CODE OF PRACTICE AND GUIDELINES FOR

MEDICALLY ASSISTED REPRODUCTIVE TECHNIQUES

MINISTRY OF HEALTH
SRI LANKA, 2024

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Abbreviations

ART	Assisted Reproductive Technologies
BOD	Board of Directors
COSHH	Control of Substances Hazardous to Health
DGHS	Director General of Health Services
FET	Frozen Embryo Transfer
FSGB	Fertility Services Governing Body
HCG	Human Chorionic Gonadotropin
HIV	Human Immunodeficiency Virus
ICSI	Intra Cytoplasmic Sperm Injection
IUI	Intra-uterine Insemination
IVF	In-vitro Fertilization
MAR	Medically Assisted Reproduction
MD	Doctor of Medicine
MoH	Ministry of Health
MS	Master of Surgery
OHSS	Ovarian Hyper-stimulation Syndrome
OI	Ovulation induction
OR	Oocyte Retrieval
OS	Ovarian stimulation
PGT	Pre-implantation Genetic Testing
PHSRC	Private Health Service Regulatory Council
SET	Single Embryo Transfer
SLMC	Sri Lanka Medical Council
SOP	Standard Operating Procedures
STI	Sexually Transmitted Infections

Definitions

1. **Assisted Reproductive Technologies (ART)** are any fertility-related treatments in which eggs or embryos are manipulated. Procedures where only sperm are manipulated, such as intrauterine inseminations, are not considered under this definition.

2. **Assisted Reproductive Technology (ART) clinic** means any premises equipped with requisite facilities and medical practitioners with the required qualifications and registered with the Fertility Services Governing Body for carrying out the procedures related to the assisted reproductive technology.

3. **Child** means any individual born through the use of the assisted reproductive technology.

4. **Egg** sharing is when a patient who is already having IVF donates some of their eggs to the clinic where they are having treatment, usually in return for some free or discounted treatment.

5. **Embryo freezing** couples with good quality embryos and not ready to use have the option of freezing them to use in the future or to donate.

6. **Embryo** means a developing or developed organism after fertilisation till the end of fifty- six days from the day of fertilization.

7. **Embryo transfer** is the process of transferring embryos from the culture in which they have been developing in the lab, into the womb.

8. **Embryologists** are scientists involved in fertility treatment and reproductive research. They collect eggs, assess, and prepare sperm samples, and inject eggs with sperm.

9. **Embryos donation** is when patients who have been through IVF treatment and have frozen embryos remaining in storage that they no longer wish to use. These frozen embryos are given for use in the treatment of another person or couple.

10. **Follicle tracking** is a series of ultrasound scans to follow the development of a follicle to see if an egg is developing.

11. **Fresh embryo transfer** is when the embryo transfer is performed in the same cycle of egg collection.

12. **Frozen Embryo transfer** is when embryos are frozen for use at a later date or in future cycles.

13. **Gamete donor** means a person who provides sperm or oocyte with the objective of enabling a sub fertile couple or woman to have a child.

14. **Gamete** means sperm and oocyte.

15. **In Vitro Fertilization (IVF)** is a procedure that involves removing eggs from a woman's ovaries and fertilising them in the laboratory outside the body. The resulting embryos are then replaced back into the woman's womb through the cervix.

16. **Intra Cytoplasmic Sperm Injection (ICSI)** can be performed as a part of some IVF cycles. During an ICSI cycle instead of mixing them together a skilled embryologist will inject a single sperm into the egg to fertilise it.

17. **Intrauterine insemination (IUI)** is a procedure that treats infertility. IUI boosts the chances of pregnancy by placing specially prepared sperm directly in the uterus, the organ in which a baby develops. Another name for the procedure is artificial insemination.

18. **Medically Assisted Reproduction (MAR)** uses medical methods to achieve pregnancy by means other than sexual intercourse.

19. **Patient** means an individual or couple who comes to any registered assisted reproductive technology clinic for management of infertility.

20. **Pre-implantation genetic testing for aneuploidy** is used in cases where patients have had several miscarriages or failed IVF cycles and want to test their embryos for problems which might lead to another failed treatment. It can also be used to check embryos for chromosome problems.

21. **Subfertility/Infertility** means the inability to conceive after one year of unprotected coitus or other proven medical condition preventing a couple from conception. They also do very detailed procedures where they select a single sperm to fertilise an egg.

22. **Surrogacy -** A 'surrogate' is a woman who becomes pregnant, carries and delivers a child on behalf of another couple. Gestational surrogacy can be due to:
    1) the gametes of both commissioning parents may be are used;
    2) both gametes may come from donors (donation of either supernumerary or de novo-created embryos); or
    3) one of the commissioning parents provides the gametes and a gamete donor the other.

