

Person Responsible key behaviours and role description

There is no more important role than that of Person Responsible (PR) for the successful running of a UK fertility clinic. The HFEA Code of Practice clearly sets out the statutory requirements and responsibilities placed on all PRs. However, we know from the past 25 years working closely with PRs that there are certain behaviours and leadership qualities that successful PRs demonstrate, beyond what is set out in statute.

This document sets out the changes we expect to see of our leaders. It brings these behaviours and responsibilities together to help support future and current leaders in this pivotal role.

Key behaviours

The person responsible must demonstrate an ability to lead. They must be honest, show integrity and have an ability to show insight into difficult situations. We expect to see a commitment to continuous improvement.

The PR must be able to demonstrate the following key behaviours:

- Providing vision, direction and leadership to enable their centre to deliver high quality patient care
- Acceptance of HFEA policy, commitment to keeping up to date with policy changes and the ability to communicate these with staff accordingly
- Taking ownership of problems and proactively leading on resolving issues, working together with all key staff and the HFEA when necessary
- Experience of working in the fertility sector with an understanding of the clinic's core business
- Managing and developing their staff to fulfil their duties and responsibilities, ensuring appraisals are undertaken and individual development and training opportunities are provided and relevant.
- Ensuring staff are competent in their regulatory responsibilities ie, consent taking
- Leading the clinic's core values and behavioural expectations to secure a positive and engaged culture between the organisation, staff and the HFEA
- Providing a means for timely and accurate disclosure of information, including as escalation route for issues
- Exhibiting a drive, energy and enthusiasm and resilience to drive through and achieve end results and improvement
- Ability to communicate ideas and to generate action and delivery through others
- Demonstrating strong commitment to achieve equality and diversity in the provision of staffing and services
- Being accessible and visible to staff in the clinic and engaging with staff in an organised and transparent manner. Ensuring open lines of communication internally.
- Encourage a culture of openness and honesty within their department and ensuring duty of candour to patients
- Probity, particularly when the PR has a personal financial interest in the centre

To support the changes we expect to see, the PR Entry Programme test will change accordingly and HFEA initiatives will provide additional leadership support, including a buddying system, quarterly non-compliance reporting and leadership events.

Role description

All UK fertility clinics must have a person responsible (PR) who must comply with the law and has overall responsibility for ensuring the clinic and its staff also comply with the law.

The role description sets out what we expect to see from a PR. This document can be used to help identify and recruit future leaders to the role of PR. If you are an existing PR you may wish to use this to highlight your responsibilities to gain the necessary support (eg, from your NHS trust or from senior management) to enable you to effectively fulfil your duties. This also highlights the serious consequences for your centre, and for your patients, if you are not able to perform your role.

The person responsible

The person responsible has ultimate responsibility for ensuring that all licensed activities are conducted with proper regard for the regulatory framework that governs treatment and research involving gametes or embryos. The PR is in charge of overseeing the clinic's activities and is responsible for leading and developing its staff. The PR must ensure staff have an appropriate level of training to fulfil their roles.

PRs must comply with inspections and be 'inspection ready' at all times. They must cooperate with inspectors whilst they are carrying out an inspection, lead on taking appropriate action in response to matters that are raised in the course of inspections, and comply with all regulatory requirements. A core feature of a good PR is someone who can recognise when things have gone wrong and take responsibility. It is crucial therefore that incidents are handled well. They're also responsible for ensuring paperwork, fees and data are submitted to the HFEA in a timely manner.

With demonstrable leadership capability, the PR must have highly developed interpersonal and influencing skills. Given the breadth of the role, the PR will need to be adept at moving between operational, strategic and regulatory matters with due regard for patient care and safety. The post holder will also have the ability to identify areas for improvement and to successfully implement change and thus deliver improvements. Their ultimate goal should be to ensure patients receive the highest quality of care.

Key statutory responsibilities

The person responsible must have responsibility for ensuring that:

- centre staff are suitability qualified and have the necessary training and experience to perform their role
- the activities are carried out on suitable premises
- the centre uses proper equipment
- proper arrangements are made for the keeping of gametes, embryos and human admixed embryos
- proper arrangements are made for the disposal of gametes, embryos or human admixed embryos that have been allowed to perish
- suitable practices are used in the course of the centre's activities
- the conditions of the licence are complied with
- conditions of third-party agreements relating to the procurement, testing, processing or distribution of gametes or embryos are complied with
- the HFEA is notified and provided with a report analysing the cause and the ensuing outcome of any serious adverse event or serious adverse reaction.
- the requirements imposed by section 31ZD of the Human Fertilisation and Embryology Act 1990 (as amended), in relation to the provision of information to donors about resulting children, are complied with

- ensuring the centre's staff co-operate fully with inspections and investigations by the Authority or other agencies responsible for law enforcement or regulation of healthcare
- ensuring fees are paid to the Authority within the timescale specified in Directions or in writing
- ensuring data about certain specified activities and register data is reported to the Authority accurately and by dates specified in Directions or in writing
- ensuring requests for information and/or documents from the Authority are responded to promptly, and
- notifying the Authority immediately if s/he becomes aware of any decision or proposal to close their centre.

