THE APPEALS COMMITTEE OF THE HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY

HODGE MALEK KC (Chairman), IAN COMFORT and TONY REDMOND OBE

IN THE MATTER OF:

iTRUST FERTILITY (CENTRES 0015 & 0086)

Appellant

-and-

THE HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY

Respondent

DECISION ON SUSPENSIONS

A. INTRODUCTION

1. This is the decision of the Human Fertilisation and Embryology Appeals Committee ("the Appeals Committee") on the applications of iTrust Fertility Limited ("iTrust Fertility") for reconsideration of two decisions of the Human Fertilisation and Embryology Licence Committee ("the Licence Committee") in respect of two fertility centres, iTrust Fertility Eastbourne ("Centre 0015") and Kent Fertility Centre ("Centre 0086") (collectively "the Centres").

2. The first decision relating to Centre 0015 was taken at a meeting of the Licence Committee on 26 January 2023 and was notified to the centre by the Notice of Decision dated 13 February 2023 ("the First Decision"). The second decision relating to Centre 0086 was taken on 1 February 2023 and notified by Notice of Decision dated 13

February 2023 ("the Second Decision"). In this decision the First Decision and the Second Decision are referred to collectively as "the Decisions". The Decisions were made by the Licence Committee on behalf of the Human Fertilisation and Embryology Authority ("the Authority") under Section 19C of the Human Fertilisation and Embryology Act 1990 ("the 1990 Act"). The reasons for the Decisions are reflected in the minutes of the relevant Licence Committee meetings and in summary in the Notices of Decision, which in turn enclose the relevant minutes.

3. By the Decisions, the Licence Committee determined it was necessary to suspend each centre's licence with immediate effect in accordance with sections 18(2) and 19C(1) of the 1990 Act. By virtue of sections 3 and 4, a clinic cannot store or use gametes or bring about the creation of an embryo or keep or use an embryo except in pursuance of a licence granted under section 16.

4. On 26 February 2023, the Centres served two notices of exercise of right on the Authority requiring it to reconsider the Decisions pursuant to section 20(4) and (5) of the 1990 Act ("the Notices of Exercise of Right"). Such reconsideration is by this Appeals Committee following the procedure set out in the Human Fertilisation and Embryology (Appeals) Regulations 2009 ("the Appeals Regulations").

5. It is for the Appeals Committee to reach its own decision as to whether or not the licences of the Centres should be suspended by way of reconsideration as provided in section 20B(1) of the 1990 Act. The Centres requested that the matter be dealt with urgently and by way of an oral hearing.

6. On 9 March 2023, a Case Management Conference was held in this matter. The Chairman of the Appeals Committee, Hodge Malek KC, heard representations on behalf of the Centres and the Authority as to the future conduct of the appeals. Directions were given as to the filing of evidence, disclosure of documents relied upon, and submissions with a view to the hearing being held on an expedited basis on 22 March 2023. It was common ground that, although the positions of each of the Centres required separate consideration, the two appeals would be heard together.

7. On 22 March 2023, the applications were heard by the Appeals Committee comprising Hodge Malek KC (Chairman), Ian Comfort (member) and Professor Tony Redmond OBE (medically qualified member). The Clinics were represented by Jenni Richards KC, and the Authority by Ravi Mehta. The Appeals Committee is grateful for the professional way the case was prepared and presented by Counsel and their solicitors, Hill Dickinson LLP for the Clinics and Fieldfisher LLP for the Authority. Emma Northey as Secretary to the Appeals Committee assisted with the case administration in the usual way, but did not take part in the Appeals Committee's deliberations. This decision of the Appeals Committee is unanimous.

8. Both parties filed a witness statement in support of their positions on the applications within the timescale directed at the CMC. Kuljit Moore-Juneja is the managing director of iTrust Fertility and has been the Licence Holder ("LH") in respect of the Centres since June 2021. Her witness statement dated 13 March 2023 deals with the impact of the Decisions on the Centres and contends that the licences should not have been suspended. [redacted] is the Authority's Chief Inspector and [redacted] witness statement dated 15 March 2023 provides some background to the Authority's concerns

as to the Centres and why the suspensions were appropriate and should continue. A second witness statement of the LH was served on the afternoon before the substantive hearing primarily dealing with actions requested by the Authority as to which she stated the majority had been addressed. The Authority also filed a witness statement on the day of the hearing on 22 March 2023 of Rachel Cutting, the Director of Compliance and Information at the Authority in respect of a complaint received on 20 March 2023 in respect of Centre 0086. Both statements were admitted subject to weight for the reasons given by the Chairman at the hearing, but no weight was placed on the complaint given it was anonymous so far as the Centres were concerned and had yet to be investigated or verified. There was no cross-examination of the witnesses. All the statements were read and considered by the Appeals Committee, which looked at the totality of the evidence before it in reaching this decision. At the hearing, the Appeals Committee was addressed both by counsel for the parties as well as by the LH and [redacted] (one of the team from the Inspectorate) on each of the areas of non-compliance identified in the reports. This exercise was a useful one and both sides were able to provide useful clarification and context.

9. In determining these applications, the Appeals Committee has applied the civil burden of proof test of balance of probabilities. Whilst under Appeal Regulation 23(1) it is the Clinics that have the burden of proof in establishing that the Decisions should be overturned, in the present case nothing turns on this, as the Appeals Committee has reached its own decision as to whether the licences should or continue to be suspended. Further, in view of the fact that the Appeals Committee decided as set out below it was procedurally unfair and incorrect not to give the Centres notice that it was considering suspension that had not been recommended in the two reports of the Inspectorate before

it, the Appeals Committee decided that it would not be appropriate to place the burden of proof on the Centres to overturn the Decisions.

B. PARTIES

10. The Authority was established pursuant to section 5 of the 1990 Act. It is not necessary to set out the background to the Authority, whose functions and responsibilities are set out in the 1990 Act, save to note that licencing decisions are taken by the Licencing Committee which is a committee comprised of Authority members established under section 9A(2) of the 1990 Act. The Authority has delegated to the Licence Committee the exercise of its complex or controversial licencing decisions and the power to issue directions under sections 24(5A) to (5E) and 24(13) of the 1990 Act. The Licencing Committee is independent of the Inspectorate, which has a team of 16 inspectors who are responsible for the inspection and licencing of fertility clinics. The Licence Committee follows the Licensing Guide which provides that it considers recommendations from the Inspectorate about regulatory actions and licence length. The Licence Committee has to form its own decisions, including whether or not it agrees with the Inspectorate's recommendations in each case and for it to provide its reasons. There may be occasions where the Licence Committee may decide not to follow the Inspectorate's recommendation, whether it be in the form of taking less or more serious action (paragraphs 1.3 and 1.4 of the Licencing Guide).

11. The Centres are two relatively small fertility clinics based in Eastbourne (Centre 0015) and Bromley (Centre 0086), who mainly deliver NHS fertility treatment. They are owned by iTrust Fertility, which was established in June 2019. As noted above Mrs Moore-Juneja has been the LH for the Clinics since June 2021. The Person Responsible

("PR") for both Centres is Dr Anna Naware, who is a gynaecologist who has previously worked at private fertility clinics. She was appointed PR in respect of the Centres in June 2022 with the approval of the Authority on the basis that she was considered to be suitable to carry out the duties of a PR under section 17 of the 1990 Act. It does not appear that she had ever been a PR previously. The Appeals Committee is conscious that it has not heard directly from the PR whether in the form of a witness statement or oral evidence. She became PR in very challenging circumstances and in retrospect what the Centres needed was an experienced PR able to deal with the various problems and compliance issues within the Centres. Nothing in this decision should be taken as a reflection of her capabilities as a qualified gynaecologist.

12. Centres 0015 and 0086 have each held a Treatment and Storage Licence with the Authority since 1992. Centre 0015 opened in 1989 and is the only specialised fertility unit in Eastbourne. In October 2019 iTrust Fertility acquired Centre 0015 from BMI Healthcare. In March 2020 iTrust Fertility moved Centre 0015 to new premises, forming a stand-alone unit rather than within the Esperance Hospital. Centre 0086 was initially located within BMI Chelsfield Park Hospital. In December 2020 iTrust Fertility acquired Centre 0086 from BMI Healthcare. Following the completion of a new stand-alone clinic in October 2021 Centre 0086 moved into its new premises in May 2022. Centres 0015 and 0086 not only share the same LH and PR, but also the Quality Manager ("QM") as well as a number of key staff who work across the Centres.

C. THE LEGAL FRAMEWORK

13. Section 8 of the 1990 Act identifies the Authority's general functions and includes:

(1) The Authority shall –

[…]

(cb) promote, in relation to activities governed by this Act, compliance with –

(i) requirements imposed by or under this Act, and

(ii) the code of practice under section 25 of this Act, and

(d) perform such other functions as may be specified in regulations. […].

14. Section 8ZA of the 1990 Act recognises, that in the exercise of its functions:

(1) The Authority must carry out its functions effectively, efficiently and economically.

(2) In carrying out its functions, the Authority must, so far as relevant, have regard to the principles of best regulatory practice (including the principles under which regulatory activities should be transparent, accountable, proportionate, consistent and targeted only at cases in which action is needed).

15. Section 9A(1) of the 1990 Act confers on the Authority the right to delegate its functions "*to a committee, to a member or to staff*". One such committee is the Appeals Committee which is established by section 20A of the Act.

16. Section 11 of the 1990 Act identifies the licences which the Authority may grant for treatment, storage, and research. Section 16 sets out the process and conditions for the grant of a licence. These include:

(1) The Authority may on application grant a licence to any person if the requirements of subsection (2) below are met.