List of Annexes

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1. Introduction

The primary aim of this document is to elevate the standards of Medically Assisted Reproductive Techniques including Assisted Reproductive Technologies (ART) in Democratic Socialist Republic of Sri Lanka to international standards. This is also prepared with the objective of protecting the service provider and also patients (clients).

Recognizing the profound public concern regarding the potential implications of new reproductive techniques on the perception and foundational values surrounding human life and familial relationships, the establishment of a Supervising Authority or "ART Authority" becomes imperative to address these ethical considerations.

Until the establishment of the relevant authority, the **Private Health Regulatory Council (PHSRC)** will assume responsibility for the **registration, annual renewal, monitoring, and supervision** of centres providing **Medically Assisted Reproductive Techniques**, including **Assisted Reproductive Technologies (ART)**.

The **PHSRC** is a statutory body established under the **Private Medical Institutions (Registration) Act No. 21 of 2006**, which was certified by the Parliament of the Democratic Socialist Republic of Sri Lanka on **14th July 2006** to exercise, perform, and discharge its powers, duties, and functions.

The "ART Authority" when established is vested with responsibility of regulating ART services while offering comprehensive guidance on the appropriate execution of all licensed activities.

The Code of Practice integrates both mandatory provisions outlined in the proposed ART Act, extensively referenced throughout the Code, and advisory measures delineating good practices. Under the proposed ART Act, the Person Responsible would be obligated to consider all aspects of the Code. Additionally, the "Licensing Committee", in the execution of its authority, must duly consider all pertinent sections of the Code.

This document is applicable to all fertility centres which include centres offering Ovulation induction and IUI only and centres offering ART.

2. Fertility Services Governing Body (FSGB)

It is proposed to establish the Fertility Services Governing Body (FSGB) within the Directorate of Private Health Sector Development at the Ministry of Health, under the direct supervision of the Director General of Health Services.

There should be dedicated staff (Medical Officers, Clerical Staff etc.) for the functioning of the FSGB to ensure all the fertility centres are registered and monitored so that all the centres adhere to the minimum standards proposed in this document and follow the guidelines given.

2.1 Functions

2.1.1. Register all medical institutions providing fertility services (Annex 1);

i. Centres providing OI/OS and IUI, Sperm freezing, and Donor IUI

ii. Fertility centres providing comprehensive fertility treatment including assisted reproductive techniques

2.1.2. Monitor medical institutions providing fertility services to ensure the proposed ethical and clinical guidelines are followed.

2.1.3. Ensure that all centres comply with reporting to FSGB

2.1.4. Ensure registered medical institutions providing fertility services get prior approval wherever relevant mentioned in the documents

2.1.5. Visit registered medical institutions providing fertility services

i. A team from FSGB should visit the registered medical centres providing fertility services to physically supervise to ensure that minimum standards are maintained.

ii. To recommend appropriate action where specific minimum standards are not met and follow-up to ensure the recommendations are followed.

iii. Separate Computer with internet and online facilities to link all registered fertility centres to the FSGB.

*Until the establishment of the **Fertility Services Governing Body (FSGB)**, the **Private Health Services Regulatory Council (PHSRC)** shall assume responsibility for **the registration, annual renewal, monitoring, and supervision** of centres or medical institutions providing **Medically Assisted Reproductive Techniques**, including **Assisted Reproductive Technologies (ART).***

3. Assisted Reproductive Technology Centre

3.1 Introduction

3.1.1. It is mandatory that each and every centre providing assisted reproductive techniques should have a registration/license from the FSGB (until ART authority is established). The fertility centre is able to offer fertility treatments only after obtaining this registration. Until the ART authority is established the FSGB will be giving the guidelines regarding the registration and its renewal.

3.1.2. Each and every Fertility centre should have the relevant minimum required Facilities (as specified in sections 4 below and section 5) when offering different types of medically assisted reproductive techniques such as Intra uterine Insemination or In Vitro Fertilization. The fertility centre should comprise a qualified clinical team, support team and an administrative team (as specified in sections 4 and 5 below).

3.1.3. The Board of Directors (BoD)/ Director of the medical institution is expected to oversee the laboratory and the clinical services of the fertility centre. The board of directors/director could delegate the supervision to a unit in-charge.

3.1.4. The Board of Directors (BoD)/ Director or the administrative lead to oversee the general function of the fertility centre. This could be a Clinical or non-clinical person or a team with required administrative qualifications and experience (as specified in sections 4 below and section 5).

3.1.5. All centres providing fertility services should have an administrative lead to for all administrative matters referred in PART 5 and the BoD or a unit head shall be responsible to oversee the clinical and laboratory services.

