HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY

LICENCE COMMITTEE

APPLICATION OF HFEA AND MR JUDE HARRIS ADEGHE

Determination

1. This hearing concerns the proposed decision on 8 May 2014 of a Licence Committee of the Human Fertilisation and Embryology Authority (HFEA) to refuse the grant (by way of renewal) of a Treatment and Storage licence to St Jude's Women's Hospital (centre 0198). The Person Responsible (PR) at the centre, Mr Jude Harris Adeghe, exercised his statutory right to make representations against the proposed decision, and our Committee heard those representations on 1 and 3 – 5 September 2014, and 27 and 28 October 2014.

2. We were assisted by written and oral submissions from both sides and before the adjourned hearing took the opportunity of refreshing our memories from the previous transcripts and reviewing the documentation.

3. We are grateful for the legal advice given by our legal assessor Mr Tom Kark QC, during the course of the hearing, and for the assistance given as to the background to this application and the relevant law. Except in relation to the issue of whether or not this committee has power to impose conditions upon a licence his advice was agreed by counsel. We have accepted his advice and taken it fully into account. Our consideration of the facts is entirely for us to decide. We have received no further advice during the course of our deliberations.

4. When we retired to deliberate we did so only with the members of the committee and with our legal assessor. We did not retire with the secretary to the committee who is employed by the HFEA and who was present during the hearing. We have only passed this determination to the secretary to the committee for assistance in transcribing this determination and publishing it after the decisions had been made.

5. In coming to our decision we have borne in mind the following principles:

i) we are an independent panel and have applied our objective judgment to the issues which have been raised;

ii) we have only taken into account that which has been put before us in these hearings and have ignored external material;

iii) we have been reminded of our obligation not to indulge in speculation and to focus upon the arguments and evidence before us;

iv) we have borne carefully in mind the difference between speculation and drawing reasonable inferences from the evidence;

v) we have borne in mind throughout that it is for the Person Responsible to persuade us that a licence should not be refused;

vi) we have also received advice which we accept that even were we to find that any witness had not told the truth about any particular issue that would not mean that inevitably we should find against that witness in relation to the entirety of their evidence. However, credibility is of considerable significance in a case where the essence of the case is whether Mr Adeghe is a suitable person to carry out licensed activities;

vii) in relation to the standard of proof which we apply in relation to issues of disputed facts we have borne in mind that the standard we apply is the civil standard meaning that before we accept a fact we have to take the view that it is more likely to be true than not;

viii) we bear in mind the duty to act proportionately which means in this case taking into account the public interest including protection of the public as well as the patients of this clinic and the interests of the clinic and the public whom it serves. We understand the duty to act in a measured proportionate way consistent with the factual findings we come to;

ix) we also understand and accept that the more substantial any interference that we propose in relation to this centre's licence the more substantial would be the justification required for it;

x) we have taken on board that we must not apply what is in effect a greater sanction than that necessary to ensure the protection of the public.

THE SCHEME OF THE ACT

6. The Human Fertilisation and Embryology Act 1990 as amended in 2008 ('the Act') established the legislative framework which governs assisted reproduction and embryo research in the UK. The Act and the regulations made under it govern this committee's process.

7. The scheme of the Act is to prohibit certain activities and allow other activities to take place under licence.

8. Under the legislation and rules governing the HFEA it has the power to licence premises to undertake gamete and embryo storage and transfer including insemination.

9. Licences for treatment, non-medical fertility services or storage may be granted for a period of up to five years but are generally only granted for four. (See Schedule 2 Para 1 (5) of the Act and evidence of Dr Bloor).

10. Every premises at which such services or activities take place requires a licence. Operating without a licence is a criminal offence. That is the importance which the law places on an appropriate and effective licensing system.

11. When the period of a licence expires the licence holder must reapply. During the period of a licence the HFEA has the power to intervene, to impose conditions upon, or even to suspend or revoke a licence.

12. By virtue of Sections 12-15 of the Act every licence issued is automatically subject to a number of standard licence conditions. These relate to basic issues such as record keeping, traceability, obtaining consents and time limits for storage.

13. The HFEA is also entitled to impose additional conditions upon such licences by reason of Schedule 2 to the Act and to require licensed premises to provide the HFEA with certain information about the treatments and activities undertaken by each licensed centre.

14. The HFEA is required under the Act to issue a Code of Practice giving guidance to licensed centres about the conduct of those centres. The Code of Practice also sets out the general licence conditions and directions issued by the HFEA. Breach of the code of practice is not necessarily a breach of a licence condition but the HFEA must take account of the code when considering whether there has been such a breach in particular any condition which requires 'proper' or 'suitable practice' to be followed.

