Minutes of the Authority meeting on 22 January 2025

Members present	Julia Chain (Chair) Tim Child Frances Flinter Tom Fowler Zeynep Gurtin Graham James Alex Kafetz	Alison McTavish Catharine Seddon Christine Watson Geeta Nargund Rosamund Scott Anya Sizer Stephen Troup
Apologies		
Observers	Steve Pugh, Department of Health and Social Care (DHSC) (online)	
Staff in attendance	Peter Thompson (Chief Executive) Clare Ettinghausen (Director of Strategy & Corporate Affairs) Rachel Cutting (Director of Compliance & Information) Tom Skrinar (Director of Finance & Resources) Paula Robinson (Head of Planning and Governance) Dina Halai (Head of Regulatory Policy) Rebecca Taylor (Scientific Policy Manager) Caroline Pringle (Head of Licensing) Shabbir Qureshi (Risk and Business Planning Manager) Alison Margrave (Board Governance Manager)	

Members

There were 14 members at the meeting – 9 lay and 5 professional members.

1. Welcome, apologies and declarations of interest

1.1. The Chair opened the meeting by welcoming Authority members and HFEA staff to the first Authority meeting of 2025.

1.2. The Chair also welcomed observers and stated that the meeting was being recorded in line with previous meetings and for reasons of transparency. The recording would be made available on the HFEA website to allow members of the public to view it.

1.3. Declarations of interest were made by:

- Geeta Nargund (Clinician at a licensed clinic and licence holder)
- Anya Sizer (Freelance advisory work with a licensed clinic)
- Stephen Troup (Consultancy work within the fertility sector)

2. Minutes of the last meeting and matters arising

2.1. The minutes of the meeting held on 20 November 2024 were agreed as a true record of the meeting and could be signed by the Chair.

Matters arising

2.2. The Chair introduced the report and informed members that the four ‘matters arising’ items had either been completed or were brought forward to this meeting for consideration as an agenda item.

2.3. Members noted the matters arising report.

3. Chair and Chief Executive's report

3.1. The Chair gave an overview of her engagement with key stakeholders and her attendance at decision-making committees of the Authority.

3.2. The Chair informed members that she had attended the all-staff event in late November and that this had been a lovely event with high attendance from staff, including inspectors. The event had been a mixture of presentations and activities, and it was pleasing to see the significant level of happiness and engagement of staff.

3.3. The Chair spoke about attending the Fertility Conference 2025 which was held in Liverpool from 8-11 January. This is the main conference for the fertility sector and the session that she spoke at was well attended and her presentation had been well received with several good, engaging questions being asked. The British Fertility Society (BFS) had paid tribute to the work being done by the HFEA and attendees at the conference were generally complimentary about the HFEA.

3.4. The Chief Executive informed members that he and the Chair had attended the Progress Educational Trust (PET) Conference in early December and had spoken about the decision the Authority had taken in November about extending the time limit on embryo research.

3.5. The Chief Executive provided further information about the interviews he had given with the New York Times and Times Radio.

Decision

3.6. Members noted the Chair and Chief Executive's report.

4. Committee Chairs' reports

4.1. The Chair introduced the report reminding members of its new format, following the decisions made by the Authority in September 2024 regarding communicating licensing, regulatory activity and incident information. Members were informed that the HFEA website has a new page which shows the latest regulatory decisions. The Chair invited Committee Chairs to add any other comments to the presented report.

4.2. The Licence Committee Chair (Graham James) stated that the committee had met last week, and the minutes had not yet been approved. The committee welcomed three new members, who had observed a previous meeting. At the November Authority meeting it had been agreed to enlarge the number of committee members and this extra resilience was welcomed. He referred to the recommendations on law reform discussed at the November Authority meeting to propose a wider range of regulatory sanctions and how this would be of benefit.

4.3. The Statutory Approvals Committee (SAC) Chair (Frances Flinter) stated that the committee had also welcomed three new members, who had observed a previous meeting. She referred to the new format of the committee chairs' report and the enhanced information which is now provided about the SAC decisions. She explained the process for considering PGT-M applications and the benefit of having an independent peer reviewer and excellent reports from the Genetic Alliance. The committee consider all this information and when considering a condition may also consider

licensing additional similar conditions. She referred to the special direction applications for import or export of items.