3.1.6. Centres should develop Standard Operating Procedures (SOP) for available for all the clinical and laboratory services.

3.2 Board of Directors (BoD) / Director or unit head appointed by the BoD

3.2.1. Responsibilities

i. The BoD or unit head should ensure that all clinicians, embryologists practising in the respective fertility centre are possessing the minimum required qualifications mentioned in the PART 5 of this document.

ii. All consultants practising in the centre should be approved by Board of Directors (BoD). If the required standard is not met it is the responsibility of the BoD not to grant permission to practice at the centre. The BoD or Unit Head should ensure the clinical staff, embryology laboratory staff and non-clinical staff are following the recommended standards and guideline when offering ART services, as mentioned in the PART 6 of this document.

iii. The Clinical team should work closely with the administrative and laboratory team to ensure the safety of all patients undergoing fertility treatment at the respective centre.

iv. Any consultant who is not a resident of Sri Lanka, irrespective of how experienced he or she may be in the field of infertility shall not practice fertility treatment or ART in Sri Lanka without the registration at SLMC, and written approval of the board of directors of the respective medical institution providing fertility services.

v. In a situation where the consultant is not available, until the completion of the treatment cycle and management of complications, the BoD of the medical institution should ensure that the patient care is continued under a qualified consultant.

vi. Board of Directors/ Director or unit in-charge of the medical institution is responsible for monitoring and acting against any misconduct/ malpractice/ mismanagement of a patient or a donor receiving fertility treatment. In such circumstances the centre should take the necessary steps to correct any irregularity occurred and ensure the safety of the patients.

vii. Any misconduct/malpractice/mismanagement during fertility treatment should be investigated by the board of directors or a team appointed by them, and a report should be submitted to the FSGB.

viii. All complications occurring as a result of fertility treatment should be appropriately managed by the specialist and the medical centre and all measures should be taken to ensure the safety of the patient. All such complications should be reported to the FSGB.

ix. All ethically controversial treatment cycles should be referred to the FSGB and written approval should be obtained beforehand. Hospitals can establish their own ethical committee with approval of the FSGB (See section 8) and the final decision should be referred and approved by the FGSB.

3.3 Board of Directors (BoD)/ Director or administrative lead appointed by the BoD

3.3.1. Responsibilities:

Overall responsibility for centre services: Ensuring that the centre operates efficiently and effectively.

i. **Licensing and approvals**: Managing the process of obtaining necessary licenses, permits, and regulatory approvals required for the operation of the ART centre. This includes ensuring compliance with local regulations and guidelines.

ii. **Human resource management**: Overseeing the recruitment, training, scheduling, and management of staff working in various roles within the centre.

This involves maintaining staffing levels, addressing HR issues, and fostering a positive work environment.

iii. **Procurement and maintenance of equipment**: Supervising the acquisition and maintenance of specialized fertility equipment necessary for various procedures such as IUI, IVF, ICSI, and embryo transfer etc. and ensuring all the equipment are functional, well calibrated, and meets quality and safety standards.

iv. **Consumables and supplies**: Managing the inventory of consumables and supplies essential for fertility treatment and procedures, including fertility medications, laboratory supplies, disposables, and other materials required for daily operations.

v. **Sterility maintenance**: Ensuring adherence to stringent sterilization and hygiene protocols within the centre to maintain aseptic conditions critical for procedures involving gametes and embryos.

vi. **Implementing quality control measures, audits**, and continuous improvement initiatives to maintain high standards of care.

vii. **Coordination and collaboration**: Facilitating communication and collaboration among different departments within the centre, promoting teamwork and ensuring coordination for efficient service delivery.

viii. **Patient and stakeholder relations**: Maintaining positive relations with stakeholders, regulatory bodies, and other external parties. Addressing patient concerns and complaints, ensuring satisfaction, and fostering a positive reputation for the centre.

ix. The BoD or unit head shall **ensure accurate record keeping** and maintenance of statistics and submit required information to the FSGB (Refer 3.13).

3.4 Required facilities at the centre

3.4.1. Staff requirements:

i. **Qualified specialists**: Board-certified specialists in Subfertility/Reproductive Medicine or Obstetrics and Gynaecology with expertise in ART (Refer 4.1).

ii. **Embryologists**: Trained professionals responsible for handling embryos and gametes in the laboratory (Refer 4.3.1).

iii. **Andrologist**: Expertise in male reproductive health and responsible for andrology lab procedures (Refer 4.4.1).

iv. **Support medical officers**: Medical officers providing medical support and assistance (Refer 4.5.1).

v. **Counselling services**: Qualified counselling staff offering counselling and guidance to patients (Refer 4.6.1).

vi. **Nursing staff**: Nurses providing patient care, medication administration, and patient support (Refer 4.5.1).