15. Further, the HFEA may take account of compliance or non-compliance with the code when deciding whether to vary or revoke a licence or to grant a fresh application for a licence at the conclusion of the existing licence period (also referred to as a renewal).

THE HISTORY

16. St Jude's Women's Hospital was first licensed in 2002.

17. Mr Adeghe is the Person Responsible but he is not the licence holder. We were told by Mr Adeghe (and it is clear on the face of the licence) that the licence holder was Dr Chaman Lal who we were told is or was married to Mrs Maman (a nurse at the centre, and involved in events under consideration, see below). Mr Adeghe explains that he owns the clinic. We have not heard any evidence from Dr Lal. Mr Adeghe has in effect represented the centre.

18. Between 2002 and 2013 we heard that there had been a number of inspections and issues raised as to the centre's compliance with various licence conditions. However, the authority was content for the centre run by Mr Adeghe to carry on under a licence with no conditions and Dr Debra Bloor, the HFEA's Chief Inspector, in evidence accepted that it was by no means unusual for issues to be discovered during an inspection – it was effectively a common occurrence.

19. We were provided as part of the centre's bundle with material and a table relating to the intervention by the HFEA with a number of other centres and various breaches which had been found and the consequences thereof. We agreed to admit this evidence; however we found this to be of limited assistance as we could not be provided with specific details to give any sensible yardstick of comparison with the centre we are currently considering. In any event each case is plainly different and the HFEA must assess each centre separately and individually.

JUNE 2013 TO MAY 2014

20. In June 2013 a renewal inspection report identified a number of areas of poor practice. Two were classed as 'critical' and seven as 'major', and the PR was given until 13 October 2013 to produce an action plan to indicate how the recommendations would be implemented. A draft of the Inspectorate's report was sent to Mr Adeghe on 19 August 2013. The report recommended that the

licence was not renewed. However, the report also suggested that given that the Licence Committee would not be asked to consider the report until November 2013, time was available to provide evidence of the implementation of recommendations made in the report.

21. Simultaneously, it appears from the evidence that the GMC were conducting its own investigations into Mr Adeghe as a result of an anonymous complaint. We are aware that there had been a compliance visit by the CQC but we have no direct evidence about that visit and we have put it out of our minds. We know little about the background to the investigations by the GMC other than that the complaint of Patient A was part of it. We have also been told that interim conditions were placed upon Mr Adeghe's registration by the GMC but we have been advised to put that out of our minds and we have done so. We do not know why they were imposed and they cannot help us in these proceedings.

22. In relation to the Licence Committee meeting scheduled for 7 November 2013, the HFEA's inspector wrote in their report: 'the PR has provided documentation as evidence that these recommendations have largely been acted upon and further that overall the executive is satisfied with the PR's response and initial actions taken by the centre regarding the key recommendations made'. The HFEA recommended a period of monitoring to ensure that the recommendations were in fact being implemented in practice.

23. On 21 November 2013 a Licence Committee met to consider the application for the renewal of the licence and it was decided, in light of the CQC and GMC concerns, to adjourn those proceedings until January 2014.

24. The licence was due to expire on 31 January 2014. On 9 January 2014 the Licence Committee met again and agreed to adjourn the proceedings for three months but, in order to allow the centre to continue to operate, issued Special Directions under its powers under s.24 of the Act.

25. On 5 February 2014 there was another HFEA inspection. This inspection was triggered by notification by the GMC of the complaint against Mr Adeghe. The target of this inspection was the issue of consent to donation of eggs and the inspectors, including Dr Bloor, examined two sets of records of patients whose treatment pathway indicated that they shared eggs following NHS funded treatment.

26. Mr Adeghe sought information about the purpose of this visit but it would appear that he was not given any other information than that revealed in an e-mail of 3 February 2014, which was submitted to us in evidence.

27. Neither set of records revealed anything untoward. The HFEA does not now rely on any criticism arising from that inspection of the records, however Dr Bloor and her co-inspector did question Mr Adeghe and as a result of that conversation further concerns arose regarding the taking of consent.

28. On 25 February 2014 the HFEA wrote to the centre to warn it that it would not be recommending licence renewal at the Licence Committee on 13 March 2014. The basis of that decision was, among other things, the receipt of the anonymous complaint shared by the GMC and the subsequent site inspection on 5 February 2014.