4.4. The Chair stated that Genetic Alliance had been a speaker at the Fertility 2025 Conference and had mentioned the good working relationship with the HFEA. The Chair spoke of the importance of such a good collaborative relationship.

4.5. The Audit and Governance Committee (AGC) Chair (Catharine Seddon) informed members that the AGC had received the internal audit reports on Opening the Register (OTR) and Government Functional Standards (GFS) and had explored at length the difference of opinions on the findings. There were a number of audit recommendations which had not been accepted by management and the committee had proposed an amendment to the memorandum of working with GIAA. The AGC Chair provided information on the closure of audit actions, the audit plan for the preparation of the accounts, bi-annual HR report and the plans for CaFC publication. Members were informed that the committee had received training on assurance mapping from GIAA and this session had been attended by representatives from other small Health ALBs.

4.6. The Chair thanked all Committee Chairs for the reports and stated that committee papers and minutes are published on the HFEA website.

Decision

4.7. Members noted the Committee Chairs' reports.

5. Performance report

5.1. The Chief Executive introduced the performance report and reminded members that the Key Performance Indicators (KPIs) measure various operational aspects of the business conducted by the HFEA.

5.2. The Chief Executive informed members that the report includes data up to the end of December. Performance continues to be consistently strong across the KPI indicators with 13 green, two red and two neutral indicators. He provided further information on the two red KPI's and stated that these were not a cause for concern.

5.3. The Chief Executive referred to the HR KPIs contained in the paper and informed members that staff turnover remains green, at 9.2% and is within the 5 - 15% target band.

5.4. Staff sickness was the lowest it had been at 1.6%, the Chief Executive remarked that HR revisited the numbers in January to ensure that they were a reflection of the actual sickness in the reported period.

Compliance and Information

5.5. The Director of Compliance and Information referred to the publication of independent reports on the CQC (interim and full) and Ofsted and how both reports were critical of aspects of the inspection regime used in each organisation. As a regulatory body it was important for the HFEA to use these reports for self-refection to see where improvements could be made.

5.6. The Director of Compliance and Information remarked that whilst there are aspects of the CQC's and Ofsted's approach and responsibilities which are different to the work of the HFEA, there is much in the reports which is relevant and this allowed the HFEA to analyse where its strengths and weaknesses lie and where there are opportunities for improvement.

5.7. Members were reminded that the HFEA's inspection regime had undergone significant change in the last few years and these changes were independently audited by GIAA on two separate occasions and the regime as a whole was independently assessed by the Public Bodies Review of the HFEA in 2023.

5.8. The strengths identified by the review were the expertise of the HFEA's inspectors and clinical governance team, a robust regulatory regime which ensure clinics are inspected in a defined timeframe and PRs having a named inspector to communicate with. The HFEA also benefits from strong oversight from the Authority and the accountability meetings with the sponsor team at DHSC.

5.9. Opportunities for improvement were identified regarding the IT platform and the HFEA had prioritised replacing its licensing IT system and clinic portal over the next 18 months. Inspectors had also received specific training on how to identify stress in individuals on inspection and how to handle these situations calmly, confidently and with empathy.

5.10. A learning point raised in the review of Ofsted was the importance of respectful and productive engagement between inspectors and those inspected. The Director of Compliance and Information reminded members that the HFEA asks for direct feedback from clinics to help it gauge whether this is the case for HFEA inspections. Survey findings for the first quarter of 2024 found that 89% of responses were positive about the support provided by inspectors at inspection. In addition, 80% of respondents strongly agreed/agreed that the inspection visit had promoted learning and improvements to the way that they work.

5.11. Members were informed that an article explaining the HFEA's analysis and reflection will be published in the next Clinic Focus newsletter.

5.12. The Chair thanked the team for the analysis. It was reassuring for the Authority to note the strengths identified and the new training for inspectors will assist even further in the positive relationships with clinics.

5.13. The Director of Compliance and Information informed members that the scoping exercise which is the new essential part of the cyber assessment framework (CAF) aligned with DSPT is in draft form and will be circulated to the Information Governance steering group before final agreement.

