<u>This judgment was delivered in private.</u> The judge has given leave for this version of the judgment to <u>be published on condition that (irrespective of what is contained in the judgment) in any published</u> <u>version of the judgment the anonymity of the children and members of their family must be strictly</u> <u>preserved. All persons, including representatives of the media, must ensure that this condition is</u> <u>strictly complied with.</u> Failure to do so will be a contempt of court.

Case No: ZC14P00742

Neutral Citation Number: [2015] EWFC 13 (Fam) IN THE FAMILY COURT SITTING IN BRIGHTON

Date: 13/02/2015

Before:

MRS JUSTICE THEIS

Between:

X	<u>Applicant</u>
- and -	
Y	<u>Respondent</u>
- and -	
St BARTHOLOMEW'S HOSPITAL CENTRE FOR REPRODUCTIVE MEDICINE (CRM)	Intervener
- and -	
CAFCASS LEGAL	Advocate to the Court

Mr Gerald Wilson & Ms Laura Scott (instructed by Giles Wilson LLP Solicitors) for the Applicant and the Respondent Ms Dorothea Gartland (instructed by Bevan Brittan LLP Solicitors) for the Intervener Ms Marisa Allman (instructed by Cafcass Legal) as Advocate to the Court

Hearing date: 27th January 2015

JudgmentMrs Justice Theis DBE:

Introduction and summary

1. When the parties in this case, an unmarried couple in a secure long term relationship, sought assistance from a fertility clinic to conceive a much wanted child they could not have imagined they would end up in proceedings in the High Court. They, and their child, have been caught up in a situation over which they have had no real control as, not unreasonably, they relied on appropriate steps being taken by others; in particular the fertility clinic they sought advice and treatment from.

- 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 difficult 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.
- 3. The section in the guidance from the Human Fertilisation and Embryology Authority (the Authority) dealing with Legal Parenthood states

'The centre should explain that there is a difference in law between the legal status of 'father' or 'parent' and having 'parental responsibility' for a child. In any case in which the people seeking treatment have doubts or concerns about legal parenthood or parental responsibility for a child born as a result of treatment services, the centre should advise them to seek their own legal advice.' (para 6.2)

'The centre should establish documented procedures to obtain written informed consent. The centre should retain the signed consent forms and ensure that a copy is available for those who have given consent.' (para 6.8)

- 4. The important message from this case is that any person considering fertility treatment should ensure they are, at the very least, familiar with what legal steps need to be taken prior to any such treatment, particularly concerning the issue of consent. This is because any failings by the clinic to follow the requisite procedures may have long term consequences for them, and any child born as a result of the treatment. The requirement in paragraph 6.8 of the guidance to *'ensure that a copy is available for those who have given consent'* is somewhat vague. If those who have given consent were provided with a copy of the consent they signed it may have avoided the difficulties in this case.
- 5. The applicant in this case, X, seeks a declaration that he is the father of Z, who was born in August 2013. X and his partner, Y, sought assistance from St Bartholomew's Hospital Centre for Reproductive Medicine ('CRM') due to difficulties they had in conceiving a child. Following various tests Y became pregnant through the use of donor sperm and Z was born in August 2013. Both X and Y considered they were the parents of Z in every sense of the word; legally and psychologically.
- 6. The arrangements for conferring legal parenthood under the relevant provisions in the Human Fertilisation and Embryology Act 2008 (HFEA 2008) are dependent on mutual compliance by the parties and the relevant clinic with a range of legal duties and procedural requirements; these are underpinned by core regulatory principles applying to licensed centres carrying out activities under the HFEA 1990 and the HFEA 2008.
- 7. The difficulties that arose in the case I am concerned with followed an audit of fertility

centres undertaken by the Authority as a result of the decision of Cobb J in $AB \ v \ CD \ [2013] EWHC \ 1418$. In that case a same sex female couple, AB and CD, had two children conceived through fertility treatment at a clinic. The couple separated, proceedings were issued by CD regarding the living arrangements for the children and an issue arose as to whether CD (who was not the birth mother) was a legal parent to the children. After a comprehensive review of the relevant provisions Cobb J decided the legal requirements under the HFEA 2008 had not been complied with by the clinic, with the result that CD was not the legal parent. This was due to the failure by the clinic to comply with the various requirements prior to treatment, in particular relating to consent, the provision of information and the opportunity for counselling.