29. On 13 March 2014 the Licence Committee again adjourned any decision to the 8 May 2014 and a Special Direction was again issued to allow the centre to continue operating.

30. On 8 May 2014 a Licence Committee meeting was held and a proposed decision was made not to grant a new licence to the centre, following which a notice under Section 19 of the Act was issued on 22 May 2014. On 3 June 2014 Mr Adeghe as the PR issued a notice exercising his right to make oral representations in relation to the proposed decision not to grant a licence to the centre. This committee was convened under the Rules – The Human Fertilisation and Embryology (Procedure for Revocation, Variation or Refusal of Licences) Regulations 2009 – in order to hear those representations.

THE PRINCIPAL ISSUES

31. The parties are in agreement that the principal issues that should concern the committee are:

    i) the taking of consent of a patient after conscious sedation; and

    ii) the adequacy of information given to NHS egg-sharers.

32. Both of these issues are relied upon by the HFEA in its assertion that Mr Adeghe is not a suitable person to carry out licensed activities.

EVENTS OF 20 AUGUST 2010

33. In relation to the first issue, on 20 August 2010 Mrs A (the patient's name has been anonymised) attended St Jude's Women's Hospital to undergo egg collection and was first sedated at 9.15a.m. From the notes which we have again reviewed, the procedure finished at 9.45a.m. The anaesthetic was given

as a bolus and, according to Mr Adeghe, would have lasted approximately 45 minutes. Therefore the effect of sedation would have begun wearing off at approximately 10 a.m.

34. In this case Midazolam was administered, which has both a hypnotic effect and can affect the memory. It can cause partial amnesia. Mr Adeghe agrees that consent should not be taken soon after sedation.

35. In the notes the time of Mrs A's discharge was 11.20a.m., 1 hour and 20 minutes after 10a.m. She had, according to the notes, been given water, tea and toast. Within that 1 hour and 20 minutes and prior to discharge it seems she signed the consent form in relation to the donation of some of her eggs. Mr Adeghe accepts that this was unacceptable practice.

36. We have examined this issue closely and we have considered whether or not the evidence leads us to take the view that this was a single instance when things went wrong or whether it was in fact a practice by this centre to take consent in this way on occasions.

INFORMED CONSENT

37. Informed consent to such a donation is of course a critical issue on these circumstances and no one has suggested differently.

38. Consent does lie at the heart of the process of donating eggs for use by another woman:

    i) although the woman can withdraw her consent at any time prior to the insertion of a resultant embryo into another woman, from that moment she can no longer withdraw her consent to her egg being used by another;

    ii) any children of that insemination would one day be entitled to details of his or her mother and may be allowed to trace them which, since 2005, they have been allowed to do. That may have an effect upon the donor and upon her family and any other children she might have;

    iii) the donation of eggs may diminish the chances of the donor herself successfully having a child because there will be fewer of her remaining eggs on that occasion to be inseminated in order to create an embryo.

39. Egg collection takes place following sedation which includes the use of Midazolam which is a Benzodiazepine, the guidance for which states that after its use patients should not drive a car, operate machinery, or sign legal documents for twenty-four hours irrespective of whether the sedation has been reversed by the use of other drugs.

40. For all of these reasons and others, to ask for written consent of a patient still under the effect of sedation is in our view wholly wrong.

MR ADEGHE'S EVIDENCE

41. We have been very concerned about Mr Adeghe's attitude to this instance and we have considered his evidence carefully bearing in mind that it is for him to persuade us that he is a suitable person to carry out licensed activities.

42. Mr Adeghe says:

    i) it was not his fault and that the consent process was left to one of his nurses on the day (that nurse was Mrs Maman);

    ii) that this was not standard practice and that on this single occasion the nurse 'let her heart rule her head';

    iii) that he was not initially aware it had happened;

    iv) that the patient had herself consented verbally in advance to the donation of some of her eggs at a time when she was not under sedation;

    v) that when he was reviewing the patient notes prior to her second treatment cycle three or four months after the first treatment cycle he had come across this anomaly in the notes;

    vi) that he had undertaken an audit and regularly reviewed the notes, which he said was how he had found out about this incident;

    vii) that there had been a staff meeting at which the points in relation to the taking of consent were reiterated.

43. Mr Adeghe claimed that he had conducted an audit some four months after this incident and thus discovered the issue with the consent process, but also explained that it had been picked up when he reviewed the patient's notes prior to her second treatment. He says he then took this up with Mrs Maman and sent her for training at another centre specifically on the issue of consent.

44. There is no independent evidence in the form of documentation or any other evidence that any staff meeting took place as mentioned by Mr Adeghe.