(2) The requirements mentioned in subsection (1) above are -

(a) that the application is for a licence designating an individual as the person under whose supervision the activities to be authorised by the licence are to be carried on,

(b) that either that individual is the applicant or –

(i) the application is made with the consent of that individual, and

(ii) the Authority is satisfied that the applicant is a suitable person to hold a licence,

[…]

(cb) that the Authority is satisfied that the character of that individual is such as is required for the supervision of the activities and that the individual will discharge the duty under section 17 of this Act.

(3) The grant of a licence to any person may be by way of renewal of a licence granted to that person, whether on the same or different terms.

17. Section 17 of the 1990 Act addresses the obligations incumbent on the "Person Responsible" for a licensed centre:

(1) It shall be the duty of the individual under whose supervision the activities authorised by a licence are carried on (referred to in this Act as the "person responsible") to secure –

(a) that the other persons to whom the licence applies are of such character, and are so qualified by training and experience, as to be suitable persons to participate in the activities authorised by the licence,

(b) that proper equipment is used,

(c) that proper arrangements are made for the keeping of gametes, embryos and human admixed embryos and for the disposal of gametes, embryos or human admixed embryos that have been removed from storage,

(d) that suitable practices are used in the course of the activities,

(e) that the conditions of the licence are complied with,

(f) that conditions of third party agreements relating to the procurement, testing, processing or distribution of gametes or embryos are complied with, and

(g) that the Authority is notified and provided with a report analysing the cause and the ensuing outcome of any serious adverse event or serious adverse reaction.

(2) References in this Act to the persons to whom a licence applies are to –

(a) the person responsible,

(b) any person designated in the licence, or in a notice given to the Authority by the person who holds the licence or the person responsible, as a person to whom the licence applies,

and

(c) any person acting under the direction of the person responsible or of any person so designated.

18. Section 18(2) of the 1990 Act addresses revocation of a licence including at the initiative of the Authority:

(2) The Authority may revoke a licence otherwise than on application under subsection (1) if –

[…]

(b) it is satisfied that the person responsible has failed to discharge, or is unable because of incapacity to discharge, the duty under section 17, […]

(f) it ceases to be satisfied that the holder of the licence is a suitable person to hold the licence,

(g) it ceases to be satisfied that the person responsible is a suitable person to supervise the licensed activity […].

19. Section 19 of the 1990 Act establishes the procedure for decisions concerning the grant, revocation, or variation of a licence:

(1) Before making a decision –

(a) to refuse an application for the grant, revocation or variation of a licence, or

(b) to grant an application for a licence subject to a condition imposed under paragraph 1(2), 1A(2), 2(2) or 3(6) of Schedule 2,

the Authority shall give the applicant notice of the proposed decision and of the reason for it.

(2) Before making a decision under section 18(2) or 18A(3) or (5) the Authority shall give notice of the proposed decision and of the reasons for it to –

(a) the person responsible, and

(b) the holder of the licence (if different).

[…]

(4) A person to whom notice is given under subsection (1), (2) or (3) has the right to acquire the Authority to give him an opportunity to make representations of one of the following kinds about the proposed decision, namely -

(a) oral representations by him, or a person acting on his behalf;

(b) written representations by him.

(5) The right under subsection (4) is exercisable by giving the Authority notice of the exercise of the right before the end of the period of 28 days beginning with the day on which the notice under subsection (1), (2) or (3) was given.

(6) The Authority may by regulations make such additional provision about procedure in relation to the carrying out of functions under sections 18 and 18A and this section as it thinks fit.

20. Section 19C of the 1990 Act grants the Authority the power to suspend a licence:

(1) Where the Authority –

(a) has reasonable grounds to suspect that there are grounds for revoking a licence, and

(b) is of the opinion that the licence should immediately be suspended,

it may by notice suspend the licence for such period not exceeding three months as may be specified in the notice.

(2) The Authority may continue suspension under subsection (1) by giving a further notice under that subsection.

(3) Notice under subsection (1) shall be given to the person responsible or where the person responsible has died or appears to be unable because of incapacity to discharge the duty under section 17 –

(a) to the holder of that licence, or

(b) to some other person to whom the licence applies.

(4) Subject to subsection (5), a licence shall be of no effect while a notice under subsection (1) is in force.

(5) An application may be made under section 18(1) or section 18A(1) or (2) even though a notice under subsection (1) is in force.

21. Section 20 of the 1990 Act confers a right to a reconsideration on a person to whom a decision under ss.19 and 19C is addressed:

(1) If an application for the grant, revocation or variation of a licence is refused, the applicant may require the Authority to reconsider the decision.

(2) Where the Authority decides to vary or revoke a licence, any person to whom notice of the decision was required to be given (other than a person who applied for the variation or revocation) may require the Authority to reconsider the decision.

(3) The right under subsections (1) and (2) is exercisable by giving the Authority notice of exercise of the right before the end of the period of 28 days beginning with the day on which notice of the decision concerned was given under section 19A.

(4) If the Authority decides –

(a) to suspend a licence under section 19C(1), or

(b) to continue the suspension of a licence under section 19C(2),

any person to whom notice of the decision was required to be given may require the Authority to reconsider the decision.

(5) The right under subsection (4) is exercisable by giving the Authority notice of exercise of the right before the end of the period of 14 days beginning with the day on which notice of the decision concerned was given under section 19C.

(6) The giving of any notice to the Authority in accordance with subsection (5) shall not affect the continuation in force of the suspension of the licence in respect of which that notice was given.

(7) Subsections (1), (2) and (4) do not apply to a decision on reconsideration.

22. Section 20B provides that an appeal is by way of reconsideration (s.20B(1)) and that regulations may make further provision for the procedure on appeal (s.20B(2)-(5)). The relevant regulations dealing with the procedure on appeal are the Appeals Regulations.

23. Section 24 confers on the Authority the power to give special directions, as follows:

> […]
> (5A) Directions may make provision for the purpose of dealing with a situation arising in consequence of –
> (a) the variation of a licence, or
> (b) a licence ceasing to have effect.
> (5B) Directions under subsection (5A)(a) may impose requirements –
> (a) on the holder of the licence,
> (b) on the person who is the person responsible immediately before or immediately after the variation, or
> (c) on any other person, if that person consents.
> (5C) Directions under subsection (5A)(b) may impose requirements –
> (a) on the person who holds the licence immediately before the licence ceases to have effect,
> (b) on the person who is the person responsible at that time, or
> (c) on any other person, if that person consents.
> (5D) Directions under subsection 5(A) may, in particular require anything kept, or information held, in pursuance of the licence to be transferred in accordance with the directions.

Regulators Code 2014

24. The Regulators Code is a statutory code of practice in relation to the exercise of regulatory functions, issued under section 22 of the Legislative and Regulatory Reform Act 2006. Paragraph 2.2 of the Code states that:

> *"In responding to non-compliance that they identify, regulators should clearly explain what the non-compliant item or activity is, the advice being given, actions required or decisions taken, and the reasons for these. Regulators should provide an opportunity for dialogue in relation to the advice,*

requirements or decisions, with a view to ensuring that they are acting in a way that is proportionate and consistent."

Paragraph 2.2 does not apply where the regulator "*can demonstrate*" that immediate enforcement action is required to prevent or respond to a serious breach or where providing such an opportunity would be likely to defeat the purpose of the proposed enforcement action.

Standing orders: Annex D – Protocol for the conduct of meetings of the Licence Committee.

25. The introduction to this Protocol refers to the Authority's common law duties and powers to ensure fairness in its procedures and to its duties to enforce in a transparent manner and to be transparent in the way in which it applies and determines penalties. The Protocol states that it aims to ensure fairness and consistency and should be followed save where fairness requires otherwise.

26. Paragraph 2.7 of the Protocol provides that the Chair of a Licence Committee shall ensure that a copy of any advice tendered by an adviser to the committee (which includes a legal adviser) is sent to the parties to the proceedings.

27. Paragraph 6.2 of the Protocol provides that the Licence Committee shall not usually receive the recommendation of the inspector or any relevant supporting documentation from that inspector, unless the applicant or person concerned has been provided with a reasonable opportunity to comment on this material beforehand.

28. The Licence Committee is required to provide reasons which set out: any relevant findings of fact made by the Committee; any matters taken into account by the Committee including any advice received; and why the Committee reached its decision: Protocol, paragraph 11.2.

29. Paragraph 13.1 of the Protocol provides that the Authority's inspector dealing with the matter should bear the burden of establishing that a licence should be revoked or suspended.

D. THE DECISIONS

(1) Events leading up to the Decisions

30. There can be little doubt that, like many businesses in the medical sector, the Centres were adversely affected in 2020 and 2021, in particular by the impact of the Coronavirus pandemic. In the UK there were national lockdowns and staffing levels would have been affected by illness as well as the need for isolation when those living with staff members were ill with Covid-19. It was in this period that iTrust Fertility acquired the Centres. The movement of both Centres in March 2020 and May 2022 would have also involved a significant amount of work and potential disruption for the Centres. There were also compliance issues with both Centres which required resolution.

31. Whistle-blower allegations were received by the Authority a number of times from February 2022 in relation to both Centre 0015 and Centre 0086. These related to a

number of matters, including staffing levels, staff training and competence, and non-compliant practices. These of course had to be followed up by the Inspectorate.