- 8. In this case the audit at the CRM revealed that the necessary consent by X relating to parenthood prior to treatment (as required by s. 37 HFEA 2008) was not on the file. X should have completed a PP form in circumstances such as this; an unmarried couple using donor sperm where they both wished X to be a legal parent of any child born as a result of the treatment. The PP form records the consent by him to be the legal parent of the child born as a result of any treatment to Y. The form must be signed prior to any treatment. Equally Y should have completed a WP form, which signifies her consent to her partner, X, being the legal parent. The absence of the PP form raised the question as to whether it had been completed at the relevant time, namely prior to treatment. If it hadn't X was arguably not the legal parent to Z, as both he and Y had clearly intended.
- 9. The first time X and Y became aware of this issue is when they were contacted, out of the blue, by the CRM and informed that the necessary consent may not have been completed. This was in February 2014, when Z was six months old.
- 10. The CRM have made it clear in their dealings with X and Y and their submissions to this court they accept full responsibility for what has occurred, have apologised unreservedly to X and Y and agreed to fund the costs of any application that needed to be made.
- 11. An application for a declaration of parentage (pursuant to section 55A Family Law Act 1986) was made by X on 13 September 2014; Y is the Respondent and supports the application. The CRM intervened to assist the court and Cafcass Legal agreed to act as Advocate to the Court. It was not considered necessary to join the child as no separate position on behalf of the child was required.
- 12. Within the court bundle I have statements from X and Y, M (the 'person responsible' at the CRM under the terms of the HFEA 2008) and N (the fertility nurse who saw X and Y in the period prior to their treatment). I heard oral evidence from both M and N. When the matter first came before me on 14 January 2015 I directed that the Authority be given notice of this application and state whether they wish to intervene. They did not wish to do so, and set out their position in a letter to the court.
- 13. I have had the benefit of detailed written and oral submissions and am enormously grateful for the industry of all advocates in making sure all the relevant information was before the court.

14. The issues can be summarised as follows:

(1) Did X sign the requisite consent (the 'PP form') at the appointment on 26 October 2012 so that it complied with s.37 (1) HFEA 2008?

(2) If X did, was the PP form subsequently mislaid by the CRM?

(3) Was the treatment 'provided under a licence' as required by section 37 (1) HFEA 2008?

(4) If the PP form was not signed can the court 'read down' s. 37 (1) HFEA 2008 to enable the court to make the declaration of parentage sought?

- 15. For reasons which I discuss more fully below, I have concluded, on the facts of this case, that it is more likely than not that X did sign the PP form on 26 October 2012, and it has subsequently been mislaid by the clinic. I have also concluded, in the circumstances of this case, the failure by the clinic to maintain records did not amount to a breach of the licence so as to invalidate it, so that the treatment was 'provided under a licence' as required by s. 37 (1).
- 16. Accordingly, I will make the declaration of parentage sought in favour of X. He is Z's father.

Relevant Background

- 17. The parties have been in a relationship for many years. They have been trying to conceive a much wanted child since December 2006. During the last five years they have endured referrals, refusals, re-referrals, testing and form filling before being accepted for treatment at the CRM in early 2012. Initially it was intended by the parties and the CRM that the infertility treatment would proceed using the gametes of both parties. However, further tests on X resulted in a diagnosis of infertility. As a consequence there was a discussion in September 2012 regarding the options. The parties opted for donor sperm and were referred for donor-intrauterine insemination ('IUI-D') to the sperm donor co-ordinator and for counselling.
- 18. The parties attended counselling on 16 October 2012. Within the papers there is a note of the matters covered at that session.
- 19. On 26 October 2012 the parties attended a 'donor selection and IUI-D information session' with the fertility nurse, N. The file held by the CRM holds the following documentation completed on that day:

(1) **Consent to donor insemination (IUD-D)**. This is a 3 page internal form used by the CRM. It was signed by both parties and the fertility nurse. The first page deals with Y's consent to the proposed treatment, which was signed by Y. The second page notes certain legal consequences, namely that the "donor will not be the legal father of any resulting

child" but that, if the donor is foreign, *"the law of other countries regarding parentage may not be the same as it is in the UK."* It also notes that X and Y have been offered a suitable opportunity for counselling. Both X and Y signed that section.