3.5 Services

3.5.1. Patient consultation: Offering initial consultations, discussions, and assessments related to fertility concerns and medically assisted reproductive (MAR)procedures.

3.5.2. Investigations: Conducting diagnostic tests and assessments to evaluate fertility issues.

3.5.3. Medication for MAR stimulation: Availability and administration of medications for ovarian stimulation management of any emergency relater to MAR.

3.5.4. Procedures: Facilities and expertise for follicular tracking, IUI, Oocyte retrieval, IVF/ICSI, Embryo/Gamete Freezing, and Embryo Transfer.

3.5.5. Counselling ervices: Providing counselling, guidance and emotional support services to patients when needed.

3.5.6. Emergency services- Resuscitation and handling of other emergency situations including anaphylaxis, availability of ambulance facilities etc.

3.6 Minimum infrastructure facilities required for a MAR/ART centre

3.6.1. Consultation rooms with adequate privacy.

3.6.2. Imaging facilities (Ultrasound scanning).

3.6.3. Theatre: Dedicated for procedures such as Oocyte Retrieval, Embryo Transfer, and other ART-related surgical procedures.

3.6.4. Recovery area: Space allocated for post-procedure recovery and patient monitoring.

3.6.5. Embryology laboratory: Specialized lab for handling and processing embryos and gametes.

3.6.6. Andrology laboratory: Laboratory specifically equipped for assessing and handling male reproductive samples and procedures.

3.6.7. Sperm sample collection area: Designated space for collecting sperm samples.

3.6.8. Administrative office: Space for administrative and managerial tasks.

3.6.9. Facilities for record keeping for minimum of 10 years, preferably until the child is 18 years (physical and digital records).

3.7 Clinical and laboratory facilities required

3.7.1. Laboratory Facilities and Cryopreservation

3.7.1.1 **Good laboratory practice**: Centres should adhere to Good Laboratory Practice Standards in par with those set by the Sri Lanka Accreditation Board. This ensures adherence to standards, precision, and accuracy in all laboratory procedures.

3.7.1.2 **Microbiological hazards and Control of Substances Hazardous to Health (COSHH) Regulations**: Awareness and compliance with COSHH regulations are essential, particularly in handling gametes and embryos, to minimize microbiological hazards and ensure a safe working environment.

3.7.1.3 **Pre-testing of blood products**: Blood products, other than those belonging to the patient undergoing treatment, that may come into contact with gametes or embryos should be pre-tested for HIV, hepatitis B, hepatitis C and any other specified infections as decided by the treating consultant.

3.7.1.4 **Proximity of operating theatre and laboratory**: The operating theatre used for egg retrieval in IVF procedures should be situated as close as practically possible to the laboratory where fertilization procedures, such as IVF or ICSI, are conducted. This proximity helps preserve the viability of collected gametes.

3.7.1.5 **Dedicated cryopreservation facilities**: Customized, secure, and dedicated cryopreservation facilities for gametes and embryos should be available within the ART centre. These facilities should match the volume and specific needs of the centre's cryopreservation activities.

3.7.1.6 **Emergency procedures for storage systems**: Implementation of appropriate emergency procedures to address failures or damages to storage vessels and systems used for cryopreservation. This ensures the safety and integrity of stored gametes and embryos.

3.7.1.7 **Equipment maintenance and calibration:** Regular maintenance, calibration, and validation of laboratory equipment (as specified by the manufacturer) used for ART procedures are crucial. Daily, monthly, and annual procedures for maintenance and calibration help ensure accurate and reliable results in laboratory processes.

3.7.1.8 **Back up electricity generator** facilities to the laboratory should be available in case of electricity failure.

3.7.2. Freezing and thawing procedures

i. **Adhere to guidelines and procedures**: It is crucial to maintain the integrity, security, and ethical handling of frozen/thawed samples in MAR/ART centres, to ensure the safety and confidentiality of patients' genetic material and contribute to the overall quality of assisted reproductive treatment.

ii. **Special inventory system for frozen/thawed samples**: Implementing a specialized inventory system that records detailed information about frozen/thawed embryos or sperm. This includes identification/reference details, location, duration of storage, and specific information about the storage tanks holding each sample.

iii. **Secure storage for gametes and embryos**: Providing secure storage facilities for gametes and embryos where access is strictly controlled, ensuring that only personnel authorized by the centre have access to stored samples. This helps maintain confidentiality and security.