32. On 30 May 2022 there was an unannounced inspection of Centre 0015 to investigate the whistle-blower allegations. Such were the concerns arising from this inspection, it was decided that the Centre 0015 renewal inspection should be brought forward from November 2022 to July 2022 to allow a full review of its activities.

33. On 14 July 2022 the Inspectorate carried out the renewal inspection in relation to Centre 0015 licence ("the Renewal Inspection"). The report of the renewal inspection, whilst noting significant matters of concern and need of remedy, recommended the continuation of the licence, but with a further inspection within 6 months ("the Renewal Inspection Report").

34. The draft Renewal Inspection Report was provided to the PR on 6 September 2022, which she returned on 30 September 2022. The Inspectorate noted that evidence on a number of matters was still outstanding from the PR, which was requested on 3 October 2022. The outstanding evidence was provided on 10 October 2022, but the Inspectorate did not consider it fully addressed the non-compliances. Despite follow-up requests, the Inspectorate did not consider staff competences to be satisfactory. There does appear to have been a process where Centre 0015 was endeavouring to be compliant and to provide evidence and assurances as to compliance. That said, the Inspectorate continued to have concerns. Both staffing levels and the amount of regulatory oversight necessary have been of particular concern. As stated by the Chief Inspector in her witness statement:

"16. As set out at page 431 to the Bundle further whistleblower allegations were received after the HFEA visit on 30 May 2022 which raised similar concerns to those previously received regarding staffing. The executive notes that there have been significant changes in key personnel at centre 0015 over the last two years, i.e., from between January 2020 and May 2021, three changes of LH and between January 2021 to June 2022, four changes of PR. There have also been numerous clinical, laboratory and administrative staff changes. The current PR came into the post for centre 0015 (and also centre 0086) at the end of June 2022, approximately two weeks prior to centre 0015 licence renewal inspection on 13 and 14 July 2022.

17. The Centre has required an extraordinary degree of regulatory oversight in the last two years. The executive also wishes the LC to note that the executive has provided the PR with an unprecedented level of support, both in terms of ensuring she has access to an experienced PR mentor and, high levels of support from the centre's lead inspector. The HFEA expects the PR to seek out and take any necessary specialist advice to allow them to run the centre professionally."

35. The whistle-blower allegations received by the Authority in February 2022 in relation to Centre 0015 also made reference to practices at Centre 0086. In May 2022 the Inspectorate carried out an interim inspection of Centre 0086 ("the Interim Inspection"). The report of that visit noted major areas of non-compliance largely relating to matters that the PR should ensure were dealt with, as well as other areas of practice requiring improvement ("the Interim Inspection Report") [585e]. The inspection came at a time when the previous PR was in the course of departing and the current PR had not yet been at her post. The draft Interim Inspection Report was not responded to by the former PR, but was responded to by the current PR after her formal appointment. Thus to a large extent the current PR inherited a difficult situation which was in need of remedy.

36. Following the Interim Inspection, it was decided to conduct an additional targeted inspection of Centre 0086, which was conducted on site on 19 October 2022. Additionally between August and October 2022, the Authority received a number of whistle-blower reports about Centre 0086. This targeted inspection also made adverse

findings and identified areas of practice requiring action ("the Additional Targeted Inspection Report"). These centre around 3 major areas of non-compliance: consent to storage, staff, and quality management systems ("QMS"). It is evident that the Inspectorate had significant concerns as to the competence of the PR and her ability to address issues satisfactorily as and when they arose.

(2) The meetings of the Licence Committee and the Decisions

37. On 12 January 2023, the Licencing Committee met to consider the reports in relation to both Centres. In relation to Centre 0015 it was supplied with the following:

(1) The Renewal Inspection Report;

(2) The Licence renewal application form;

(3) ITE Import Certificate; and

(4) Licencing minutes from the last 3 years.

38. In relation to Centre 0086 the Licence Committee was supplied with the following:

(1) The Additional Targeted Inspection Report.

(2) Licencing minutes from the last 3 years.

39. As regards Centre 0015, the Renewal Inspection Report recommended the renewal of the licence but for only one year (rather than the usual 4 years) and that there be a focused interim inspection within 6 months of the report being considered by the Licence Committee. As regards Centre 0086, the Additional Targeted Inspection Report recommended the continuation of the licence. Neither report was free of criticisms and concerns in respect of the Centres. The Additional Targeted Inspection Report was particularly critical of the PR.

40. The Renewal Inspection Report in respect of Centre 0015 was submitted to the Licence Committee for consideration, rather than the Executive Licencing Panel ("ELP") because of the number and nature of the non-compliances identified, coupled with the concerns raised about the Centre 0015 by whistle-blowers. The summary for the licencing decision included the following:

> ***"Summary for licensing decision***
>
> *Taking into account the essential requirements set out in the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the HF&E Act 2008 and the HFEA Code of Practice (CoP) and standard licence conditions (SLCs), the inspection team considers that it has sufficient information to conclude that:*
>
> - *the application has been submitted in the form required;*
> - *the application has designated an individual to act as the PR;*
> - *the PR's qualifications and experience comply with section 16(2)(c) of the HF&E Act 1990 (as amended);*
> - *as a result of a subsequent targeted inspection of centre 0086 on 19 October 2022 (centres 0015 and 0086 have the same PR) the executive has concerns about the PR's ability to discharge their duty under section 17 of the HF&E Act 1990 (as amended);*
> - *the premises (including those of relevant third parties) are suitable;*
> - *the centre's practices are suitable with the exceptions noted in this report;*
> - *the application contains the supporting information required by General Direction 0008, in application for renewal of the centre's licence;*
> - *the centre has submitted an application fee to the HFEA in accordance with requirements.*
>
> *The LC is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including five critical, seven major and three 'other' areas of non compliance."*

41. The Renewal Inspection Report did identify 5 critical and 7 major areas of non-compliance:

> *"**Critical areas of non compliance:***
> - ***The PR should ensure that medicines management practice is compliance with regulatory requirements, best practice and professional body guidelines.***

- ***The PR should ensure that the qualify management system (QMS) is robust and fit for purpose.***
- ***The PR should ensure that staff are available in sufficient numbers, qualified and competent for the tasks they perform.***
- ***The PR should ensure that procedures for documenting legal parenthood consent are robust and compliant with statutory requirements and HFEA CoP guidance.***

Major areas of non compliance:

- *The PR should ensure that ITE import certificate authorisation is in place before any imports occur and that compensation given to donors of gametes and embryos imported from outside the UK is compliant with requirements.*
- *The PR should ensure that all consumables are traceable.*
- *The PR should ensure that all adverse incidents, including serious adverse events and reactions, as well as near misses, are reported to the HFEA.*
- *The PR should ensure that surrogacy treatments are compliant with regulatory requirements, HFEA CoP guidance and DHSC practice guidelines.*
- *The PR should ensure that effective consent is in place for all stored gametes and embryos.*
- *The PR should ensure that proper records are maintained in such form as the Authority may specify in Directions.*

'Other' areas that requires improvement:

- *The PR should ensure that air quality testing is undertaking at regular intervals."*

42. The Renewal Inspection Report included a schedule of areas of practice requiring action which included 4 columns: (1) area of practice and reference; (2) action required with timescale; (3) PR response; and (4) executive review [394]. Whilst it does appear that a significant number of matters had been addressed satisfactorily, for others it was noted the non-compliances had either not been addressed or not fully addressed, and further action was required.

43. The Licence Committee at its meeting on 12 January 2023 did not determine the licence renewal application in respect of Centre 0015. It decided as recorded in the minutes:

"6.3 The committee noted that the centre has required an extraordinary degree of regulatory oversight in the last two years, and that the executive has provided the PR with an unprecedented level of support.

6.4 The committee discussed the non-compliances described in the executive's report, and the history of non-compliances at the clinic. The committee also noted the frequency of changes of PR since 2020, and the fact that the current PR was appointed shortly before the inspection in July 2022.

6.5 The committee was particularly concerned at the potential for patient care to be affected by the staffing issues described in the executive's report, and the overall seriousness and recurrence of the non-compliances also set out in the report.

6.6 In considering this item further, the committee was conscious that there were a range of potential options open to it, some of which could potentially have an impact on patients. With patient care and wellbeing in mind, as well as applicable duties under the HFE Act 1990, the committee wished to seek additional legal advice about the options open to it before coming to a decision. The committee therefore adjourned, with a view to reconvening as quickly as possible to receive that legal advice and then make a decision."

44. The Additional Targeted Inspection Report in respect of Centre 0086 noted that two major areas of non-compliance had been dealt with. The report went on to note:

"The PR has given a commitment to fully implementing the following recommendations:

Critical area of non compliance:

- ***The PR should ensure that she fully discharges her duties under section 17(1) of the HF&E Act 1990 (as amended) and has robust oversight of all activities at the centre.***

Major areas of non compliance:

- *The PR should ensure that the changes to storage laws effective from 1 July 2022 are fully incorporated into the centre's practices and processes.*
- *The PR must ensure that all critical processes are audited at least every two years and that auditing and document control processes are effective.*

'Other' area of practice that requires improvement:

- *The PR should ensure that information about success rates provided to patients on the clinic's website is compliant with the requirements of the CoP guidance.*

The centre provides a good level of patient support however leadership at the centre requires significant improvement.

The executive continues to have significant concerns about the PRs ability to effectively demonstrate the key behaviours expected by the HFEA in terms of leadership and oversight of all activities of the centres for which she is PR. The level of concern is such that it was agreed that a critical non compliance is cited. The executive also notes that the PR has been heavily reliant on the support of inspectors during her early months as a newly appointed, first-time PR. It is not the role of the regulator to provide this level of support and guidance to PRs, who should be sufficiently autonomous and proactive to be able to fully discharge their duties.