The form them provides (emphasis added):

All the information listed in paragraph 4.2 of the Human Fertilisation and Embryology

Authority's 8th Code of Practice has been given to the patient. The patient has been offered a suitable opportunity to take part in counselling about the implications of the proposed treatment. The patient has been provided with Barts CRM information regarding legal parenthood and **HFEA PP and WP forms have been completed**. This section is confirmed by the signature of N (the fertility nurse).

X then completed a further "consent" on the final page of the form:

I am not married to/civil partners with [Y] but I acknowledge that we are being treated together, and provided that we complete HFEA PP and WP forms, I will be the legal father/second parent of any resulting child. I acknowledge receipt of [CRM] information regarding legal parenthood.

This is followed by X's signature.

(2) A WP Form signed by Y consenting to X being the legal parent of the child.

(3) A Characteristics Sheet, setting out the parties' respective physical characteristics for the purpose of choosing a matching donor. Although the form is undated, the medical note for 26.10.12 states "characteristic sheet done $\sqrt{}$ ".

- 20. Following this appointment the parties were then sent 3 matching donors to choose from. They selected one and both confirmed their consent in writing on 19 November 2012. It appears that the parties also agreed to pay an additional sum to retain some of the frozen sperm for possible use in future treatment to conceive a sibling. The insemination was carried out on 30 November 2012. On 3 December 2012, the parties were registered as patients with the Authority. The insemination was successful, Z was born in August and the birth was reported to the Authority on 3 September 2013.
- 21. The parties' recollection of events around this time is understandably fairly uncertain. They remember signing various forms, and in particular X recalls signing several similar forms on the one day in October, but not any particular form. Y recalls a session where the parties completed several forms and in particular that she signed the WP form, which she recalls because someone read out its purpose *'The form for consent for being the father'*.
- 22. In their statements the parties detail many documents that went missing in the early course of their referral to the CRM. It has not been necessary to investigate the precise circumstances of these difficulties, but it gives a context in which these matters are being considered.
- 23. The parties and the CRM proceeded on the basis that X would be the child's father. In due course he was registered as Z's father on her birth certificate.
- 24. As set out above in late 2013 the CRM undertook an audit of their files, as requested by the

Authority. The audit noted that on X and Y's file the PP form was missing.

25. In early February 2014, Dr Ryan (Medical Director) for Barts Health NHS Trust spoke to the parties, followed up by an email where he informed them that "we found that the consent form we expected to be completed by [X] establishing legal parenthood was not completed and we do not hold a copy in the notes". That arguably overstates the position, which is that when they carried out their audit in October/November 2013 there was no PP form in the notes. No direct evidence has been produced that X did not sign the PP form.

The Legal Framework

- 26. The statutory framework for the assigning of legal parenthood to persons not genetically related to a child born following assisted conception is contained within the HFEA 1990 and HFEA 2008.
- 27. The HFEA 1990 created the Authority and s 8(1) (cb) requires it to promote compliance with the requirements of the Act and the Code of Practice under s.25.
- 28. Section 25 requires the Authority to maintain a Code of Practice (the 'Code'). Although the Code does not have statutory force, it must be approved by the Secretary of State and laid before Parliament and will then 'come into force' (s26 (5)). Compliance with the Code is not expressed to be a condition of a licence, but s 25(6) requires the Authority to take the Code into account when considering whether there has been a breach of a condition.
- 29. The express purpose of the Code is to give guidance to those licensed and providing treatment, in particular s.25

'(1)...about the proper conduct of activities carried on in pursuance of a licence under this Act and the proper discharge of functions of the person responsible and other persons to whom the licence applies.

(2) The guidance given by the code shall include guidance for those providing treatment services about the account to be taken of the welfare of children who may be born as a result of treatment services...and of other children who may be affected by such births.'