5.14. During 2024 the OTR team had provided information to almost 1,300 people and the waiting list is at the lowest it has been since the first quarter of 2023/2024, standing at 972.

5.15. The waiting times for all types of OTR have gone down in the last 3 months but applications continue to be received at the rate of 70-90 a month.

5.16. The Chair congratulated the OTR team for managing the situation in a systematic way to reduce the waiting list.

Strategy and Corporate Affairs

5.17. The Director of Strategy and Corporate Affairs stated that the family formations report was published at the end of November 2024 and all major news outlets had covered it. The national patient survey report is due to be published in March and the next Fertility Trends report will be published later this year.

5.18. The new data research newsletter had just been issued and included details of the webinar that the HFEA will host in early February regarding accessing the UK national fertility register for

research. 80 attendees had already registered for this event. A poster presentation of the latest data from the family formations report was showcased at the Fertility Conference 2025.

5.19. Members were informed that the recruitment process for the Patient Engagement Forum (PEF) had closed and that the HFEA team looked forward to working with the new members of this forum.

5.20. The Director of Strategy and Corporate Affairs welcomed Caroline Pringle, Head of Licensing, who had joined the HFEA recently. Members were reminded that Licensing will now function as a distinct team under her directorate.

5.21. The Director of Strategy and Corporate Affairs spoke of the work being done to implement the recent changes in law relating to screening in fertility treatment. The changes meant that enhanced screening is no longer necessary for couples having reciprocal IVF, and people who are HIV+ with an undetectable viral load can now donate their gametes for use in treatment as 'known donors'. To implement the second change a licence update is required and already four applications from clinics have been processed. We will be looking at how we can make it easier for patients to find clinics with these licences on our website.

5.22. Members were informed that the next SCAAC meeting will be held in early February and will consider a number of topics including health outcomes in children conceived by ART, impact of stress on fertility treatment outcomes and prioritisation of topics for horizon scanning.

5.23. The Chair on behalf of the Authority extended a warm welcome to Caroline. The Chair remarked that the HFEA holds a wealth of wonderful data, and it is encouraging that this is made available for research projects and interest in the data is shown by the high number of registrations for the webinar. The Chair stated that at the Fertility 2025 Conference the BFS had spoken of the use of the HFEA's data in their research.

Finance, Planning and Technology

5.24. The Director of Finance, Planning and Technology informed members that an overspend of £132,000 is being forecast, before taking into account any accounting adjustments such as potential provisions reversals. It has been agreed with the department that unused Grant in aid (GIA) will be returned and he stated that this has been factored into the forecast.

5.25. The Director of Finance, Planning and Technology spoke of the thorough procurement exercise for the Epicentre replacement. As this had taken longer than first anticipated, the timescales for the project had changed with the bulk of work commencing in 2025/26; therefore, not all the additional GIA funding had been drawn down.

5.26. Members were informed that whilst the DHSC Finance Team were supportive of rolling over the GIA funding there were no guarantees, and it may be necessary to increase fees next financial year to fund this project. The Director of Finance, Planning and Technology informed members that the 2025/26 budget would be brought to the next Authority meeting.

5.27. The Director of Finance, Planning and Technology informed members that Sophie Tuhey will join the HFEA as Head of Planning and Governance in early February and recruitment of an IT Project Manager for the Epicentre project is currently underway.

5.28. The Planning and Governance Team had been busy with the preparation of the new Strategy, managing the review of committee effectiveness and development of the new strategic risk register.

5.29. Members were informed that the business continuity and disaster recovery plans were made available to staff via the Hub and an exercise is planned for later in the year. Security testing will also take place later in the year.

5.30. The Chair reminded members that as of 1 January, Tom Skrinar, was employed full time by the HFEA and his remit had been extended to include technology and planning. Members would be kept appraised of the developments of the Epicentre replacement project.

5.31. In response to a question the Chief Executive explained the difference between the PRISM and Epicentre projects. He spoke of the realisation and benefits of PRISM and that funding and staffing is now in the on-going maintenance phase; some resources will be redirected to assist with the Epicentre project and there may be opportunities for some savings but this would be limited.

