clinic and told that a single embryo had been kept in storage. On perusal of the communications from the time it emerges that the clinic in fact chased for payment for storage on an e mail sent 4th October 2105 headed 2nd reminder. YY writes in response on 12th October 2015:

We are completely baffled to what this means. I have attached the green form we completed at the time regarding storage, if you look at page 3 and page 11. We both said no to storage so we cant understand why there is a charge for storage. Apart from invoice you sent there is no letter explaining what is this process of embryo/gamete freezing sent to us. It might seem like something straight forward for your team but for

us it was our first IVF and we were told by [Dr Z] that before anything goes ahead we would be contacted by your company. We were not contacted or told that there was an embryo or gamete still alive. Which for us it was fine because we had said we didn't want to freeze it.

Following on then from expressing her dismay at being threatened with debt collectors (for unpaid storage fees) YY continues '*I would like to ask if you could look into this and explain why it was still gone ahead with freezing and storage*'.

223. The results of the enquiry the following day, 13th October 2015, e mailed back from the person handling the matter at the clinic to YY includes this:

"As I explained to [Dr Z] your consent forms were both signed for 10 years storage and since the embryo was of very good quality we froze it. Unfortunately, it looks like you have not been informed on the day of freezing, which is unfortunate and I apologise for this.

I will try calling you again today and discuss the situation in more detail but also the options you have of whether you wish to keep this embryo or not. With regards to the freezing and storage bill this will be credited and you will not have to pay for it." It does not address the question of the consent form sent over by YY indicating no consent to storage. On 16th October 2015 the final part of the run of e mails produced for this hearing is an e mail from the clinic: *thank you for your time on the phone today. I did speak to accounts and they confirmed that your bill will come through [clinic], there will be no extra charges from out part. if you have any more questions about billing you cant ask [named staff member] directly. Kind regards and best wishes with your treatment.*

224. From that correspondence it seemed that one possibility was that in 2015, during the phone call which took place between the e mail on 13th October and that on 16th October, a position had been reached where, by some means, YY and ZZ had changed their position and/or agreed that the second set of forms amended to '*yes*' for consent to storage represented their position. There is an ambiguity where there is mention of storage fees as to whether that is a reference to those which had been chased for, or some future billing. The best wishes for 'your treatment' might also tend to the possibility.

225. However in the statement of evidence for this hearing YY says of the 2015 contact with the clinic:

"We were surprised by this as it contradicted our wishes and recollection of events and brought additional confusion and distress as the matter was very delicate for us and we thought this decision was behind us. As I understood it the clinic went ahead with storing the embryo as they were [sic] of a good quality. We have not been paying for storage all these years. There was no follow up from the clinic regarding the future of the embryos [sic] and the issue dropped from my mind"

YY does not suggest that there was any change of position or any decision or purported decision to consent or seek to consent to storage after all in 2015. There is on, the evidence, no further consideration of the embryo at all until 8 years later. YY's evidence states: *in 2023 we were contacted again and informed the embryo was still in storge, and that a decision regarding its future was required*.

226. Within the contemporaneous recordings from the clinic there is the record of a call made to YY on 3rd March 2023 in which it is noted " I *called [YY] and she was surprised that I have contacted her about embryos because she thought that they had already been discarded. I explained to her that we cannot discard of any embryos until her and [ZZ] complete the WCS FORM. She told me that I should e mail her the forms and she will fill it in and she will sent the forms back to me".* The e mail attaching with it the form is sent at once with the message *"I have attached the HFEA WCS Form for the discard of your embryos. You and [ZZ] will need to complete a form each and send it back to me as soon as possible so we can process your request."*

227. On this occasion, unlike the position in 2015, it is clear that there was a reconsideration by YY and ZZ of their wishes. There is a further recording of a contact with the clinic on 8th March 2023 in which it is clear that YY is reconsidering whether to agree to embryo discard and a note that there is time for her to decide.

228. Again it is useful to consider the evidence filed in support of their application in relation to the position in 2023.