- 30. The Code is comprehensive. It has guidance notes that cover each subject area in turn. Each subject area in the Code is broken down with references to the regulatory principles for licensed centres, mandatory requirements (relevant quotes from the statutory provision, licence conditions and directions), the Authority's interpretation of mandatory requirements, the Authority's guidance and other legislation, professional guidelines and information.
- 31. HFEA 1990 s 23 enables the Authority to issue directions from time to time. Examples relevant to this case include the direction that specifies the forms to be used for recording consent to be a parent e.g. PP form (Direction 0007/2), and the one that requires licensed clinics to maintain for a period of 30 years from the date on which any gametes or embryos were used in treatment some specific records of information, including in particular all consent forms and any specific instructions relating to the use and/or disposal of gametes

and embryos (Direction 0012/2).

- 32. Section 11 (1)(a) HFEA 1990 gives the Authority power to grant licences to clinics under Schedule 2 paragraph 1 to carry out fertility treatment services as specified in that paragraph; it may grant a licence subject to conditions (Sch 2 para 2) and the licence may last for up to five years (Sch 2 para 5).
- 33. Every licence granted also has the conditions provided for in HFEA 1990, which include
 - (1) to maintain proper records in such form as the Authority may direct (s 12 (d));
 - (2) to record such information as the Authority may direct (s 13(2));

(3) such records to include any information recorded in pursuance to subsection (2) above and any consent of a person whose consent is required under Schedule 3 to this Act.

These statutory conditions are set out in the Code and many are replicated as Licence conditions (for example, Licence conditions T60 and T61 effectively re-produce the provisions in s. 13(6) and 13(6A). The 'T' refers to treatment as opposed to licence conditions with the prefix 'R', which refer to research).

- 34. The licence must designate a person responsible for supervising the licensed activities (s 16 (1) (2)) and that person is under a duty to ensure compliance with the conditions of the licence (s 17(1)(e)). At the CRM the 'person responsible' is M.
- 35. The Authority may revoke a licence on the grounds set out in s.18 HFEA 1990, which include, if it is satisfied, that the person responsible has failed to discharge his duty under s. 17 or failed to comply with directions (s.18(2)(b),(c)). The Authority may suspend a licence if it has reasonable grounds to suspect there are grounds to revoke it (s.19C HFEA 1990).
- 36. Part 2 HFEA 2008 is entitled 'Parenthood in cases involving assisted reproduction'.
- 37. Section 36 HFEA 2008 ('Treatment applied to woman where agreed fatherhood conditions apply') provides

If no man is treated by virtue of section 35 as the father of the child and no woman is treated by virtue of section 42 as a parent of the child but—

(a) the embryo or the sperm and eggs were placed in W, or W was artificially inseminated, in the course of treatment services provided in the United Kingdom by a person to whom a licence applies,

(b) at the time when the embryo or the sperm and eggs were placed in W, or W was artificially inseminated, the agreed fatherhood conditions (as set out in section 37) were satisfied in relation to a man, in relation to treatment provided to W under the licence, (c) the man remained alive at that time, and

(d) the creation of the embryo carried by W was not brought about with the man's sperm, then, subject to section 38(2) to (4), the man is to be treated as the father of the child.

38. Section 37 HFEA 2008 ('The agreed fatherhood conditions') provides:

(1) The agreed fatherhood conditions referred to in section 36(b) are met in relation to a

man ("M") in relation to treatment provided to W under a licence if, but only if,—

(a)M has given the person responsible a notice stating that he consents to being treated as the father of any child resulting from treatment provided to W under the licence,

(b) *W* has given the person responsible a notice stating that she consents to *M* being so treated,

(c)neither M nor W has, since giving notice under paragraph (a) or (b), given the person responsible notice of the withdrawal of M's or W's consent to M being so treated,

(d)W has not, since the giving of the notice under paragraph (b), given the person responsible—

(*i*) a further notice under that paragraph stating that she consents to another man being treated as the father of any resulting child, or

(ii) a notice under section 44(1)(b) stating that she consents to a woman being treated as a parent of any resulting child, and

(e)W and M are not within prohibited degrees of relationship in relation to each other.

(2)A notice under subsection (1)(a), (b) or (c) must be in writing and must be signed by the person giving it.