iv. **Handling of contaminated samples**: Establishing protocols for handling contaminated samples to minimize risks. Contaminated samples should be handled according to specific guidelines as approved by the FSGB (Standard Operating Procedures, guidelines and protocols by the centre), with proper disposal procedures to prevent cross-contamination and potential risks to other samples or personnel.

v. **Embryo/sperm disposal procedures**: Implementing proper procedures. For the disposal of embryos or sperm that are no longer viable or required. This includes adherence to good medical practices for the disposal of biological materials, ensuring appropriate and respectful disposal. The client should be informed about the procedure of discarding the embryos, documentation and record-Keeping: Maintaining meticulous records of all procedures related to freezing, thawing, storage, handling of samples, and disposal. Detailed documentation ensures traceability and accountability of each sample's history and disposition.

vi. **Quality control and monitoring**: Annual quality control checks, monitoring, and audits of storage conditions and inventory systems to ensure accuracy, reliability, and compliance with established protocols shall be carried out by an accredited body approved by the FSGB.

vii. **Staff training and protocols**: Providing staff training on proper handling, storage, and disposal procedures for gametes and embryos is the responsibility of the centre.

3.8 Counselling facilities and services at the MAR/ART centre

3.8.1. Creating a dedicated and **comfortable counselling environment** within MAR/ART Centre is crucial to ensure that individuals or couples receive the necessary information, support, and guidance to make informed decisions about their fertility treatments and reproductive choices.

3.8.2. **Mandatory counselling opportunity**: Individuals seeking licensed treatments like in vitro fertilization (IVF) or treatments involving donated gametes, as well as those consenting to the use or storage of embryos or donation/storage of gametes, and surrogacy should be offered suitable opportunities for proper counselling.

3.8.3. Private and comfortable counselling rooms

3.8.3.1 Providing a dedicated, private, and comfortable room specifically designated for counselling purposes within the MAR/ART centre.

3.8.3.2 Ensuring that the counselling room offers privacy and a tranquil environment, allowing individuals or couples to engage in discussions undisturbed.

3.8.4. **Suitable environment for discussion:** Creating a conducive environment, where patients can openly discuss their concerns, queries, or decisions regarding fertility treatments, donation, or storage of reproductive material.

3.8.5. **Trained counselling staff**: Employing qualified and trained counselling staff who are skilled (refer section 5.5) in providing emotional support, guidance, and information about the various aspects of assisted reproduction, including the emotional, ethical, and legal implications.

3.8.6. **Respecting confidentiality and sensitivity:** Upholding strict confidentiality and sensitivity during counselling sessions, ensuring that the information shared by patients remains private and that their emotional needs are respected and addressed.

3.8.7. **Comprehensive information and support**: Offering comprehensive information and support during counselling sessions, covering various aspects such as treatment options, procedures, potential risks, success rates, emotional implications, and legal aspects.

3.8.8. **Respecting patient choices**: Allowing individuals or couples the space and time to make informed decisions regarding their fertility treatments or decisions involving the use or storage of reproductive materials, without pressure or coercion.

3.9 Confidentiality

All individuals associated with the ART centre should strictly adhere to below mention confidentiality commitments to ensure the protection of patient information at all times.

3.9.1. Confidentiality of activities and patient identities

3.8.8.1 All activities conducted within the licensed ART centre and the identities of patients should be treated with strict confidentiality.

3.8.8.2 Maintaining the privacy of patients' information, medical records, and any details related to their treatment procedures is imperative.

3.8.8.3 Retain a Copy of national ID or passport in case of a foreign patient with the medical records.

3.9.2. Written undertaking for confidentiality

i. All individuals employed or associated with the ART centre must provide a written undertaking to uphold and maintain strict confidentiality.

ii. This written commitment to confidentiality remains valid during their tenure at the centre and extends even after the period of service.

3.9.3. Commitment to confidentiality: Employees, including medical professionals, administrative staff, nursing staff, counsellors, and any other personnel associated with the centre, should adhere to ethical standards and legal obligations regarding patient confidentiality.

3.9.4. Protection of patient information: Implementing measures to safeguard patient information from unauthorized access, disclosure, or misuse, ensuring that it remains secure and protected.

3.9.5. Ethical and legal compliance: Abiding by ethical guidelines, professional codes of conduct, and relevant laws regarding patient confidentiality and privacy rights.

3.9.6. All individuals associated with the ART centre should adhere to these confidentiality commitments to ensure the protection of patient information at all times.

3.10 Privacy

Ensuring comfort and privacy in MAR/ART centres is crucial to respecting the dignity and autonomy of individuals seeking fertility treatments or considering donation. Establishing an environment that upholds confidentiality and offers a supportive space contributes significantly to the overall well- being and experience of clients undergoing MAR/ART treatments.