Whilst it is recognised that a PR cannot be an expert in all elements of licensed activity for which they are legally accountable, the HFEA expects the PR will ensure they are informed and up to date with HFEA requirements, and that the PR will seek all necessary specialist advice to allow them to fulfil the role effectively and with autonomy."

45. The Additional Target Inspection Report also contained a schedule of areas of practice that require the attention of the PR. It noted that whilst for many entries no further action was required, there were still areas of concern where further action and improvement was needed.

46. At its meeting on 12 January 2023 the Licence Committee decided to obtain legal advice before taking a decision. As noted in the minutes:

"5.3 The committee noted the Executive's report, and discussed the serious non-compliances identified.

5.4 The committee was particularly concerned at the potential for patient care to be affected by the staffing issues described in the Executive's report, and the overall seriousness and recurrence of the non-compliances also set out in the report.

5.5 In considering this item further, the committee was conscious that there were a range of potential options open to it, some of which could potentially have an impact on patients. With patient care and wellbeing in mind, as well as applicable duties under the HFE Act 1990, the committee wished to seek additional legal advice about the options open to it before coming to a decision. The committee therefore adjourned, with a view to reconvening as quickly as possible to receive that legal advice and then make a decision."

47. The legal advice obtained is set out in the memorandum of DAC Beachcroft dated 20 January 2023. In essence, it set out various potential options which could be taken depending upon the Licence Committee's assessment. No criticism has been made as to the content of the advice given.

48. On 26 January 2023, the Licence Committee met again to consider Centre 0015's licence renewal application. The Licence Committee's findings as reflected in the minutes included the following which set out the basis for its decisions not to renew the licence, to suspend it for the maximum period of 3 months, and to issue special directions:

> *"5.3 The committee remained significantly concerned about the centre's compliance picture and regulatory history, particularly in light of:*
>
> - *the extraordinary degree of regulatory oversight in the last two years, and the unprecedented level of support provided by the Executive to the PR*
> - *the number and significant nature of the non-compliances described in the Executive's report, as well as the history of non-compliances at the clinic*
> - *the frequency of change of PR since 2020, and the fact that the current PR was appointed shortly before the inspection in July 2022.*
> - *the potential for patient care to be affected negatively by the staffing issues described in the Executive's report, and the overall seriousness of the non-compliances, and the fact that some of these remained unresolved, as also set out in the report.*
>
> ...
>
> *5.9 The committee was not satisfied that there any mitigating factors on the evidence before it, although it took into account that the PR had attempted to co-operate with the Executive and put in place some remedial actions, as requested by the Executive. However these had not been sufficient to address the non-compliances and the Executive's concerns.*
>
> *5.10 On the other hand, however, it noted that there were a significant number of aggravating factors. Those were:*
>
> - *The PR failing to understand the requirements or standards that they are expected to meet, alongside a failure to take responsibility for a*

significant prolonged history of non-compliances. The committee noted that the centre's history of non-compliances spans a period of time which pre-dates the current PR being in post. As noted by the Executive, however, the PR is a role with statutory responsibilities and which requires the PR to take responsibility for any historic non-compliances and to commit to rectifying them. The committee noted the Executive's comments as to the 'extraordinary' level of regulatory oversight provided to the centre over the preceding two years, as well as the 'unprecedented' level of support provided to the PR. As a result, and in view of the current compliance picture at the centre, the committee took the view that the PR does not understand the statutory duties and responsibilities to which she is subject and that it had no assurances or confidence that the PR could adequately respond to the ongoing non-compliances identified by the Executive.

- *The number and seriousness of non-compliances, and a failure to take initiative to address them. The committee was particularly concerned by the history of regulatory oversight associated with this particular centre, and the evident failure to address both the critical and major non-compliances;*
- *The extent to which the PR, Licence Holder and/or other senior staff knew, or ought to have known, of the non-compliances and the risk of them recurring. As noted by the Executive, the PR is required to confirm as part of the change of PR application process that she accepts both the role and its inherent responsibilities. Further, the Licence Holder has acted in such capacity since May 2021 and so ought to have been aware of the ongoing regulatory picture pertaining to the preceding two years. The Licence Holder was also responsible for appointing the PR. The committee noted the significant ongoing concerns regarding staffing, to include high turnover, lack of appropriate clinical oversight, qualifications and clinical competence. It also noted that a number of whistleblowing concerns have been received by the Executive regarding staffing arrangements and the centre.*
- *The ongoing failures to identify the appropriate and effective remedial steps that should be taken to address non-compliances.*
- *The PR's apparent lack of insight in being unable to recognise the seriousness and impact of non-compliances.*
- *The history of non-compliance, to include ongoing breaches of the statutory framework (including licence conditions) alongside ongoing failure to comply with recommendations made by the Executive.*
- *The extent to which the PR has:*
    - *fulfilled her duties under section 17 of the 1990 Act. The committee was particularly concerned about the PR's leadership despite the unprecedented level of support provided to her by the Executive.*
    - *acted with insight, knowledge and understanding, especially (again) taking into account the level of Executive support and the number of recurring and outstanding non-compliances.*

- *shown insight and taken the initiative to implement remedial actions without prompting from the Executive.*
- *demonstrated that she will embed and sustain the required improvements or changes. The committee had no assurance that the PR would be able to do this, again despite the Executive's level of support provided to date and in light of the number of recurring and/or unresolved non-compliances.*

5.11 Having taken into account the lack of mitigating factors and the number and nature of aggravating factors the committee decided that this was in fact a very high risk non-compliance picture, and noted that the indicative list of regulatory actions in such circumstances is refusal to grant a licence, suspension and/or revocation of the licence.

Licence renewal application

5.12 In light of the findings outlined above the committee moved on to consider the applicable decision tree. It had regard to the statutory criteria applicable to the renewal of a licence under section 16 HFE Act 1990, and concluded that the criteria were not met. In particular, it decided that section 16(2)(cb) was not met, because based on the centre's compliance history and the failures of the PR to address the Executive's findings as to non-compliances the committee was not satisfied that the character of the PR is such as is required for the supervision of the licensed activities and/or that the PR will discharge the duties under section 17 of the HFE Act 1990.

5.13 The committee's decision was therefore to refuse to renew the centre's licence. In reaching this decision the committee carefully considered the proportionality of refusing to renew the licence, particularly in light of the impact this could have on patients. The committee also carefully considered the recommendation of the Executive, mindful that it is not obliged to follow it. The Executive's conclusion that the centre presented a high risk compliance picture resulted in recommending a one year licence renewal, which is a significant departure from the customary four year licence for a centre with a low risk compliance picture. It was therefore apparent to the committee that the Executive has significant concerns about this centre, as further demonstrated in the findings of the inspection report.

5.14 In reaching its decision the committee was particularly persuaded by the number and serious nature of aggravating factors applicable to this particular centre, and in light of which the risk of harm to patients, gametes and embryos is significant in circumstances where non-compliances have persisted for such a long period of time without remediation. The committee also had regard to the regulatory aim of limiting the risk that the public may lose confidence in the conduct of licensed activities. Ultimately, therefore, the committee's assessment was that the proportionate and necessary action is to refuse the renewal as, in

its view, the centre's poor and ongoing regulatory compliance history presents a significant risk to the safety of patients, gametes and embryos.

Suspension and/or revocation

5.15 The committee also considered whether to suspend and/or revoke the centre's licence, as the licence would otherwise continue to run until it expires in June 2023. In doing so it had regard to the relevant decision tree, and in light of the findings outlined above concluded that the threshold for enforcement action had been crossed due to the seriousness of its concerns. In particular, the committee noted that there are critical and major non-compliances in circumstances where:

- *Those non-compliances remain unresolved*
- *There are ongoing or recurring issues*
- *The evidence provided by the PR is insufficient to provide assurance of non-recurrence.*

5.16 Based on those findings, the committee considered that grounds for revocation (which are also the grounds for suspension) arise under section 18 of the HFE Act 1990. In particular, the committee determined that it ceases to be satisfied that:

- *The character of the PR is such as is required for the supervision of the licensed activity*
- *The Licence Holder is a suitable person to hold the licence.*

5.17 Insofar as the Licence Holder is concerned the committee particularly noted the period of time for which they have held that position, which overlaps with the history of recurring and/or ongoing non-compliances. Further, the Licence Holder was responsible for the recruitment of the PR who, in turn, has required an unprecedented level of support from the Executive. The significant staffing issues affecting the centre have also persisted over a period of time in which the Licence Holder has been in post.

5.18 The committee therefore determined that grounds for revocation arise, and went on to determine that it is necessary to suspend the licence with immediate effect due to the severity of its concerns regarding the non-compliances. On that basis, the committee decided that it would exercise its power under section 19C(1) of the HFE Act 1990 to suspend the centre's licence for the maximum possible period of three months. It was particularly concerned about the risk of patient, gamete and embryo safety if the committee did not take action with immediate effect.

5.19 The committee moved on to consider further enforcement action, and in particular whether revocation is necessary or, as an alternative, whether it should vary the licence to impose conditions. The committee ultimately decided, particularly in light of the aggravating factors identified above, that revocation is necessary. It particularly noted the extensive regulatory oversight the centre has received over a prolonged period of time, and the fact that so many non-compliances remain unresolved such that varying

the licence to impose conditions would not mitigate the risk because there are no meaningful conditions which could be imposed to adequately address the risk presented by the centre's regulatory failings.