(3)A notice under subsection (1)(a), (b) or (c) by a person ("S") who is unable to sign because of illness, injury or physical disability is to be taken to comply with the requirement of subsection (2) as to signature if it is signed at the direction of S, in the presence of S and in the presence of at least one witness who attests the signature.

39. The PP form is the notice required under s 37 (1)(a) and WP form is the notice required under s 37 (1)(b).

The evidence

40. In her witness statement N, the fertility nurse, states that whilst she has no direct recollection of the parties in this case, she confirms she was the nurse who saw them on 26 October 2012. The purpose of that appointment was to discuss the proposed treatment and sign the necessary forms. She describes her standard practice at such appointments, the importance before the appointment to review the file and put together a pack of all the forms that need to be signed during the appointment. She states 'Each couple would need to sign a WP form and a PP form. For heterosexual couples, the female partner would sign the WP form and the male partner would sign the PP form. If both forms are not signed then the male partner does not have legal parenthood for the child and so it is very important that the forms are signed.' She refers to the declaration in the CRM consent to donor insemination set out in paragraph 19 above and states 'I would not have signed this declaration if I had not completed all of the tasks listed in the paragraph. It is, therefore, my belief that the Applicant signed the PP form but that it was then misplaced within the Trust. I know the PP and WP forms go together and I would not have asked the Respondent to sign the WP form without a corresponding PP form being signed by her partner. I have no reason to believe that the standard protocol was not followed in relation to the treatment of the Applicant and the Respondent. All of the other forms were signed and counter-signed

on 26 October 2012. I believe that it is also likely that the PP form was also signed that day but was subsequently misplaced, hence the absence from the patients' records.'

- 41. In her oral evidence N gave details about the layout of the files and where documents are put. The practice seemed to be not to have the whole file during the appointment, although it was reviewed prior to the appointment to prepare the necessary pack of forms that needed to be completed. At the end of the appointment her practice was to slide the signed documents (including signed consents) into an envelope section at the back of the file, often whilst it was still in the filing cabinet. This section of the file has no flap or method of securing the documents in it. She recognised there was a possibility during this procedure for the documents she was seeking to put in the file to slip behind the file itself.
- 42. In her statement M details her actions in undertaking the audit requested by the Authority. The audit was to include all patients that received treatment at the CRM from 6 April 2009 using donor sperm or embryos created with donor sperm; were treated with a partner to whom they were not married or in a civil partnership or where the status of the relationship is not known; and the treatment resulted in a current on-going pregnancy or live birth or where the outcome is unknown. The CRM audit identified 184 patients that have undertaken fertility treatment using donor sperm during the relevant period. 170 had no legal parenthood issues (of which 102 were unsuccessful following treatments; 1 was a new patient; 11 were unsuccessful but have frozen embryos stored to use in future treatment; 54 were successful and 2 were not able to be contacted) and 14 had parenthood issues. This figure reduced to 13 when it was discovered one of the couples had entered into a civil partnership. 9 treatments had a PP form missing (as in this case) and 2 a WP form missing, 1 was undertaken without the WP form including the correct details of the patient's partner and in 2 cases the forms had been completed after the treatment had been started. N had dealt with all but 1 of these cases and had dealt with a significant number of the cases where there were no parenthood issues. An analysis of the information from the audit did not reveal any underlying systematic reasons for the anomalous cases. For example, the fact that the forms were missing did not necessarily mean they had not been completed at the relevant time. A copy of the audit was sent to the Authority and the relevant personnel were notified within the Trust. This was classified by the Trust as a serious incident.
- 43. In her statement M outlines the steps that have been taken by the Trust in the light of these events. This included a further audit to review the patient pathway for individuals and couples who intend to use donor sperm as part of their treatment. It is now standard practice within the CRM for all couples, regardless of their relationship status, to sign the WP and PP forms before their treatment begins. All consent forms are now checked at the daily meetings to ensure the correct consent has been given well before treatment is due to begin.

Discussion and Decision

44. It is submitted on behalf of the parties, the CRM and the Advocate to the Court that

(1) On the particular facts of this case the court can draw the necessary inferences and find, on the balance of probabilities, that the PP form was signed by X on 26 October 2012. Therefore, it was in place prior to the treatment on 30 November 2012 and it is more likely than not subsequently mislaid by the clinic.