45. There is no documentary evidence of any such audit having taken place. He made no mention of such an audit or taking up these concerns with Mrs Maman when he spoke to Dr Bloor and Gill Walsh on 5 February 2014 when they were specifically asking him about the issue of consent after sedation.

46. There is no evidence of any retraining of Mrs Maman. His evidence was in direct contravention of the note we received into evidence from Mrs Maman (dealt with below).

47. Finally we note that this issue was never brought to the attention of the HFEA, the centre's regulator as we would expect any Person Responsible to do, nor indeed was the fact that Mr Adeghe was made aware of a complaint by the GMC against him in relation to the issue of consent. This was only realised by the HFEA once the GMC contacted them. We received no reassurance that Mr Adeghe at any stage brought these issues to the HFEA's attention either when he claims to have discovered them in 2010 or subsequently.

48. Unfortunately, we have been unable to accept Mr Adeghe's evidence about this incident and we do not think he has been truthful about it. Furthermore, we are very concerned that Mr Adeghe still does not take responsibility for the incident which undoubtedly occurred when he was the Person Responsible and he had the duty to supervise appropriately those working in the Centre.

MRS MAMAN'S NOTE

49. Setting aside the evidence of Mr Adeghe we have looked independently at the evidence of the forms themselves and the note from Mrs Maman.

50. The note from Mrs Maman is curious. It has plainly been drafted for other purposes and appears to be a response to the GMC complaint as it makes references to refuting that she 'giggles' and a reference to the layout of the premises which is no part of our consideration. She makes no direct admission to having taken the consent in the way suggested. She gives no apology and indeed appears to defend what happened. She makes no mention of having been spoken to four months later by Mr Adeghe as he contends, and she makes no mention of any retraining as he also contends. In the last paragraph she expresses her surprise at hearing about this complaint apparently for the first time four years after the treatment.

51. The note from Mrs Maman, submitted on his behalf, appears therefore to be in direct contravention of Mr Adeghe's evidence to us.

THE PATIENT RECORDS RELATING TO CONSENT

52. The documents relating to consent are also revealing. There are several sets of forms. One set was filled in according to the documents on 4 July 2010. Those forms are as follows:

    i) two forms which deal with the welfare of the child;

    ii) a form marked 'MT' and entitled 'Your consent to the use and storage of your sperm and embryos for your partner's treatment';

    iii) a form marked 'WT' and entitled 'Your consent to the use and storage of your eggs and embryos for your treatment';

    iv) a form marked 'CD' and entitled 'Your consent to the disclosure of identifying information'.

53. The second set of forms was filled in on 20 August 2010 when the procedure of collection of the eggs actually took place. These forms included the WD Form entitled 'Your consent to the use and storage of your donated eggs' and also includes the form 'D' entitled 'Donor Information'. We have received no explanation of why these forms were not filled in on 4 July together with the other forms, other than that the patient might want to wait until after the procedure to see how many eggs had been collected as asserted by Mr Adeghe to Dr Bloor on 5 February 2014. This is relevant to the issue of whether this was a practice of the centre or not.

54. The committee requested the production of the original forms including the medical records and examined them when produced. It was unclear who had filled in various parts of the forms and different pens appear to have been used and Mr Adeghe accepted as much in evidence.

55. It was obvious that in relation to the forms on the 20 August 2010 either they were not filled in by the patient herself or they were filled in during a period when her sedation had not worn off. This patient has a law degree and a responsible job working as a legal adviser to a court. Despite this, her form is littered with spelling and grammatical errors as well as poor English. It is unlikely that she filled the form in. In our view it is more likely that it was filled in on her behalf by another and simply signed by her. We note also that the final page which contains an important declaration is not signed at all but

simply bears the patient's name and it was not witnessed as it was supposed to be.

56. None of the errors appear to have been spotted or corrected by the patient herself. That does not give us confidence that she was fully aware of what was going on, or was 'recovered and fully alert' as was claimed by Mrs Maman.

DR BLOOR'S EVIDENCE

57. We found Dr Bloor to be a careful, candid and considered witness who told us the truth. She made admissions that others might not have made. We took into account the note (submitted in evidence to us) made by Ms Gill Walsh, Dr Bloor's co-inspector, on 5 February 2014 of the visit and the conversation on that day with Mr Adeghe.