5.32. In response to a question regarding business transformation and the Epicentre project the Chief Executive informed members that the main internal users of Epicentre were the inspection and licensing teams and these had been involved in the procurement process and will be heavily involved in the testing phase.

Decision

5.33. Members noted the performance report.

6. Strategic Risk Register

6.1. The Risk and Business Planning Manager introduced the paper and reminded the Authority that they review the strategic risk register (SRR) twice a year.

6.2. Members were informed that the Audit and Governance Committee (AGC) had reviewed the register at their December 2024 meeting and the version before the Authority includes amendments suggested by the AGC.

6.3. The Risk and Business Planning Manager summarised the recent changes to the SRR as:

- Commercial: risk title has been amended, following AGC feedback, to better reflect the risk.
- Financial: the sub risk around DHSC spending controls remains following the latest DHSC update in September 2024.
- Governance: this risk will be reviewed in its entirety as part of the SRR review accompanying the new strategy, planned for the June AGC meeting. The sub risk about reviews of other regulators has been updated.
- Information: this risk will be reviewed in its entirety as part of the SRR review accompanying the new strategy, planned for the June AGC meeting.
- Information 2: risk updated to reflect AGC's comments about pace of delivery and the impact from DNA testing. Minor updates made to the risk as the OTR system is now getting more stable and reference to the waiting list added.

- Operational: this risk has been updated with the procurement and delivery timelines for Epicentre. The CaFC sub risk has been amended with an interim CaFC being considered.
- People: this risk will be reviewed in its entirety as part of the SRR review accompanying the new strategy, planned for the June AGC meeting.
- People 2: this has been closed at the recommendation of AGC.
- Reputational: AGC considered the primary risk to be around the discussions Authority is willing to engage in which may have reputational impact.
- Security: minor updates had been made.

6.4. The Risk and Business Planning Manager informed members that the SRR will be completely revised to align with the new strategy and this will be presented to the AGC in June and then brought to the July Authority meeting.

Decision

6.5. Members noted the strategic risk register.

7. Strategy 2025-2028

7.1. The Chair introduced the item stating that like all public bodies the HFEA is required to agree a strategy which sets out the HFEA's vision and provides a framework for key activities. The Chair commented that the draft strategy had come to the Authority in various iterations with members having had plenty of opportunities to comment on it.

7.2. The Chair thanked the Head of Planning and Governance for her hard work in creating this strategy and noted that the document before the Authority reflects the discussions with members.

7.3. The Head of Planning and Governance introduced the paper and reminded the Authority of the process for preparing the proposed new strategy and the input and feedback which had been sought from Authority members, staff and stakeholders.

7.4. The Head of Planning and Governance explained the changes to the strategy since the Authority last considered this item in November 2024.

7.5. Members were reminded that the goal for this strategy is to ensure a well-regulated fertility sector, which is trusted by patients and the wider public, that the information provided is useful and accessible and that biosciences that lead to innovations in treatment can flourish, within an ethical framework.

7.6. The vision for the period 2025-2028 is "regulating for confidence: – safe treatment – right information – supported innovation". The main strategic themes are regulating a changing environment and supporting scientific and medical innovation.

7.7. The Head of Planning and Governance stated that the HFEA's goal of achieving law reform in the short to medium term remains central, but that the possible timing of this work is unknown. Any announcement of a parliamentary timetable for this work would necessitate a fresh look at strategic priorities, since focus would need to shift towards legislative change and implementation. Therefore, a degree of flexibility around how both the strategy and corresponding business plans would be delivered needs to be kept.

7.8. Members were informed that the Corporate Management Group (CMG) will be considering what these plans might look like in the next couple of weeks and the 2025/26 business plan will be brought to the March Authority meeting.

7.9. The Head of Planning and Governance stated that another unknown is the Government's new 10-year plan for health, which is likely to be published this Spring. The HFEA will need to ensure that its strategy and business plans are appropriately aligned with the 10 year plan.

7.10. The Head of Planning and Governance stated that if any final editorial changes are needed in response to events just before publication, in April 2025, then these will be communicated to members via email.

7.11. Several members congratulated the Head of Planning and Governance on the strategy and the priorities identified in the paper.

7.12. A member questioned whether the data from the recent national patient survey will be used to influence the HFEA's work.