5.20 The committee was mindful throughout its deliberations on the best course of action to it based on the powers available and the impact on patients. Ultimately, the compliance picture was such that enforcement action was unavoidable. It carefully considered the extent to which it would be proportionate to impose a lesser sanction than refusal to renew, suspension and revocation, but decided that the risk to patients, gametes and embryos was too significant.

Special directions

5.21 The committee was very mindful of the implications of its decisions, particularly for patients currently undergoing treatment at the clinic. The committee noted the centre's right to make representations before the decision to refuse and/or revoke the licence take effect, and to appeal the decision to suspend the licence. The suspension of the licence will take immediately effect irrespective of whether the centre appeals it and/or decides to invoke its right to submit representations.

5.22 In order to allow patients who have already begun a treatment cycle to be given a choice as to whether to complete their cycle at the clinic or to be supported to transfer to another clinic, the committee decided to issue Special Directions to the Person Responsible, under Section 24(5A)(b) of the HF&E Act 1990 (as amended), to permit the continuation only of those licensed activities which are currently underway at the centre from 13 February 2023 until such future time as the centre's licence is formally revoked, expires, or the coming into effect of a renewal licence, whichever is sooner. Those Special Directions are to be limited in scope to the patients currently undergoing a cycle of treatment with the centre, i.e. where a patient has already commenced medication to initiate a treatment cycle, and will enable that cycle only to be completed, if the patient chooses to do so. The Special Directions will also require the PR to share with such patients an information sheet provided by the HFEA to explain the action it is taking, so that patients are able to make an informed decision.

5.23 The Special Directions will also allow the ongoing storage of gametes and embryos at the centre until such a time as they may be transferred to another HFEA-licensed clinic; and the ongoing secure storage of patient information held in the clinic, until such a time as records may be transferred to another HFEA-licensed clinic. The Special Directions will also require the PR to share with all patients who have gametes and/or embryos in storage at the clinic an information sheet provided by the HFEA to explain the action it is taking, so that patients are able to make an informed decision."

49. For similar reasons, on 1 February 2023, the Licence Committee decided in relation to Centre 0086 that there were grounds for revocation of its licence, and it was necessary to suspend the licence with immediate effect due to the severity of its concerns. The suspension was for the maximum period of 3 months. It also decided to issue special directions.

50. On 13 February 2023, the Authority sent the Centres the Notices of Decision, which enclosed the Licence Committee minutes in respect of Centre 0015 dated 26 January 2023 and Centre 0086 dated 1 February 2023. The suspensions were due to expire on 13 May 2023 at which point the Licence Committee would have needed to make a new decision on whether or not to continue the suspensions.

(3) Events since the Decisions

51. The Decisions and their implication have had a very substantial impact on the ability to operate and reputation of the Centres. Staff morale has been naturally affected. In addition patients would have been concerned about their own treatment. The financial impact is set out in the LH's first witness statement. [redacted]

E. THE ISSUES AND GROUNDS OF CHALLENGE

52. The issue for the Appeals Committee is whether the licences should remain suspended. The position of iTrust Fertility is in a nutshell that the Decisions should never have been made and the suspensions should be lifted.

53. The issues may be broken down as follows:

(1) Were the Decisions reached in an unfair and procedurally incorrect manner?

(2) Did the Licence Committee act consistently?

(3) Did the Licence Committee fail to give reasons or only inadequate reasons for their Decisions?

(4) Should the licences be suspended?

Issue (1): Unfairness and procedural defects

(a) Submissions of the parties

54. iTrust Fertility contends that the Decisions were unfair and were reached in a procedurally unfair manner.

55. The first criticism is that the Licence Committee before reaching a decision ought to have put the Centres on notice that it was considering or was minded to suspend the licences after its meeting on 12 January 2023. The reports from the Inspectorate on both Centres as provided to the PR as well as the Licencing Committee did not recommend either the non-renewal of the licences or suspension. Had notice been given, the Centres would have been able to make submissions to the Licence Committee.

56. In support of the contention that fairness requires notice with the opportunity to make representations prior to a decision having a significant impact on the addressee of a decision, reliance was placed on a number of well-known decisions including McInnes v. Onslow-Fane [1978] 1 W.L.R. 1520 at 1529; Bank Mellat v. HM Treasury (No.2)

[2014] AC 700 at [29]; R (Balajigar v. Secretary of State for the Home Department [2019] 1 W.L.R. 4647 at [61]; Jain v. Trent SHA [2009] 1 AC 823.

57. The case was not put on the basis that this arises out of a general situation. It is necessary to look at the facts of the particular case and emphasis was being placed on the facts in the present case that the Centres were given copies of the inspection reports and from those it was not apparent that suspension was a possibility.

58. The Authority did not dispute that it has a duty to act fairly. It was submitted that the 1990 Act does not require prior notice of a suspension. Section 19(1) and (2) refer to decisions where, before they are made, the Authority must give notice to the PR and/or the LH. These include decisions to revoke a licence. Section 19C, however, deals with the power to suspend a licence. Unlike section 19, it does not provide for notice or an opportunity to make representations prior to deciding to suspend. It therefore follows that the Committee should not read in an implied provision requiring notice prior to making a decision to suspend. The Licensing Guide correctly identifies that the Licence Committee may take a decision different from what the Inspectorate may recommend and, if so, should give reasons (paragraphs 1.3 and 1.4). It does not provide that notice should be given in advance. The LH or the PR have the ability to seek a reconsideration by the Appeals Committee.

(b) Analysis

59. The Authority has a duty to act fairly in reaching licensing decisions such as the present. This is reflected in the introduction to the Protocol for the conduct of meetings of the Licence Committee. Ordinarily fairness requires the person who is the subject of an

adverse decision to be given the opportunity to make representations. This is for good reason. As stated by the Court of Appeal in R (Balajigari) v. Home Secretary [2019] EWCA Civ 673, [2019] 1 W.L.R. 4647 at [60]:

> *"60. This leads to the proposition that, unless the circumstances of a particular case make this impracticable, the ability to make representations only after a decision has been taken will usually be insufficient to satisfy the demands of common law procedural fairness. The rationale for this proposition lies in the underlying reasons for having procedural fairness in the first place. It is conducive to better decision-making because it ensures that the decision-maker is fully informed at a point when a decision is still at a formative stage. It also shows respect for the individual whose interests are affected, who will know that they have had the opportunity to influence a decision before it is made. Another rationale is no doubt that, if a decision has already been made, human nature being what it is, the decision-maker may unconsciously and in good faith tend to be defensive over the decision to which he or she has previously come. In the related context of the right to be consulted, in Sinfield v London Transport Executive [1970] Ch. 550, at p. 558, Sachs LJ made reference to the need to avoid the decision-maker's mind becoming "unduly fixed" before representations are made. He said:*
>
> > *"any right to be consulted is something that is indeed valuable and should be implemented by giving those who have the right an opportunity to be heard at the formative stage of proposals - before the mind of the executive becomes unduly fixed."*

60. The protocol at paragraph 6.3 provides that the Licence Committee shall not usually receive the recommendation of the Authority's inspector dealing with the matter or any relevant supporting documentation from the inspector unless the applicant or the person concerned, as appropriate, has been provided with a reasonable opportunity to comment on the material beforehand. This was followed in the present case.

61. Whilst the Centres and the PR were aware of the concerns of the Inspectorate in the reports and were given the opportunity to respond and meet those concerns, they were unaware that such concerns might lead to decisions entailing suspension of the licences,

which were key to the business of fertility clinics. The Licence Committee took legal advice (received on 20 January 2023) which was not provided to the PR or LH at the time. Even though the Licence Committee may have been concerned by the seriousness of the failing and risks with the clinics continuing to operate, they could and should have given notice to the PR or LH in the period prior to the meetings to consider what action should be taken. A copy of the legal advice should have been provided to the PR or LH (Protocol, para.2.7).

62. Thus the PR should have been given a reasonable opportunity to respond to the possibility of a suspension or revocation of a licence. That is not to say that there is a general duty when considering suspension to give notice to the PR, as Mr Mehta correctly pointed out. Section 19C does not contemplate an express duty to provide notice in advance unlike section 19(1) and section 19(2) decisions. The problem in the present case is not likely to be a general one because in most cases the Licence Committee will not be considering a sanction more serious than that envisaged in the inspection report. Here, the inspection reports made specific recommendations which the PR was entitled to consider would not be moved from unless the Centres were given notice, particularly given the seriousness of the sanction of suspension.

63. The Appeals Committee does not consider that the failure to provide a copy of the legal advice was deliberate, in the sense that it was not provided as the Licence Committee did not wish to alert the Centres as to what the options were under active consideration by the Licence Committee. The legal advice itself did not advise the Licence Committee that the advice should be provided to the Centres.

64. As to the impact of the failure to notify and provide a copy of the legal advice, there can be little doubt that the Decisions of the Licence Committee would have been the same given the concerns expressed had the Centres been able to respond and make submissions on suspension to the Licence Committee. Further one has to look at the whole process including the ability to challenge the Decisions before the Appeals Committee where the Centres have been given a full opportunity to respond and present their case. The Appeals Committee has been able for itself to go into the matters raised in the reports in some detail. It is for the Appeals Committee to reach its own decision. In view of the failures to notify and provide a copy of the legal advice, the Appeals Committee decided that in looking at matters afresh in the light of all the materials before it (including materials showing progress since the Decisions were made), it would not be appropriate to place the burden of proof on the Centres to establish that the Decisions should be overturned.