(2) Treatment '*under a licence*' in s. 37 does not create an additional test that the clinic must be operating in compliance with directions given by the Authority. The Advocate to the Court only accepted this proposition is respect of record keeping.

- 45. It is submitted by Mr Wilson and Ms Scott, on behalf of X and Y, that in the event that the court is unable to make a finding that the PP form was signed by X prior to the treatment it is invited to give a purposive construction and 'read down' s. 37 in a way that would enable the court to make the declaration of parentage applied for. Such a construction is underpinned by Article 8.
- 46. They submit Article 8 is engaged as the private and family life of X, Y and Z are all affected by the decision whether X is to be recognised in law as Z's legal parent. In particular

(1) The parties would not have the form of family that they intended from the outset.

(2) The nature of X's status in relation to Z would be different; he could only acquire the status of legal parent by adoption at a later date.

(3) There would be a fundamental interference with Z's identity as X's daughter.

(4) Adoption of Z by X would mark a difference in his status compared to that of Y. It is recognised the lack of a genetic relationship between X and Z is already a point of difference, but the parties' original decision reflected an intention to override this.

(5) The parties' sense of security in their status as a family has already been shaken by the issue that has been raised over X's status; this insecurity would be entrenched.

(6) If the parties choose to have another child with the donor's sperm, the parties will have the opportunity to ensure that the correct procedures are followed and X is that child's legal parent *ab initio*. Z would then have a different status to her full sibling, as an adopted child, to the detriment of both children.

- 47. They make the following powerful point; that a restrictive interpretation of s. 37 in these cases makes paternity *'precarious'*. This is because, in reality, the uncertainty is almost entirely outside the control of X and Y. Although s.37 puts the onus on the prospective parents to give the requisite notice, the law does not expect them to know in advance what the law is or to be aware of this particular duty, but places a prior onus on the clinic to inform and counsel them and to provide them with the appropriate forms. Parents have no effective control over the clinic's compliance with the conditions of its licence or its retention of the necessary consents.
- 48. Ms Allman, on behalf of the Advocate to the Court, cautions that such a course requires careful consideration. She draws the court's attention to the differing approaches taken in previous cases depending on the nature of the provision to be 'read down'; whether there is a dispute and whether there are competing Article 8 rights to be balanced. In *A v P [2011] EWHC 1738 (Fam), Warren v CARE Fertility (Northampton) Limited and the HFEA [2014] EWHC 602 (Fam)* and *Re X (A Child) (Surrogacy: Time Limit) [2014] EWHC 3135 (Fam)* there was no conflict between the various rights in those cases, and the relevant provisions were applied in a way which gave effect to the Article 8 rights of all concerned. In contrast, however, in both *Leeds Teaching Hospitals NHS Trust v A [2003] 1 FLR 1091* and *Evans v Amicus Healthcare (SoS for Health Intervening) [2004] 3 WLR 681* there were clear conflicts and in each case the court was not prepared to apply the relevant provisions in what was said by the applicants in those cases to be a purposive way.
- 49. Turning to consider the facts I am satisfied, in the particular circumstances of this case that I can draw the necessary inference on the evidence available to the court that it is more likely than not X signed the PP form on 26 October, and it has subsequently been mislaid by the clinic. I have reached that conclusion for the following reasons:

(1) The CRM complied with other requirements, such as to offer counselling for X and Y.

(2) The documents that were signed on 26 October are more consistent with the PP form also being signed at the same time. At that appointment Y signed the WP form; X signed an internal CRM form stating that he understood he would become the legal parent upon completion of the signed WP and PP forms; N stated her standard practice for heterosexual couples was to get both forms signed; N signed a declaration that the WP and PP forms have been completed by X and Y.

(3) N in her statement and oral evidence acknowledged the importance of these forms being completed prior to treatment.

(4) I accept N's evidence about how the consent forms were kept on the file; slipped into the open top envelope pocket at the back of the file. The forms were not secured and there was, as N

accepted, a risk when putting them into the file in this way that they could slide down behind the file.