Decision

7.13. The Authority approved the strategy for 2025-2028.

8. Law Reform – Stem cell-based embryo models (SCBEMs)

8.1. The Chair spoke about the suite of proposals on law reform which the HFEA had published in 2023. Within these proposals were several items which required further work and therefore these two agenda items are brought to the meeting today for debate and decision. As an expert regulatory body, it is expected that the HFEA advises the Government on proposed changes to the law.

8.2. Rosamund Scott informed the Authority that she is currently the Chair of the UK Stem Cell Bank (UKSCB) Steering Committee. She also advised that she was previously a member of the working group that drafted the first UK code of practice for the governance of stem cell-based embryo models (SCBEMs), first published in July 2024, but that, upon her appointment as a member of the HFEA in October 2024, she had left the working group. Frances Flinter informed the Authority that she had been a member of the Nuffield Council working group on SCBEMs.

8.3. The Head of Regulatory Policy introduced the paper and stated that despite their biological similarity to embryos, SCBEMs are not explicitly regulated by the HFE Act. The paper before the Authority looks in more detail at this policy area and makes recommendations for change.

8.4. Members were informed that the Scientific and Clinical Advances Advisory Committee (SCAAC) considered the technical issues associated with SCBEMs at their October 2024 meeting.

8.5. The Head of Regulatory Policy referred to the paper and stated that the Authority is asked to consider the questions in section seven.

8.6. The Chair of SCAAC summarised the committee discussions and agreements that SCBEMs should be regulated in their own right and that there had been absolute agreement that these should not be transferred to humans. He spoke of the difficulties in defining a fixed upper limit and that different types of models would require different limits.

8.7. Members discussed that whilst SCBEMs do not have the same special status as human embryos they (particularly the more complex models) should still be treated with respect and therefore regulation was necessary.

8.8. Members discussed the difficulties of defining an upper fixed limit for these models due to the way that SCBEMs develop, meaning that their age in days does not equate to the same developmental point as live human embryos (SCBEMs do not have a clear day zero to equate to the fertilisation of an egg by a sperm). It was suggested that any time limit needs a description of the development stage reached, rather than a specific timing.

8.9. In response to a question the Chief Executive explained that the term 'sandboxing' means a regulatory regime that allows conditional approvals in tightly controlled circumstances. It is an idea that has been used in a variety of regulatory environments and is not unique to bio-sciences regulation.

8.10. Members discussed whether it would be the HFEA who would regulate SCBEMs or the Human Tissue Authority (HTA) which regulates the use of human tissue and cells for medical treatment. The Chief Executive stated that this was ultimately a decision for government, but the debate so far had focused on the HFEA being the regulator for both principled and practical reasons.

8.11. Members discussed the research opportunities that SCBEMs could provide for what is considered the "black box" of research and concluded that the learning potential is great.

8.12. Members discussed the Oversight Committee proposed in the Code of Practice for the Generation and Use of Human Stem Cell-based Embryo Models, and endorsed in the Nuffield Council report and what role the HFEA could take in this committee, resources allowing.

Decision

8.13. The Authority agreed the following:

- that there was a case for recommending that SCBEMs are subject to some form of statutory regulation.
- that SCBEMs should be regulated on their own terms, separately from human embryos.
- that it should be explicit in law that SCBEMs must not be transferred to a human.
- that having a fixed upper limit on embryo model culture time is important and will be necessary in the future, but that this limit could not be fixed now and should be informed by consensus over time.

Action

8.14. The HFEA to continue to discuss with DHSC and Government the law reform proposals.

9. Law Reform – In vitro gametes (IVGs)

9.1. The Scientific Policy Manager introduced the paper and explained that in vitro gametes (IVGs) are gametes (sperm or eggs) created in a laboratory using cells. The cell source can vary and include immature germ cells, embryonic stems cells and somatic cells (e.g. skin cells).

9.2. The cells are reprogrammed to become functional egg or sperm cells (gametes) through the process of in vitro gametogenesis (IVG). The Scientific Policy Manager explained that IVGs have

the potential to vastly increase the availability of human gametes for research and, if proved safe and effective, to provide new treatment options for people experiencing infertility.