Issue (2): Consistency

(a) Submissions of the Parties

65. The Centres argue that the Authority is bound to follow the principles of best regulatory practice set out in section 8ZA of the 1990 Act. Those principles include the principle of consistency. It is said that in practice a series of critical non-compliances or concerns about the suitability of a PR and the sense of a lack of engagement, which has been found by the Licence Committee in this case, giving rise to their decisions, have not generally led to a suspension or revocation in other cases. And a schedule has been prepared comparing the present case with various other cases where critical non-compliances have been noted but without a suspension or a revocation.

66. It has also been pointed out that the reports themselves have not indicated that suspension or revocation should be applied in this case. The matter is put in this way in the skeleton argument on behalf of the Centres at paragraph 48,

> *"In relation to consistency, the Licence Committee appears to have paid no regard whatsoever to the approach taken in relation to other clinics. The Appeals Committee should, however, do so. The Licence Committee's decisions in relation to Centres 0015 and 0086 stand in marked contrast with the approach adopted by Licence Committees (with different memberships) and the Executive Licensing Panel in relation to centres with very serious safety concerns, criminal and regulatory breaches, serious adverse incidents, and serious patient complaints: see further exhibits KMJ 3-KMJ6"*

67. On behalf of the Authority, Mr Mehta says that this point really goes nowhere because you need to look at the facts of every specific case. The Licence Committee, he says, appreciated that suspension was a serious step and would involve concerns being raised by patients themselves and that there would be a real impact on patients and of course, a real impact on the Centres. So everything, he says, is context specific.

(b) Analysis

68. The Appeals Committee has considered the submissions of both sides and they do not consider it is a fertile exercise to look at the position of other centres and other cases. Of course, the principle of consistency does apply but we find there is no inconsistency, generally or on the facts of the present case, in the way that the Licence Committee has treated the Centres in the present case and the Licence Committee on other cases has treated other centres. It is all very fact specific. The Appeals Committee does take into account that the Inspectorate did not recommend suspensions in its reports and the materials provided to the Licence Committee and the Inspectorate has a great deal of experience in dealing with compliance issues.

69. This discussion and analysis on Issue (2) is helpful because it does mean that the Appeals Committee should be looking in a critical way as to whether this case is one where suspension is appropriate. That question arises when we considering Issue (4), whether or not suspension is a proportionate response to the matters that were before the Licence Committee in the form of the two inspection reports and the additional material before the Appeals Committee.

Issue (3): Reasons

70. The Committee was invited by Miss Richards KC for the Centres not to give a freestanding ruling on Issue (3) until Issue (4) had been considered. The third criticism is that the Licence Committee failed to give reasons or adequate reasons for the Decisions. It was submitted on behalf of the Centres that in effect the Licence Committee failed to provide any real reasons for taking the step of suspension and in effect against the recommendations of the Inspectorate, which whilst expressing significant concerns and non-compliances did not see fit to suggest revocation or suspension of licences.

71. In the light of the Appeals Committee decision on Issue (4) it was strictly unnecessary to come to a concluded view on Issue (3) as the Appeals Committee has decided to set aside the suspensions with effect from the date of this decision. In any event the submission is not made out when one examines the Decisions, which explain why it was decided to suspend the licences.

Issue (4): Should the Licences be suspended?

(a) Submissions of the Parties

72. The Appeal Committee now turns to the final issue, which is as to whether or not the suspension should be continued. In this regard the Appeal Committee have various options. One option is to remove the suspension altogether with nothing in its place. Another option is to leave the suspensions in place so they will expire on 13 May 2023. In between there is an option for us to suspend for a shorter period in order that certain steps can be taken, or to remove the suspensions but impose conditions in their place. The Appeals Committee has the power to impose conditions. It is a committee of the Authority under section 20 of the 1990 Act. The Authority does have the power to vary a licence under section 18A(5) of the 1990 Act. The Appeals Committee can impose special conditions under a licence. Even if that is not correct, the Appeals Committee can, and in this case will, direct the Authority, simultaneously with any direction that it gives, to make the same direction and impose conditions on the licence to the same effect.

73. Mr Mehta on behalf of the Authority accepted there has been much improvement particularly in the period since 13 February 2023 when the suspensions were notified to the Centres, and many of the issues have been addressed since the reports were formulated and indeed, even since the matter came before the Licensing Committee when it made its decisions on 26 January 2023 in respect of Centre 0015 and 1 February 2023 in respect of Centre 0086. However, Mr Mehta pointed out that this whole matter has required a huge amount of resources of the Authority and much of the compliance has been recent, and many of the areas of concern do not simply relate to administration

but they go further, and that they should not have occurred and some of them are serious. They took far too long to rectify. It is not necessary to repeat the points that Mr Mehta made in his skeleton argument as well.

74. Miss Richards KC on behalf of the Centres gave an impassioned speech to the effect that there is no imminent risk of harm within the meaning of the legislation and that the Licence Committee should never have imposed a suspension in the light of the assessment of the inspectorate, who have the day to day experience of dealing with the Centres and the standards to be expected there, and who did not themselves recommend the step of suspension. She said that the impact of a suspension is very, very serious. It is a draconian step and should only be taken in the most serious circumstances. She pointed to the consequences of the suspensions in the present case. Patients are upset, they may go elsewhere. The business has been affected in money terms. Staff morale has been affected. The longer that the suspensions continue, the more likely that the business will just evaporate, and staff will leave. They have had to cease activity and there is reputational damage.

75. She says if the suspensions continue, there will be no Centres in the long run and the Centres do provide an important public service mainly for NHS patients in the Kent area. She says it is not proportionate to have the suspensions for the reasons at paragraph 49 of her skeleton argument,

> *"In relation to the principles of proportionality and targeting only cases in which action is needed:*
>
> *a. Neither inspection report recommended the suspension or revocation of either centres' licence or suggested that there was an immediate and serious risk to the safety of patients.*

b. *Although they noted non-compliances, both inspection reports – based on the first-hand experience of the inspection team – recommended the renewal of the licence for Centre 0015 without conditions, and the continuation of the licence for Centre 0086. If either inspection had revealed concerns which justified immediate intervention through the suspension of either licence, it would have been highlighted by the inspectors.*

c. *The inspection reports for Centres 0015 and 0086 were not considered by the Licence Committee until 12 January 2023; the Licence Committee then adjourned; having reconvened and taken further decisions on 26 January and 1 February, no action was taken until 13 February 2023.*

d. *No responsible regulator would wait such long periods of time if rationally and properly concerned that there was an urgent and immediate need to suspend a licence to protect the safety of patients.*

e. *This course of events reflects the fact that there was no justification for the immediate suspension of the licences and that suspension was a disproportionate response to the concerns and non-compliances identified.*

f. *This was not a case in which the Authority, through its committees, could rationally conclude that there were any urgent safety or clinical concerns requiring the immediate suspension of the licences or that suspension was proportionate.*

g. *The minutes of 26 January and 1 February 2023 state that the decisions to suspend the licences were based on "…the risk to patient, gamete and embryo safety if the committee did not take action with immediate effect". In fact, the majority of concerns and non-compliances identified by the inspectors during their inspections of the two Centres are focused on the ability and competence of the Person Responsible and raise largely administrative and regulatory matters. These are, of course, important matters, but even the existence of critical areas of non-compliance (which are not uncommon in inspection reports) should not be equated with an immediate risk to patients/gametes/embryos that warrants suspension. The Licence Committee failed to consider rationally whether the non-compliances raised in the inspection reports constitute a risk to patient safety: rather, they have conflated the two."*

76. She stated that there is no imminent risk of harm to patients and she refers to the Licensing Guide at paragraph 4.2. She says that since the time the matter came before the Licence Committee, there are fewer ongoing non-compliances. She submitted that at the end of the day, the Licence Committee can review non-compliances as part of its

function under the section 19(4) licence process, which has yet to commence and may take some time to work through.

77. As regards the possibility of getting a new PR, she stated that it is not a solution to have a suspension and then say look for a new PR because it may not be possible to find a new PR in relation to a business that has got the stamp or the stigma of a suspension on its licence. [redacted]

(b) Analysis

78. The Appeal Committee has analysed each of the areas of non-compliance and its views are as follows.

Medicines Management – Centre 0015

79. In respect of the first area of practice and reference which is medicines management, the schedule for Centre 0015 deals with the area of practice, the action required and timescale for action, the PR response and the executive review. During the hearing, counsel for the parties as well as the LH and [redacted] of the Inspectorate all made comments on this schedule. It appears to this Committee that as regards the non-compliances which have been specifically addressed in relation to the medicines management and the controlled drugs SOPs, those SOPs had certain deficiencies and inaccuracies.

80. Those deficiencies and inaccuracies have all now been rectified in versions supplied by the Centre to the Authority on 17 March 2023. To that extent, the matter has been dealt with. However, the Centre does have a duty to ensure that these SOPs are correct. Not just today but when they took over. When the Centres were taken over by iTrust Fertility, they should have gone through the SOPs and rewritten them with care. What is disturbing from the Authority's point of view is that the Inspectorate had to repeatedly point out that there were defects in these documents. The documents would be returned and those returned documents would contain defects. They are now all remedied, so on one level, one can say well, it is all water under the bridge. On the other hand, the Authority says that the mistakes being seen show a lack of understanding and a lack of attention to detail, which in itself is disturbing. The Authority does expect the LH and the PR and the Centres to know what is required, and the sort of errors that they were seeing are not errors that one would expect a properly run centre to have.