After reflecting together with [ZZ], we reconsidered and decided that we wished to attempt to use the embryo. However, the situation has been extremely emotionally

taxing for us. I had placed this matter to the back of my mind and its reopening caused significant distress both for [ZZ] and myself. We had to consult with the priest to make sure that the decision to pursue childbirth and use remaining embryo would be aligned with our religious beliefs as well as to consider treatments abroad or using a surrogacy route. That is the reason we took time with it.
As regards communications with the clinic only I was contacted, even though [ZZ] attended all appointments with me. I believe the clinic has his e mail too but he was never copied or addressed directly. I did not fully read or understand some of the communications due to the emotional difficulty of the situation. We missed the final deadline for renewing consent by a few weeks. By the time we tried to affirm our decision to retain the embryo, we were informed it was too late.

229. On August 12th 2024, YY and ZZ e mail to say that they wish to extend [storage] and will be sending completed forms that day. The clinic response the same day is that it is too late.

230. The complexity of the factual situation against which YY and ZZ make their application for declaratory relief has made it necessary to look in such detail at the history. Ms Sutton in her oral submissions submitted both that the consent forms refusing consent to storage in 2014 represented the accurate consent position of YY and ZZ and that they should be given an opportunity to renew their consent on the basis of the form which they did not agree was accurate but on which it appeared the clinic had acted. I have some difficulty with the logic of that submission. It was developed by Ms Sutton in the following way: YY and ZZ ask the court to accept the refusal of consent to storage as their original intent. After reflecting on the mistake of the clinic they realised that it allowed them the opportunity. They want to seize upon the mistake if there is an opportunity. Their consent began in late July 2024 as a consequence of liaising with a priest, they had a change of heart. From the clinic perspective there has-been continued consent throughout because of the form which the clinic used but YY and ZZ say did not represent their wishes.

231. I regret to say that whilst this submission was developed by Ms Sutton with skill I found the logic of it remained impossible to accept. The submission would have had more force were it founded on the premise that the Court should prefer and accept as reflective of consent, the form on which the clinic has acted. That avenue was however

firmly closed to Ms Sutton since YY and ZZ were explicitly clear in their evidence that it was not so. The logic of the argument advanced for YY and ZZ is not something assessed in a freestanding way, the question to which the argument is directed in this, as in the other 14 applications, is whether YY and ZZ were given a fair and reasonable opportunity to renew their consent in accordance with the legislation. It is not, on any view of their own evidence or the case that they advance, right to say that they seek to renew consent. There was never, on their case, a consent to renew. To be permitted to take advantage of the storage of the embryo which they say 'contradicted' their express wishes because the clinic acted on the wrong consent form to change their mind is not in my judgment renewing consent. It is a change of consent.

232. Even were I to reach a conclusion that YY and ZZ had been unable to renew their consent because they were not given a fair and reasonable opportunity to do so in accordance with the legislation, I do not regard the circumstances of this case as ones which justify declaratory relief. Whilst it is argued on behalf of YY and ZZ that so unusual are their circumstances and so boundaried that there is no risk of undermining the objectives of the scheme, that is in my view too sanguine a view given the way in which the case is advanced and the objectives of the scheme. One of the ways in which YY and ZZs application is unusual is that it seems to me to cut across both the protection of informed consent aims of the scheme ***and*** those elements of the scheme directed to the aims of certainty, avoidance of arbitrariness and avoidance of indefinite storage. It would not be reading in of consent, it would be reading in a facility for a change of mind. I do not regard that as permissible or appropriate.

233. I accept that YY and ZZ now say that the embryo they never intended to store represents their chance of parenthood. I accept also that both at the time when they decided it was right to destroy embryos and when they decided it was right to fight to preserve the embryo stored in error, they made those decisions in large part influenced by their religious faith. The very detailed examination of the particular facts and matters raised leads me to conclude that their application for declaratory relief must be refused.

BA and BC

234. BA and BC make application for declaratory relief in relation to stored embryos. The HFEA does not oppose the declarations sought. The SSHSC takes no position on this

case but invites the Court to scrutinise the particular factual circumstances of the case with care so as to determine whether relief should be granted.

235. On 7th July 2013, BA and BC signed HFEA consent forms. Each indicated by ticking the relevant box for 55 years of storage. BA believed that she was entitled to this, as she was at risk of premature ovarian failure and so believed that she was likely to be prematurely infertile. In her evidence she states that the clinic was or should have been aware of the condition she had which led her to believe herself eligible since but there was no MPS obtained.

236. On 19th July 2013, the embryos were stored. In fact, since no MPS had been obtained confirming that BA was prematurely infertile or likely to become so BA was accordingly subject to the standard 10-year storage period, meaning that the correct storage expiry date was 18th July 2023.