3.10.1. Comfort and privacy for patients

i. MAR/ART centres should prioritize the comfort and privacy of individuals seeking treatment, undergoing procedures or egg and sperm donors within the facility.

ii. Creating an environment that respects and safeguards the privacy of patients, is

essential to ensure their emotional well-being and comfort during what can be a sensitive and personal journey.

3.10.2. Facilities acceptable to clients

i. Taking reasonable steps to ensure that the facilities and settings within the MAR/ART centre, are designed and organized to meet the privacy expectations of clients.

ii. Facilities should be arranged in a manner that provides private spaces for consultations, procedures, and discussions, ensuring confidentiality and comfort for individuals undergoing treatment or seeking services.

3.10.3. Respecting individual choices

i. Respecting the choices and preferences of individuals regarding privacy during consultations, procedures, or discussions related to fertility treatments or donations.

ii. Allowing individuals to have control over the disclosure of their personal information and ensuring that their confidentiality is maintained.

3.10.4. Confidentiality measures

Implementing policies and procedures to maintain strict confidentiality regarding patient information, medical records, and any discussions or treatments within the ART centre.

3.10.5. Sensitive and supportive environment

Creating a supportive and empathetic environment within the centre, where individuals feel comfortable discussing their fertility concerns or undergoing treatments without fear of judgment or breach of privacy.

3.11 Managing MAR/ART related complications

3.11.1. Ensuring the availability of emergency clinical facilities and preparedness to manage unforeseen situations such as surgical complications are crucial to safeguard patient safety and mitigate risks during ART procedures. This includes having the necessary resources, protocols, and trained personnel readily accessible to handle any emergency that may arise within the scope of assisted reproductive treatments.

3.11.2. Backup and emergency clinical facilities: The ART centre should have adequate backup and emergency facilities for each technique practiced within the centre.

3.11.3. Local availability of emergency facilities: It is mandatory that emergency facilities are readily accessible and available within the vicinity of the ART centre.

3.11.4. These facilities should be capable of addressing and managing all foreseeable emergency situations that might arise during ART procedures or patient care. Ambulance services need to be available and a referral hospital needs to be identified.

3.11.5. Preparedness for emergencies: The centre should have protocols in place for handling surgical emergencies related to ART procedures, ensuring prompt and effective responses to unforeseen events or complications.

3.11.6. Staff training and preparedness: Staff members should be adequately trained, prepared, and equipped to handle emergency situations that may occur during ART procedures or patient care.

3.11.7. Risk mitigation measures: Implementing measures to mitigate risks associated with ART procedures and ensuring that emergency facilities and resources are proportionate to the potential risks involved in these procedures.

3.12 In-Service training

3.12.1. Centres should arrange in-service training for all staff taking part in scientific, clinical, nursing or counselling activities for which the existing formal qualifications are not entirely sufficient. Providing in-service training opportunities is crucial for continuous professional development, ensuring staff members are well-prepared, competent, and capable of delivering optimal care and services in the dynamic and specialized field of assisted reproductive treatments.

3.12.2. Enhancing skills beyond formal qualifications: In-service training is essential for staff members engaged in scientific, clinical, nursing, or counselling roles where formal qualifications might not entirely cover the specialized skills required in the field of assisted reproductive treatments.

3.12.3. Updating knowledge and techniques: Providing on-going training helps staff members stay updated with the latest advancements, techniques, and best practices in MAR/ART, ensuring they are equipped to provide high-quality care and services to patients.

3.12.4. Fostering continuous professional development: In-service training programs facilitate continuous learning and professional development for staff, allowing them to expand their expertise, refine their skills, and adapt to changes in the field of reproductive medicine.

3.12.5. Addressing specific needs and challenges: Tailoring training programs to address specific needs or challenges encountered in ART procedures, patient care, counselling, or laboratory practices within the centre.

3.12.6. Supporting staff confidence and competence: In-service training boosts staff confidence and competence in performing their roles, which ultimately contributes to improved patient outcomes and experiences.

3.12.7. Compliance with evolving standards: Keeping staff informed and educated about

evolving standards, guidelines, and regulatory requirements in ART practice as specified by FSGB, ensuring compliance with ethical, legal, and quality & safety standards.

3.13 Reporting to FSGB

3.13.1. Having a robust **reporting mechanism** and monitoring system is crucial for MAR/ART centres to maintain transparency, identify areas for improvement, address issues promptly, and ensure the delivery of high-quality, ethical, and safe services to patients undergoing assisted reproductive treatments.