81. Two particular examples are one where there is reference to the NMC Code of Professional Conduct in 2008 when that had been effectively rewritten by the Code in 2015. Secondly, there were references to medicines that were not being used at the Centre and positions which did not actually reflect what was going on. The problem with that is that the SOPs are live working documents and are specific for each centre. If they are not accurate, locums or new staff may take these documents at face value and make errors. Thus whilst one can say it has now been rectified, these are matters which the Appeals Committee will have to take into consideration in the round.

Quality Management System – Centre 0015

82. There were a number of issues, which cumulatively were of concern, and the Appeal Committee can see why they were correctly categorised at the time as critical matters because, clearly, they are important. However, all the matters have now been addressed. A significant number of documents had already been submitted. As of 20 February 2023, there were a total of 53 documents which had been reviewed and submitted. Since the update of 20 February 2023, a large number of documents have been received by the Authority, they have got all the appropriate wordings and the Authority is now satisfied that there is compliance in this regard.

83. Again, there may be a residual concern as to why these problems were in existence at the time of the investigation and have subsisted until today or until recently.

Staffing – Centre 0015

84. The Inspectorate was concerned by two matters in particular as set out in the audit findings. One is that the Centre had 11 staff members of whom only 45% were listed as fully competent. Secondly, there was a high, if not extraordinarily high, level of staff turnover. In the four month period of the audit, it was 36% of the workforce. The position is that the reference to 45.5% listed as fully competent is not a reference as to whether or not the relevant medical professional is qualified by their regulator or by their training but is fully competent as regards the systems and controls of each centre. Of course, one would not expect staff members who are not fully competent on the systems and controls of the specific centre to be dealing with patients or providing treatment unless they are supervised.

85. The Centres are small centres. In 2022, Centre 0015 had 190 cycles and Centre 0086 had 60 cycles. There was a full staff complement, there were for example two full time embryologists at each centre, there was one part time embryologist, there was a part time lab manager. At both centres there were two full time nurses and one full time doctor as well as a part time doctor at Centre 0086. There was a part time medical director, there was theatre staff on a sessional basis. The healthcare staff, there was a full complement, and the nurses were registered and full time. A list of staff members was submitted to the Appeals Committee at the hearing. The Centres should clarify whether that list related to the position on 22 March 2023 and, if it did not, should submit a revised list stating the current position to the Appeals Committee and the Authority by 10:00am on 5 April 2023.

86. The concern of the Inspectorate is not simply the number of people or percentages who are listed as fully competent. There was a whistle blower allegation of an inappropriate person signing off someone as competent when that person themself had not been assessed as fully competent. Further, there was an allegation that there was pressure to sign off people as fully competent when they were not ready for that. Those are matters of concern. What is happening now is that the PR will meet both the person signing off and the person being signed off to satisfy herself that the procedures and the training has been fully carried out properly and the right person has signed off and the person who has been signed off is suitable. That is something that will be put into a written memorandum to be supplied to the Authority by 24 March 2023.

87. As regards the high level of staff turnover. One can understand why in these times there has been a high staff turnover and particularly when one looks at the conditions at the

two Centres. These are Centres run previously by one of the big groups, BMI Healthcare. They have been taken over by iTrust Fertility and at that point of course there would have been some staff leaving. Some staff were probably happy with their last employer, and they want to go to maybe another centre run by them. They may not want to work for a small centre, or they may be worried about their job security. During the pandemic, there were hard times. People may reassess where they want to work in life. There is another provider who could potentially tempt staff away with a higher salary. It may well be that more people could disappear if the suspensions continue indefinitely as people think about job security. So the Appeals Committee can understand why the turnover is high, but it seems to be particularly high.

88. But then when one looks at what the figures are, perhaps they are not as concerning as might seem at first sight. The reference to 36% of the workforce in the previous four months at the Centres, which is nine members of staff leaving, only one of those was a clinical practitioner and that was a nurse who was dismissed. The other eight were administrative staff. Miss Richards KC on behalf of the Centres confirmed that the high level of turnover figures has improved and indeed, in the last quarter, the turnover figure is just less than 8%.

89. On the other hand, when there is defective documentation, the mistakes occurring that we have seen in the material, and the potential gaps in staff with a high turnover, there is a cause for concern. One cannot just wipe away those concerns. But it does seem that these concerns, if they are the only concerns, may be manageable. That is something we will have to assess at the end of the day, once we have looked at all the other aspects. There is a residual concern when you do have a high turnover of staff that things can

be dropped and mistakes made. The situation does appear to the Authority to be extremely fluid when it relates to staff positions and the turnover of staff.

Welfare of the Child Assessments (WCA) – Centre 0015

90. The Centre's own audit of the WCA identified in excess of 25 WCAs that had not been properly recorded. Although the assessments had been carried out and recorded in the doctor's own notes, they were not in the electronic format which was required to be submitted to the patients. The Appeal Committee consider that this matter should be regarded as something that should not be held against the Centre as of today. It may show a lack of proper systems and controls that it was allowed to happen in the first place, but it was picked up by the Centre's own audit and has now been remedied.

Legal Parenthood – Centre 0015

91. It appears that the Centre itself accepts that there were issues in relation to the practices and not getting the proper documentation signed. Legal parenthood documentation is absolutely critical because if it is not done, it leads to problems later on in life and then it could end up in the Family Division. An audit was carried out by the Centre, as required by the Inspectorate, and there were 24 patients within the relevant period who should have had the correct forms being done. 13 of these patients, that is 54% were fully compliant, but the rest were not. There were 11 patients who did not have correctly completed parenthood consent forms. The issues in relation to those were bottomed out and clarified by way of updates. The legal parenting review was provided, dated 17 February 2023 and there was a further update on 18 March 2023.

92. It is clear from what has gone on that further training was needed and it is said that there was further training in October 2022 that was provided to all the staff. Whether or not that training was adequate or covered all the things that were needed to be done may well be an issue in the future. It is disturbing that these issues arose in the first place. However, there is further training on legal parenthood fixed for 25 March 2023. The Centre should provide evidence that that staff training has been carried out and provide the course material so that can be reviewed by the Authority and any other course materials that they think that the Authority need to look at within 7 days of the training, so that it can then be assessed.

93. There does not seem to have been a root cause analysis to determine why the patients were asked to complete incorrect consent forms. However, it does seem that that work was done, at least to a certain extent as set out in the LH's second statement at paragraph 5 (f). So, in relation to this, it can now be regarded as now satisfactory, subject to the provision of the information that has been identified. There is a residual issue as to why all this happened in the first place and whether this is a problem that is symptomatic of a wider concern within the Centres that affects how safe the Centres are and whether or not there should be continued suspension.

Imports and Exports – Centre 0015

94. It was agreed to be quite a common problem that there are issues in relation to import certificates, authorisation and sometimes the right paperwork has not been completed or not completed properly. This is something that is not going to be held against the Centre in any major sense. Clearly it should have been done properly, but the particular banks that they were using are well known banks which have got a good reputation.

However, when the Centre applied for permission to import from Cryos International, the application contained missing information and was confusing. The Committee was told today that it has been redone correctly, and a copy of that re-submitted form needs to be provided to the Authority by 24 March 2023. Meanwhile, there are no patient safety concerns because, whilst the non-compliance remains active, the Centre is not permitted to import samples.

Traceability – Centre 0015

95. It was agreed that lack of consistency in relation to batch numbers of cultured data and laboratory consumables used in patient treatment is quite a common problem across the sector. An audit noted out of 40 patient records, only 77.5% were compliant with traceability requirements. A root cause analysis has been undertaken and corrective actions have been put in place. So far as the Authority is concerned, this non-compliance has been addressed and hence the same considerations apply as in relation to Imports and Exports (see paragraph 94 above), i.e. that it may have some relevance to the decision this Committee has to take, but it is not an overwhelming item.

Adverse Incidents – Centre 0015

96. It does appear that in the past not all complaints were reported to the Authority correctly or at all, which in itself is at least disturbing. But audits have now been performed and a review of the incidents been carried out and the most recent update shows that a review has been conducted of all the incidents and this non-compliance has been addressed. The lesson has been learnt by the two Centres that this is something that needs to be done properly and they do appear to now be dealing with it correctly.

Surrogacy – Centre 0015

97. There was an error in relation to complying with the various forms and consents in relation to surrogacy in the past. The Centres are not providing surrogacy treatments and an audit has been performed and a further revised surrogacy audit has been provided on 13 February 2023. This is considered to be satisfactory by the Authority. So this non-compliance has been addressed. If in the future, the Centres do decide to provide surrogacy treatments, they should give at least 28 days' notice to the Authority, who can then consider the position and ensure that they are satisfied that this is something that they should be providing.

Complaints – Centre 0015

98. It appeared to the Authority that there may have been a number of complaints received by the Centre from patients, which were not fully investigated and responded to, or that had appropriate corrective action. However, it is not accepted by the Centres that there was anything wrong with the way complaints were handled. The PR was asked to review all of the processes, and that process has now been completed. The Centres have explained that the review confirmed there was nothing wrong with the way complaints were handled. Therefore this is not a live non-compliance. Complaints handling is important, and the Centres should bear in mind in future that they should be investigated thoroughly, and any lessons are taken on board.

Consent to Storage – Centre 0015

99. New legislation came into effect on 1 July 2022. The Centre was not initially using the relevant consent forms or following the new regulations in their entirety. It is understood that this is a widespread problem in the sector as there was very little notice

of the new regulations and new forms coming into force. The matter has now been rectified. The residual point of concern is why it took so long to get it all rectified but it does not seem in the scheme of things that this is something that should be held against the Centres materially.