(5) There was a wider concern expressed by X and Y about previous records the CRM had lost. Whilst it was not necessary, for the purposes of this hearing, to investigate those other matters it does raise a concern about the robustness of record keeping at the CRM generally.

- 50. The next issue, having made that factual finding, is whether the failure by the CRM to retain the necessary records (namely X's consent in PP form) had the consequence that the treatment provided to Y 'under a licence' as required by s. 37(1) was not satisfied. The written submissions on this aspect have ranged far and wide, not always in a way that has been entirely helpful.
- 51. Section 12 (1) (d) HFEA 1990 provides that one of the conditions of every licence granted is that 'proper records shall be maintained in such form as the Authority may specify in directions'. Direction 0012 requires licensed centres to maintain for a period of 30 years certain specific records, including 'all consent forms and any specific instructions relating to the use and/or disposal of gametes and embryos' (paragraph 1 (f)). Licence condition T47 provides 'All records must be clear and readable, protected from unauthorised amendment and retained and readily retrieved in this condition throughout their specified retention period in compliance with the data protection legislation'. At paragraph 31.2 of the guidance it provides 'A record is defined as 'information created or received, and maintained as evidence by a centre or person, in meeting legal obligations or in transacting business. Records can be in any form or medium providing they are readily accessible, legible and indelible.'
- 52. It is clear from the findings I have made about the clinic not keeping the PP form for X that the CRM is in breach of Direction 0012. Mr Wilson sought to suggest that the consent required under s.37 was not covered by paragraph 1 (f) of Direction 0012, as they do not relate to *'use or disposal'* but to the quite separate legal question of parentage. His analysis ignores the word *'and'* in paragraph 1 (f) which, in my judgment, does not limit the requirement on the clinic to keep records of *'all consent forms'* to those relating to the use/or disposal of gametes and embryos.
- 53. In its letter to the court dated 20 January the Authority states as follows

'..failure to ensure that either a PP form is completed or that a copy of a completed PP form is retained in a patient's records is not a breach of the Act which amounts to a criminal offence. It is instead considered a failure to do something which the clinic was licensed to do to the standard or in the manner required, rather than something which could never be done lawfully in 'pursuance of' its licence.

In addition, the Act gives the Authority the power to impose a very limited range of regulatory sanctions including the addition of conditions, suspension or revocation of the licences where circumstances warrant such action. If it were the case that a clinic's failure to comply with directions or licence conditions rendered its licence invalid or affected the subsistence of the licence, there would be no licence against which the Authority could impose a sanction.'

The letter went on to express the view, although acknowledging it was a matter for the court, that the treatment in this case had been provided lawfully and within the terms of the clinic's licence as the necessary consents were in place at the time of treatment.

- 54. Ms Allman sought to develop an argument in her written submissions that the purpose of the licence condition as to record keeping is qualitatively different to the purpose of the licence conditions as to consent, the provision of information and counselling.
- 55. She submitted some of the licence conditions clearly mirror the statutory criteria, and therefore where there is breach of a licence condition, it also represents non-compliance with the statutory criteria. She submits sections 36 and 37 or 43 and 44 HFEA 2008 read together

require the notice to have been given 'at the time when' the embryo or the sperm and eggs were placed in the woman, or the woman was artificially inseminated. The Code, she submits, at licence condition T61 specifically prohibits the treatment of a woman with an intended second parent unless they have been give a proper opportunity to receive counselling and been provided with relevant information. Licence condition T62 specifies that the reference to 'intended second parent' refers to a person in respect of whom the agreed fatherhood or agreed parenthood condition have been met, that can only be the case where notice has been given pursuant to s.37. This path leads her to submit '*Reading licence*' conditions T61, T62 together with sections 36 and 37 or 43 and 44 confirms that a licensed clinic is prohibited from treating a woman where there is intended to be an agreed second parent unless the notice has already been given'. She submits, as a result, that the Authority are wrong in their letter to the court when they state 'neither section 3 nor section 4 of the Act prohibits the provision of treatment service to a man and a woman in circumstances where the man has not completed specifically the consent to legal parenthood form (PP form)'. Therefore, she submits, since treatment of a woman is prohibited without the requisite notices having been given, and without the requisite counselling and information offered or provided as a result of T61, it is difficult to see how such treatment would be provided to W 'under a licence' as required by s. 36(b).