237. Although the embryos were in storage on 1st July 2020, BA and BC were never advised about the option to extend storage from 10 to 12 years in accordance with the Coronavirus Regulations 2020.

238. There was regular contact from the clinic in writing about payment throughout the period of storage. BA and BC continued to make payments. Although their payments included a payment and renewal of their direct debit in June 2024, 11 months after the lawful storage period had expired the clinic was not by this alerted to the fact that storage fees were being collected in respect of consent which had already expired. Nor during the earlier communications did the clinic mention the need to extend written consent and of the consequences of failing to do so.

239. On 30 June 2023, the clinic sent an email informing BA and BC that the storage would end on 19 July 2023. The email says that an HFEA notice was attached. The notice provided indicates that consent to storage needs to be renewed

240. On 1 May 2024, BA received an email from the clinic asking if she wanted to continue or discontinue storage. The email said, *"It has been a privilege to look after your gametes/embryos this last year. As we now enter a new year of storage for you, I am reaching out to discuss the next steps."* It said that an annual storage fee is needed, and there was no mention of the need to complete any additional forms. From that letter,

BA's evidence is that she understood that if she dealt with the new direct debit, no further action needed to be taken. The terms of that letter are interesting in that although sent as a request for storage fees, it sets out the two options. The first is no longer storing and the second is continuing storage. In relation to the first option, the letter of 1st May says this '*if you do not wish to continue with the storage of your gametes/embryos please let us know and you will be sent a withdrawal of consent form. On this form you can choose either to donate your embryos to embryology or discard the embryo. If you would like to donate your gamete/embryos to research please contact the clinic.*' In contrast in respect of the second option i.e. continuing to store the embryos, the letter sets out detailed instruction for payment and information about methods of payment but makes no mention of any steps to be taken or forms to be sent. The letter simply reads, immediately before the payment instructions '*if you wish to continue storing your samples, you will need to pay the annual storage fee for the period of one year'* [emphasis added]

241. On 3 June 2024, BA received an email from the clinic in relation to the need to renew consent. BA's evidence is that because it came from a generic clinic email account she did not open or read it. BA acknowledges now that she should have opened this email and in her evidence gives a number of explanations for not doing so. First that she had only just been in touch with the clinic about the payment of storage fees ; second that she thought it may have been spam; third that since she is someone who works within the NHS the email was not in the form that she would expect confidential and important information to be sent to patients.

242. The next day, 4 June 2024, BA emailed the clinic to say that she had paid the balance and renewed the direct debit. Her evidence is that she did this as she thought that the email the previous day had been chasing for payment. On 25 June 2024, she received an email from the clinic confirming that the direct debit had been set up and understood that she had done all she needed to do for continuation of storage. On 22 July 2024, the relevant completed consent forms were sent by both BA and BC, but it was too late. On 28 August 2024, an email was sent from the clinic confirming the withdrawal of consent.

243. In this case it is submitted for the applicants that they were not given a fair and reasonable opportunity to renew their consent in accordance with legislation. In part

that submission is founded on the fact that BA worked within the NHS and so it is explicable that she chose not to open the e mail sent by the clinic on 3rd June. In effect BA decided, without opening it, that the e mail was unimportant. When in the context of the facts of this case I ask myself: *Did the clinic send the notice it should have sent? . Did BA know there was an e mail from the clinic? Did she have the opportunity to open it read it and thereby renew her consent?* The answer to all three questions is *yes*. I have come close in this case to concluding that BA and BC did indeed have the opportunity to renew their consent, and but for the letter of 1st May considered in detail above that may well have been the conclusion reached. The terms of that letter however, are such that I am satisfied that they undermine the clarity of the notice of time limit for renewal of consent by importing confusion as to what is required, the letter saying as it does in terms: '*if you wish to continue storing your samples you will need to pay the annual storage fee'*. That confusion affects the fairness of the opportunity and on the narrowest of balances I accept Ms Sutton's submission that the applicants were not given a fair and reasonable opportunity to renew their consent.

244. BA and BC's evidence that they wish to expand their family, I am satisfied that the interference with BA and BC's Article 8 rights would be significant, final and lifelong. I am satisfied that there are no weighty countervailing factors to permitting their application and that to do so would not undermine the fundamental objectives of the statutory scheme. It follows that BA and BC's application is granted.

245. I will invite Counsel to prepare draft orders reflecting my decisions.