58. We noted that it was not contemporaneous and was not shown to Mr Adeghe afterwards for confirmation by him. There were errors within it particularly in relation to the drugs used for sedation. We think it unfortunate that the original notes were destroyed and hope that in the future that practice will be reconsidered. Despite these reservations we accepted generally that the note accurately reflected the sense of the conversation with Mr Adeghe. We were persuaded that the note was an accurate reflection of the sense of what had been said by Mr Adeghe on that day.

WAS THIS A 'PRACTICE'?

59. Taking that note into account as well as the e-mail dated 7 February 2014 (submitted in evidence to us) sent by Mr Adeghe to Gill Walsh we find that:

    i) although taking consent following sedation was not a standard practice it was one as Mr Adeghe said which he felt was 'necessitated by desire (sic) to help needing (sic) patients given the severe shortage of egg donors nationally, especially among ethnic minorities';

    ii) his response to the e-mail from Gill Walsh was evasive because it did not directly answer the questions she raised about the practice of seeking consent following the administration of intravenous sedation;

    iii) Patient A was not from an ethnic minority and so the practice was plainly wider that Mr Adeghe admitted in his e-mail;

iv) his e-mail used the words ‘arising from this practice’, ‘not our standard practice’ and ‘this approach’ in such a way that we were persuaded that this was a practice or approach adopted on occasion;

v) similar language was used during his conversation with Dr Bloor and Ms Walsh, such as: ‘on occasion, but stressed not usual practice’; ‘consent to donation is sought on the day of collection following the procedure’; ‘in that event verbal consent is sought and egg sharing commenced’.

60. Had Mr Adeghe identified this problem soon after the event and taken steps to stop it we would have expected there to be documentary evidence of systems put in place to prevent this happening again. We would also have expected Mrs Maman to receive a written warning. We saw no such documentation.

61. We were also concerned that his oral evidence to the committee about when he would have checked the consents for donation of eggs was inconsistent.

CONCLUSIONS

62. The evidence has led us to accept on the balance of probabilities that it was in fact a practice by this centre to take consent in this way on occasions after sedation had been given but before a patient had been discharged. We cannot assess how often this has happened but we have been persuaded that this was not a one-off occasions and must have happened on more than a single occasion.

63. We note also that there was no evidence that the patient herself had been recalled to discuss the issue with her and to apologise nor does any apology appear to have been offered when the patient returned for her second or third cycle.

64. Mr Adeghe could have taken advice from the HFEA but he did not. He could and should in our view have arranged an external audit of the centre’s consent policy and practice but he did not.

65. For all of the reasons set out above we find that the evidence given to us by Mr Adeghe was not credible or truthful. He sought to avoid responsibility for what had happened. He tried to give a false impression of what was in fact a practice by the centre. He pretended that things had been corrected when there was no supporting evidence that this had happened. He failed to

demonstrate accordingly any real insight into the serious failings in relation to consent.

66. In light of our findings in relation to his credibility and to the practice which he allowed to take place at the centre, and his lack of insight into the seriousness of this event, he has not persuaded us, on the balance of probabilities that he is a suitable person to act as a Person Responsible.

67. Furthermore, in light of our findings in relation to Mr Adeghe's evidence to us and our considerable reservations about his trustworthiness we have no confidence that even were we to apply conditions to a licence, if one were granted, he would in fact comply with them as opposed to simply stating his agreement to them.

68. We note also the attempts by the HFEA to arrange an inspection of this centre since April of this year and the centre's apparent resistance to that inspection for various reasons. That again gave us no comfort in the willingness of Mr Adeghe to comply with the statutory regime.

CONSENT TO DONOR EGG SHARING BY NHS PATIENTS

69. The second issue is the question of consent to egg sharing for NHS patients and the documentation provided to such patients.

70. The issue is the adequacy of information given to patients receiving treatment under the NHS when donating eggs. Egg sharing was allowed at this centre for NHS patients who might not receive a benefit in kind from the process and it is said that patients were not provided with clear information to that effect.

71. It was a surprise to this committee that the HFEA has not produced any guidelines on this issue and we note that the centre had not produced any specific information for NHS patients in this position.

72. None of these issues go to the question of credibility nor do we take the view that the failure to produce such information, whilst unfortunate, goes to the issue of whether Mr Adeghe is or is not a suitable person to act as Person Responsible.

73. Therefore we have not taken this issue into account in deciding that Mr Adeghe has not demonstrated that he is a suitable person to act as a Person Responsible.

Determination

74. **Having listened to and weighed all of the arguments including but not limited to those outlined above, we are not persuaded that Mr Adeghe is a suitable person to act as Person Responsible and accordingly we refuse this application for a licence.**

10 November 2014