Record Keeping and Document Control – Centre 0015

100. There are two concerns in the report. The first is that there were several issues noted on inspection which are set out under information management. Six sets of patient notes had no offer of counselling documented, two cases where a patient partner's identity had not been verified, one case where a patient's partner had not completed a clinic registration form, and for one patient record there was an alert on the system regarding a consent form but no information to say what the alert is about. The second area of concern is the retention policy dates in the documents. The Centre did not have a documentary procedure to outline the patient donor records required for full traceability, which must be kept for a minimum of 30 years.

101. The response to this is that the Centre's retentions policy has been provided. It is now dealt with to the satisfaction of the Authority so that point has been closed down. As regards the other matters which are the substantive concerns, these non-compliances are material in one sense because they go to a general picture of non-compliance. On the other hand, one would expect on an inspection to find some examples of non-compliance, one does not expect 100% compliance on everything. It is a question of degree. No further action is required.

Air Quality – Centre 0015

102. It is accepted that the Centre was broadly compliant with the requirements. No further action is required, the matter has been fully dealt with and so it is effectively a matter of historic interest. It really does not go to the issues that this Committee has to decide on suspension.

Pre-emptive pre-operative assessment and the surgical pathway – Centre 0015

103. This relates to the emergency call bell system. It appears that the SOPs provide that this should be checked weekly. In fact, in December 2022 and January 2023, only two checks were performed, which is contrary to the SOP. Reasons have been given for that because the QM was on holiday. It is unsatisfactory that the SOP is not performed although it is understood why it was not performed. It may be that the SOP might need revision to take into account of that, but it is something that should not be held against the Centre in a general sense.

Satellite Agreements – Centre 0015

104. Compliant satellite agreements were not provided to the Authority. The Authority had to, repeatedly request that the matter be sorted out. They were sent unsatisfactory non-compliant agreements on 28 of July 2022 and defects were pointed out. The next version on 3 August 2022 again was defective and then again the version on 9 September 2022 was defective. Only on 23 September 2022, a compliant satellite agreement was provided. Clearly, that should have been provided sometime before and the Authority should not have to repeatedly follow up seeking something as basic as that. It takes up the Authority's time and it can give rise to a concern that whoever is

dealing with this does not really know what they are doing, which is one of the general concerns of the Inspectorate in their reports.

Person Responsible – Centre 0086

105. As regards Centre 0086, the critical area of non-compliance identified is in relation to the Person Responsible. The PR was new to the role in May 2022. The Appeals Committee does take into account the fact that those times were relatively turbulent. The pandemic had obviously caused havoc right across the sector. There were historical issues in relation to both Centres. The new PR inherited a difficult situation. At that stage, in relation to Centre 0015, when that report came out, the Authority was still trying to figure out where they were and they were being as understanding as they could, given the new position of the PR.

106. The concerns in relation to the PR are outlined in the report in relation to Centre 0086. Those concerns are pretty extensive. It is unnecessary to repeat here what is stated under Person Responsible in that report. It cuts across from page 492 to 496. They are points of concern and one is concerned that the incidents and the failings took so long to work out, and about the provision of inadequate responses. It is only really now that many of the action points which have been identified both in relation to Centre 0015 and Centre 0086 have been done. Indeed, in the last week a lot of further information has been provided. So we do consider that this is a serious matter particularly given the central role of a PR in the compliance process which is critical to good practice and safety aspects. Now, it may well be that there will be a new PR in place in a relatively short period of time and that it will be ensured that whoever is going to be the PR is someone who has had extensive experience of being a PR. That person must be a person who is

able to respond to difficulties and follow up things a lot quicker and in a lot more professional manner than the Appeals Committee has seen to date in relation to a number of the failings which by and large, are mostly historical. But it has really taken a long time. As a regulator, the Appeals Committee can see why the Authority does have concerns in the light of the things that we have already gone over, and all the matters set out in the report.

Consent to Storage – Centre 0086

107. See the comments in relation to Centre 0015 above.

Staffing – Centre 0086

108. See the comments in relation to Centre 0015 above.

Quality Management System – Centre 0086

109. It appeared that in the last two years the Centre had not audited the following processes: multiple birth rate, offers of counselling, confidentiality data protection, completion of travel questionnaire. There were also issues about document control. These are all relatively serious matters. Clearly, they should have been audited, which is one of the basic things that should have been done. The Committee accepts that these are historical matters in the sense that these were inherited and that it has taken time to work through these issues. But they now have been rectified with the last piece of evidence required as part of the QMS review on 20 January 2023. So the outstanding audits have now been completed.

Counselling – Centre 0086

110. Out of five patient records during the review of the inspection, for two of them there was no documentation of an offer of counselling having been made. It is important to have things like that in writing, for the protection of everyone. Clearly, that should not have occurred. But action has been taken implementing recommendations arising from that and it is said on behalf of the Centre that the counselling, the offer of counselling, was made orally but not recorded. It is impossible really to verify that unless one speaks to the patients, but this non-compliance appears to have been addressed.

Website Data – Centre 0086

111. It appears that there were issues in relation to the data published, in relation to how it was presented. It was unclear whether the data contained was for both Centre 0015 and Centre 0086 or just Centre 0015, and if the timeframes were a reflection of the actual numbers or only percentages and what data was being referenced. The PR was asked to rectify that by 19 January 2023. It is unclear when it was rectified. The Authority think it was rectified late and certainly after 19 January 2023. But it was done prior to 20 February 2023. There was a technical error in relation to the statistics in the table and the bar chart, but that was really an IT problem, which was not really the fault of anyone, so we do not hold that against the centre.

Conclusions

112. Looking at all those areas overall, the Appeal Committee is concerned about the running of the businesses under this PR. One of the conditions in relation to revocation of the licence under section 18(2) of the 1990 Act is the authority may revoke a licence, otherwise on an application, if (b) it is satisfied that the Person Responsible has failed

to discharge or is unable to discharge because of incapacity the duty under section 17, and (g) it ceases to be satisfied the person responsible is a suitable person to supervise the licence activity. The duties of the Person Responsible are under section 17. The failings that the Appeals Committee has seen, albeit most of them have been rectified, indicate to this Committee that the Person Responsible does not satisfy the requirements, and that, when one looks at the number of problems, the time it took to resolve, there is an overwhelming impression by the Appeal Committee that there is something seriously wrong with the way the business is being run and administered by the PR. The risk of imminent and serious harm is there what with so many deficiencies and the time taken to resolve them gives the distinct impression that some serious harm may be caused with such a lack of proper care and direction. Having proper record keeping, SOPs and other written guidance for the Centres is both basic and critical in establishing a safe environment at the Centres. But that is not the end of it because of the significant progress since the Decisions of the Licence Committee and the prospect of a new PR coming into place.

113. As regards the original Decisions of the Licence Committee, the Appeals Committee understands why those Decisions have been made. However at the end of the day, the Appeals Committee has to give its own decision and decide what is the appropriate way forward and what is required in the light of the further material and submissions before it. We do not consider that with appropriate special conditions, there is a risk of imminent harm within the meaning of section 19 of the 1990 Act. That means that if suitable conditions are in place, there should not be any continuing suspension.

114. We make the following directions therefore:

i. the above outstanding matters which we have directed should be done, should be done;

ii. a new PR should be put in place within a period of 6 weeks from today; and

iii. that there be no licensed treatment until conditions (i) and (ii) have been complied with.

115. There is one other matter that needs to be looked at. In the witness statement that has been filed on 22 March 2023 on behalf of the Authority, there is a reference to a complaint. The Appeals Committee do not hold that against the Centres in this determination, because the complaint has just been received, it has not been verified and it would be unfair to rely on it in circumstances where the Centres have not had the opportunity to investigate themselves. But we would invite both the Authority and the Centres to work together to get to the bottom of that complaint and, if rectification action needs to be done, then it should be done. It is not going to be part of any order, but we are recording that in our decision so there is a proper record that this is something that does need to be resolved, but not immediately.

F. DECISION

The decision of the Appeal Committee is therefore as follows:

1. The licences of Centre 0015 and Centre 0086 are no longer suspended.

2. The licences of Centre 0015 and Centre 0086 are varied, pursuant to section 20B and section 18A(5) of the Human Fertilisation and Embryology Act 1990, alternatively the

Authority is directed to vary pursuant to such provisions, by the addition of the following conditions:

a. The Centres shall provide to the Authority the following documents:

   i. Evidence of the legal parenthood training completed in October 2022 (to be provided by 5 pm on 24 March 2023).

   ii. Evidence of the further legal parenthood training arranged to take place in March 2023 (to be provided within 7 days of completion of the training).

   iii. Evidence of the completion of medicines management training by healthcare staff (to be provided by 5 pm on 24 March 2023).

   iv. A list of the current staffing arrangements (to be provided by 5 pm on 24 March 2023).

   v. A memorandum, to be sent by the current Person Responsible, to all healthcare staff, explaining that when staff are being signed off as fully competent, the Person Responsible will:

      - check that the person signing off the staff member as fully competent is suitable to do so;
      - satisfy themselves that the staff member is correctly being signed off as fully competent.

   vi. Proof of the amended ITE submission (to be provided by 5 pm on 24 March 2023).

   vii. Written confirmation that, in the event that the Centres decide to provide surrogacy treatments, they will give no less than 28 days' notice to the Authority of their intention.

b. The Centres shall appoint and contract with a new Person Responsible within 6 weeks of 22 March 2023.

c. The Centres shall not undertake licensed fertility treatment until each of conditions (a) i. to vi. and (b) above are completed.

Dated: 29 March 2023