9.3. Members were informed that in many countries there is interest in the use of IVGs for research and clinical use, and research is being undertaken in both public and private institutes in the UK, Japan, the USA, the Netherlands and Belgium. To date though only the Netherlands and Norway have addressed IVGs in legislation.

9.4. The Scientific Policy Manager stated that the HFEA and other regulators are looking at using 'sandboxing' to develop and test new approaches to regulating innovations like IVGs and that the HFEA has engaged with UK Regulation Innovation Office (RIO) and the Regulatory Horizon Council (RHC) on this. The RHC is now planning a regulatory sandboxing project using IVGs as a test case and the HFEA will be involved with this initiative.

9.5. Members were informed that the Scientific and Clinical Advances Advisory Committee (SCAAC) considered the issue of IVGs at their October 2024 meeting

9.6. A member explained the difference between single and 'solo parenting': in single (social) parenting the sperm and egg come from two different people but solo parenting would involve the sperm and egg coming from the same person (through in vitro gametogenesis). The high risk of recessive conditions through solo parenting was explained.

9.7. The Scientific Policy Manager explained "multiplex parenting" which is where two couples create embryos which are then used to make in vitro gametes to create a further embryo. Any resulting child would be the genetic grandchild of all four "parents", and its genetic parents would be the embryos used. As long as the "parents" are not closely genetically related, this does not pose greater risk of genetic disorders, but it raises many social and ethical questions.

9.8. The Chair of SCAAC summarised the committee discussions and agreements regarding IVGs. He spoke of the significant financial investments which is being made in this research because of the huge potential it could offer.

9.9. In response to a question the Chief Executive explained the potential use of secondary legislation and how this could be used to future proof the Act. He referred to how secondary legislation was used when the Act was last amended in 2008 with respect to mitochondrial donation.

9.10. Members discussed that whilst the ultimate aim of IVGs is to produce children who are genetically related to their parents, it must be done safely. The risk of serious inherited diseases, which had a high chance of arising through 'solo parenting', was an extremely serious concern for members.

9.11. Members discussed that IVGs may provide solutions in the future for people with fertility problems and potentially for at least some of those in same-sex relationships but that regulation was necessary to ensure patient safety.

9.12. Members discussed the current prohibition on the clinical use of IVGs as they are not 'permitted gametes' under the HFE Act. Consideration was given to whether a clear statement to that effect would negate the need to specify that they cannot be transferred into a human.

9.13. Members highlighted some ethical matters in relation to IVGs including the possible future impact of IVGs on the special status of the human embryo.

9.14. Members discussed the potential for IVGs to enable parents to have a genetically related child, should they wish, when they could not otherwise do so. One member noted that, from an ethical

and legal point of view, there are strong arguments supporting the right to have a genetically related child, and therefore that there is a strong case to legalise IVGs in the future, provided that research establishes that their use is sufficiently safe. It was noted that the legal arguments are supportable with reference to the European Convention on Human Rights and other international law.

9.15. Members asked for clarity in relation to the current (implicit) ban on clinical use of IVGs and future legislation. The Chief Executive explained that this was a matter of timing. It was necessary to close any current loopholes now and to maintain a ban on clinical use, then to develop a workable regulatory regime for clinical use in due course.

Decision

9.16. The Authority agreed the following:

- to recommend that IVGs are subject to some form of statutory regulation in time.
- that secondary legislation would be one means regulating the clinical use of IVGs in time.
- that there should be a clear statement that “IVGs are not permitted gametes” to avoid any confusion about current legislation.
- that the biologically dangerous and socially distasteful use of IVGs like ‘solo parenting’ should not be permitted.
- that it was premature to decide whether IVGs should be permitted for ethically complex clinical use, and this should be kept under review as the science develops.

Action

9.17. The HFEA to continue to discuss with DHSC and Government the law reform proposals.

10. Any other business

10.1. The Chair thanked everyone for their active participation in the meeting which had considered a full and detailed agenda.

10.2. There being no further items of any other business the Chair closed the meeting and reminded members that the next Authority meeting will be held on 12 March 2025.

Chair’s signature

I confirm this is a true and accurate record of the meeting.

Signature

Chair: Julia Chain

Date: 12 March 2025