3.13.2. Annual reporting to the FSGB: The ART centre is required to submit comprehensive annual reports to the designated FSGB as per the format (Annex 2). These reports should detail the centre's activities, including the treatments provided, outcomes, any notable achievements, and serious problems encountered during the reporting period.

3.13.3. Immediate reporting of breach of the guideline or serious problems: In case of any breach of the recommendation in this guideline or encountering serious problems within the centre, prompt reporting to the FSGB addressed to DGHS is mandatory, with copy to SLMC. Centres should inform the authority as soon as possible to address and rectify the issues (Annex 3).

3.13.4. The institution is bound and mandatory to report all triplet and higher order multiple pregnancies to the FSGB within the first trimester itself. This responsibility of reporting lies with the BoD of the centre.

3.13.5. The institution is bound to report all serious complications to its patients including severe OHSS and significant injuries during procedures needing hospital admission, Higher order pregnancies to FSGB within 72 hours of the occurrence. This responsibility of reporting lies with the BoD (Annex 3).

3.13.6. Reporting incidents by other parties;

A. Obstetricians and gynaecologists

i. When a triplet or higher order ongoing pregnancy is detected

ii. When triplets or more babies delivered in the unit

iii. When severe or critical OHSS is detected in a patient undergoing fertility treatment

iv. Any other significant event, related to fertility treatment which the consultant thinks should be reported.

B. Neonatologist/ paediatricians/ neonatology units

Any triplet or higher number of babies coming under their care should be reported.

C. Judicial medical officers

Any medicolegal event which may have resulted due to fertility treatment. e.g. Maternal deaths.

D. Other medical professionals

Any significant event, related to fertility treatment which the consultant thinks should be reported FSGB.

3.14 Monitoring and quality control

3.13.7. Monitoring and assessment systems: Implementation of effective monitoring and assessment systems within the ART centre is essential. These systems should encompass laboratory, clinical, and counselling practices.

3.13.8. Ensuring satisfactory procedures and outcomes: The monitoring and assessment systems should ensure that procedures and outcomes meet satisfactory standards set by professional colleagues.

3.13.9. Continuous improvement and quality assurance: The monitoring system should facilitate continuous improvement, aiming for high-quality care and adherence to professional standards. This includes identifying areas for improvement and taking corrective actions when needed.

3.13.10. Transparency and accountability: Maintaining transparency and accountability in reporting and addressing any concerns raised through the monitoring systems. It helps in maintaining public trust and confidence in the centre's practices.

3.13.11. Compliance with ethical and professional standards: Ensuring compliance with ethical, legal, and professional standards in the provision of ART services, reflecting a commitment to patient safety, quality care, and ethical practices.

3.15 Advertising

Centres may wish to circulate information about the services they provide. All publicity material should conform to the guidelines issued by the SLMC and FSGB on advertising.

ART centres must ensure that their advertising practices are responsible, ethical, and provide accurate information to individuals seeking fertility treatments, maintaining transparency and integrity in their communication with the public, in strict adherence to established following guidelines.

3.15.1. Advertisements of an MAR/ART centre:

i. False claims via hoardings and paper or digital advertisements are a cheap way of attracting a clientele that is vulnerable and, therefore, easily swayed. Such advertisements shall be banned.

ii. An honest display at appropriate places or publicity of statistics, fee structure, quality of service and of service provided, will be encouraged, provided the guidelines laid down by the Medical Council of Sri Lanka in this regard, are not violated.

3.15.2. Dissemination of information:

Must circulate information regarding the types of treatment they offer to raise awareness among the public about available services.

3.15.3. Conformity to FSGB guidelines:

All advertising or publicity material disseminated by MAR/ART centres should adhere to the general principles outlined in the guidelines given in this document.

3.15.4. Ethical and accurate information:

Advertisements and promotional material should be ethical, accurate, and not misleading. They should provide factual information about the services, treatments, success rates and available options without creating unrealistic expectations or promises.

3.15.5. Transparent and clear communication:

Communication in advertising should be transparent and clear, avoiding any language or content that might create confusion or mislead individuals seeking fertility treatments.

3.15.6. Respect for patient dignity and privacy:

Respecting patient dignity and privacy in advertising practices by avoiding the use of identifiable patient information or any content that might compromise patient confidentiality.

3.15.7. Avoidance of sensationalism or unrealistic claims:

Avoiding sensationalism or exaggerated claims about success rates or treatment outcomes. Advertising should steer clear of making unrealistic promises that could mislead or exploit potential patients.

3.15.8. Compliance with legal and regulatory standards:

Ensuring compliance with legal and regulatory standards governing advertising practices in the healthcare sector, including guidelines set by the FSGB, Sri Lanka Medical Council and other relevant governing bodies.