- 56. This approach, she submits, is consistent with Parliamentary intention and the importance of consent to the operation of legal parenthood. This was re-stated by Butler Sloss P in *Leeds Teaching Hospital NHS Trust v A [2003] 1 FLR 109 at paragraph 20.* In that case a clinic had inadvertently used the sperm of Mr B rather than Mr A to fertilise the eggs of Mrs A. Mr A desperately wanted to be the legal parent of the child but the court found that in the absence of consent to the particular treatment which was delivered he was not the father of the child, it was Mr B whose sperm had been inadvertently used.
- 57. The licence condition requiring the maintenance of records, she submits, is a more general requirement. There is no readily identifiable reason why a child should be deprived of his/ her parentage where the treating clinic has simply failed to maintain proper records, provided it can be established what has taken place; this is unlikely to have been Parliament's intention.
- 58. Mr Wilson submitted Ms Allman's position as to T61 and T62 arises from a misunderstanding of the relevant provisions. He supports the position set out in the Authority's letter. T61 only applies where there is *'an intended second parent'*, a term defined in T62. This requires compliance with the agreed fatherhood conditions in s.37 (namely forms PP and WP must have been signed). If they have not been signed there is no *'intended second parent'* and T61 (and the prohibition of treatment thereunder) does not apply. He submits the consent in *Evans* and *Leeds* involved a very different type of consent to a far more fundamental act: in each of these cases, the man consented to the use of his gametes to conceive a child for someone else or for someone else's gametes to conceive a child for himself. In this case X was consenting to being the child's legal father, which required the consent from him and Y under s. 37.

- 59. Mr Wilson submits the condition for record-keeping is not fundamental, because it derives from guidance in the Code and therefore relevant to the Authority's functions of regulating licensed clinics and not to the subsistence of the licence, which subsists until revocation.
- 60. It is not necessary for me, in the circumstances of this case, to resolve the issue between Ms Allman and Mr Wilson as to whether a failure to provide information, the opportunity for counselling or the notice (consent) required under s. 37 prior to the treatment is a category of breach that does comply with treatment *'under a licence'* as required in s. 37. In *AB v CD* Cobb J concluded in that case (at paragraphs 88 and 89) that treatment provided to W [CD] in that case was not offered *'under the strict terms of 'that licence'* (*s.43*)...'. These observations have to be viewed in the context of that case where Cobb J based his conclusion on the finding that the required consent forms had not been completed prior to the treatment taking place, as well as the other matters set out (provision of information and counselling). Consequently his observations about the effect of treatment not being offered under the strict terms of the treatment not being offered under the strict terms of the licence forms had not been completed prior to the treatment taking place, as well as the other matters set out (provision of information and counselling). Consequently his observations about the effect of treatment not being offered under the strict terms of the licence did not form the underlying rationale for his conclusion in that case.
- 61. I am satisfied that the breach of record keeping in the circumstances of this case does not invalidate the CRM's licence in such a way that offends against s.37. I have reached that conclusion for a number of reasons:

(1) It is agreed that the notice required under s 37(1)(a) in PP form needs to be completed prior to treatment provided to Y.

(2) It follows that if that requirement is complied with (along with other requirements such as completion WP form, counselling etc) then at the time of the birth of the child X is treated as the legal father of the child (by operation of s. 36 HFEA 2008).

(3) If that is the case it would be wholly inconsistent with that provision, and the underlying intention to provide certainty, if that status could then be removed from the father and the child in the event of the clinic mislaying the consent in PP form, possibly many years later.

(4) The requirement to keep records concerning consent is provided by way of a direction pursuant to s. 23 whose requirements shall be complied with. I agree with the analysis in the letter from the Authority that any non-compliance in these circumstances is dealt with through the regulatory powers given to the Authority. As they state in that letter the CRM had co-operated with the Authority about the findings identified by their audit and 'no sanctions were imposed against the clinic and the clinic's licence remains in force'.

(5) There is no evidence in the enacting history of s.37 to suggest any intention to create an additional test of compliance by the clinic with directives given pursuant to s.23 and the acquisition of paternity.