

QM 1.0 Scope of Quality Management System

1.1 Company Background

1.1.1 Midland Fertility Services was established in 1987, in September 2000 the present Board (*ref figure1 (page 2): Organisation Chart*) bought into MFS, and took sole executive responsibility for the management and strategic direction of the organisation. Shares in the company are owned by the Board, current and ex-employees and an Employee Benefit Trust.

1.1.2 Text archived

1.1.3 Midland Fertility Services is located in Aldridge in a modern office block covering some 9,000 square feet. Working facilities are well-equipped, expansive and modern, comprising: offices, counselling rooms, reception areas, nurses work station, laboratories, treatment rooms, a cryo store, staff room, training/ / board room, store rooms.

1.1.4 The staff (*ref figure1 (page 2): Organisation Chart*) include obstetrician/gynaecologists, fertility nurse specialists, embryologists, bio-medical scientists, support staff, and independent counsellors. Staff are recruited and trained to an acceptable level of competence in accordance with this quality management system which requires compliance with the regulatory requirements of the HFEA, CQC Health and Safety Executive and the requirements of other quality, statutory and professional bodies as appropriate, to include by example but not exclusively ISO9001, CPA, IBMS, NMC, RCOG, BFS, HPC, ACE etc. Induction, training and ongoing professional development are provided to promote the knowledge and skills of staff.

1.2 Company Activities

1.2.1 Midland Fertility Services provide a comprehensive and specialised programme of tests and treatments for sub-fertility including “in vitro” fertilisation services and a service for fertility preservation.

1.2.2 Treatments are either self funded by the patient or by the NHS. MFS operating as a preferred purchasing organisation has contracts with Primary Care Trusts. Additionally, it will provide one-off treatments on an extra-contractual basis for patients funded by NHS Trusts, with whom it has no formal contractual agreement. Whilst the company’s clients reside mainly in the Midlands, they have a client base throughout the UK, Middle East, Asia, Europe, Africa and America.

1.2.3 The clinical process involves counselling, treatment and aftercare; administration of drugs; examination of clients and tests (including steroid hormones, peptide hormones, blood borne viruses and semen analysis); laboratory fertilisation and transfers; cryopreservation of oocytes, semen, and testicular tissue; and further care either directly or through the clients GP or consultant. The process is not always successful and so is repeated, when necessary.

1.2.4 Three separate functions are provided by the laboratories at Midland Fertility Services:

1.2.4.1 Semenology - routine seminal fluid analysis including strict morphology assessment by Kruger criteria. Suggesting appropriate treatments based on current semen analysis. Preparation of semen for use in IVF and IUI by ‘Sperm Prep’ density gradient centrifugation. Cryopreservation of semen for use in a Donor Insemination program or client storage. Preparation and culture of epididymal sperm and testicular tissue for use in ICSI and for cryopreservation.

1.2.4.2 in vitro Fertilization/Embryology - qualitative assessment of cumulus oocyte complex and oocyte maturation, assessment of granulosa maturation, preparation of insemination chambers, assessment of normal and abnormal fertilisation, in vitro culture of gametes and embryos, assessment of embryo quality for embryo transfer and cryopreservation, cryopreservation of embryos from pronuclear to blastocyst stages, thawing of cryopreserved embryos for embryo transfer. Culture of embryos to the blastocyst stage of development in order to reduce the order of multiple pregnancies. Intra-Cytoplasmic Sperm Injection using ejaculated and surgically retrieved spermatozoa. Embryo Hatching using Acid Tyrode media to breach the zona pellucidae of three day old, 8 cell embryos. Oocyte Cryopreservation of MII oocytes using both the slow rate freezing and vitrification technique for patients whose future fertility may be at risk.

1.2.4.3 Blood Laboratory - analysis of blood samples using an automated analyser (Abbott AxSYM) for the following tests: HIV I & II, HBsAg, HCV, CMV IgG, E₂, βhCG, Rubella, FSH, LH. Anitmüllerian hormone (AMH) is tested for via a manual ELISA technique.

1.2.5 Other tests and investigations outside of the scope of the laboratories within MFS are sent off site for analysis. Service Level Agreements are held for all external testing laboratories used and are CPA accredited. Results from either internal or external laboratories should be made available in a timely manner as determined by the appropriate work instruction.