The above requirements are mandatory and are set out by the Human Fertilisation and Embryology Act 1990 (as amended), in the [HFEA Code of Practice](#), and in [HFEA licence conditions](#).

Key regulatory responsibilities

The person responsible is responsible for:

- strategic and operational matters
- compliance
- leadership
- performance management
- accountability
- confidentiality and compliance with relevant data protection and GDPR requirements
- health and safety
- risk management
- safeguarding and raising other concerns
- incident reporting and handling of complaints

The role of the person responsible should include:

- maintaining an up-to-date awareness and understanding of legal obligations
- responding promptly to requests for information and documents from the HFEA
- co-operating fully with inspections and investigations by the HFEA or other agencies responsible for law enforcement, regulation or healthcare, and
- informing the HFEA of any change to their professional registration. The HFEA should be informed if the PR is subject to any disciplinary proceedings by their employer, any investigations which might result in criminal sanction or any regulatory or fitness to practice proceedings brought by any other regulators or professional bodies.
- Clear authority from and direct communication with more senior staff in their organisation (i.e. NHS Trust board level) to support them in their role

The person responsible should ensure that all staff:

- maintain an up-to-date awareness and understanding of their legal obligations
- possess the competencies necessary for their role and have access to learning and professional development
- are encouraged, as appropriate, to contribute to discussions and decisions about improving patient care.

The person responsible is accountable for the overall performance of the centre and to that end should ensure that:

- there are clear responsibilities, roles and systems of accountability to support good governance
 - appropriate action is taken following feedback from the HFEA, staff and patients. This includes taking action on outcomes of inspections, audits, incident investigations, patient complaints and feedback.
 - The HFEA expects the person responsible to take any necessary specialist advice to allow them to run the centre professionally.
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How do I prepare for this role?

To prepare for this role the person responsible should:

- Use the resources around them, courses and tools. This includes familiarising themselves with the HFEA Code of Practice, HFEA consent forms, HFEA Directions, Licence Conditions, relevant primary and secondary legislation, professional body standards and guidelines
 - Attend relevant courses, meetings and conferences to receive up to date developments in the field of assisted reproduction and patient care
 - Successfully complete the Person Responsible Entry Programme (PREP) on becoming a PR and use it for continuous learning
 - Regularly use the clinic portal, read clinic focus articles and relevant updates, including training material provided by the HFEASeek advice from other experienced PRs and draw upon best practice
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Delegation, support and succession planning

Can I appoint a ‘Deputy’ PR?

The law does not permit a PR the ability to delegate their responsibilities to a deputy or deputies. It is crucial that as PR you remain accountable and ultimately responsible for ensuring that all licensed activities at your centre are conducted with proper regard for the legal and regulatory framework.

It is important that you have trained staff that you can appropriately delegate to and who can support you in your role. For example, some find having a dedicated Quality Manager helps them perform their role more effectively. Where you feel you need additional support to enable you to fulfil your regulatory requirements seek support from your HFEA Inspector.

As PR you should also be thinking about succession planning and taking the necessary steps to prepare someone else to take up this role if you should unexpectedly not be able to fulfil your duties (ie, due to illness) or decide to leave your position. Staff should have an understanding of your responsibilities as PR and where appropriate feel empowered to take on this role. Involving staff in activities such as inspections, where appropriate, can build resilience within your clinic. Frequent competency assessments will also help you identify the knowledge and the dexterity of your staff.

Person specification

	Essential	Desirable
Leadership	<ul style="list-style-type: none"> can demonstrate an ability to lead. They must be honest, show integrity and have an ability to show insight into difficult situations. has provided vision, direction and leadership to achieve strategic goals and objectives 	experience of managing and developing a team in the fulfilment of their duties and responsibilities
Qualifications	<ul style="list-style-type: none"> possesses a diploma, certificate or other evidence of formal qualifications in the field of medical or biological sciences, awarded on completion of a university course of study, or other course of study recognised in the United Kingdom as equivalent, or is otherwise considered by the Authority to be suitably qualified on the basis of academic qualifications in the field of nursing has successfully completed the PREP 	
Experience	<ul style="list-style-type: none"> has at least two years' relevant practical experience understands the scientific, medical, legal, social, ethical and other aspects of the centre's work to be able to supervise its activities properly. the managerial authority and capability necessary to perform their duties. 	
Communication	<ul style="list-style-type: none"> can communicate ideas and to generate action and delivery through others has highly developed interpersonal and influencing skills 	