3.15.9. Professional conduct and accountability:

Maintaining professional conduct and accountability in all advertising practices, reflecting the centre's commitment to ethical healthcare provision and patient-centered care.

4. Staff

4.1 Clinician in charge of the patient undergoing MAR/ART

Each institution should have a designated individual consultant responsible for overseeing the entirety of clinical care provided to each and every patient undergoing fertility treatment under his/her care at the MAR/ART centre, ensuring the safety and well-being of the patient throughout the treatment process.

4.1.1 The Clinician in charge should only be a person falling in to one of the following three categories;

A. Board certified consultant in subfertility:

i. Holds an MD in Obstetrics and Gynaecology from Postgraduate Institute of Medicine, University of Colombo.

ii. Holds Board certification as a specialist in Subfertility in Sri Lanka.

B. Board certified consultant in obstetrics and gynaecology with MAR/ART expertise:

i. Holds an MD/MS in Obstetrics and Gynaecology from Postgraduate Institute of Medicine, University of Colombo.

ii. Board Certified as a specialist in Obstetrics and Gynaecology in Sri Lanka.

iii. Holds significant expertise and experience in the field of ART (approved by the FSGB), demonstrating comprehensive knowledge and skill in providing ART-related services within the scope of Obstetrics and Gynaecology.

C. Foreign consultants

i. Registered and practicing as a consultant specifically in Subfertility in the country of origin.

ii. who hold a temporary registration of the Sri Lanka Medical Council (SLMC) and are duly recognized and accepted as a Specialist in Subfertility by the SLMC.

4.1.2 Responsibilities of the clinician in-charge

A. Thorough and relevant medical assessment of the couple undergoing MAR/ART:

i. **Relevant medical history**: Gathering comprehensive medical histories of both partners to assess any existing conditions, previous treatments, surgeries, HIV infections or other health issues pertinent to fertility and pregnancy.

ii. **Physical assessment**: Conducting a thorough physical examination to evaluate overall health, fitness to through a pregnancy and to identify any physical factors that might affect fertility.

iii. Plan out relevant fertility investigations, other medical investigations and

screening for infections as deemed appropriate: requesting and reviewing diagnostic tests and screening tests to assess fertility status, potential underlying medical issues, and relevant infections.

B. Counselling on fertility treatment options:

Providing guidance and information on fertility treatment options available, including the possibility of using donor gametes and embryos where necessary or advisable.

i. Fertility counselling and explanation of the procedure: Offering counselling and detailed explanation of the steps involved in the MAR/ART process, such as ovarian stimulation, oocyte retrieval, embryo transfer, pregnancy testing, and subsequent follow-up procedures.

ii. Counselling on possible side effects and potential complications: Educating the couple about possible side effects associated with ovarian stimulation, oocyte retrieval procedures, and embryo transfer. This includes discussing risks like ovarian hyperstimulation syndrome (OHSS), multiple pregnancies, and ectopic pregnancies etc.

C. Consents and investigations:

Ensuring that all necessary written consents are obtained from the couple and that all required diagnostic investigations are completed before commencing MAR/ART procedures to mitigate risks and ensure compliance with legal and ethical standards.

D. Ovarian Stimulation:

i. **Planning the ovarian stimulation protocol**: Strategizing and designing the stimulation protocol tailored to the individual and optimizing the chances of successful follicular development and retrieval of oocytes.

ii. **Ensuring availability of required medication**: Verifying and ensuring that all necessary medications for the stimulation protocol are available prior to commencing ovarian stimulation.

iii. **Follicular tracking**: Monitoring follicular growth and development through ultrasound scans during the stimulation phase to assess the response to medications and adjust the protocol if indicated.

iv. **Identification and management of side effects and complications**: Being vigilant in identifying any side effects resulting from ovarian stimulation and managing them appropriately. This includes being competent in detecting and managing all grades of Ovarian Hyperstimulation Syndrome (OHSS).

v. **Triggering final maturation prior to oocyte retrieval**: Administering the trigger medication (e.g., HCG - Human Chorionic Gonadotropin) to induce final oocyte maturation in preparation for oocyte retrieval at the appropriate time.

4.1.3 Oocyte Retrieval (OR):

i. **Explaining the OR procedure:** Providing a detailed explanation to the patient about the OR procedure, including the steps involved, the anaesthesia or sedation used during the procedure, and what to expect before, during, and after the process.

ii. **Explaining of possible side effects**: Educating the patient about potential side effects or discomfort associated with the OR procedure, such as mild cramping, pelvic discomfort, bloating, and possible vaginal spotting or bleeding. It's essential to provide information on how these side effects can be managed and what symptoms warrant immediate medical attention.

iii. **Managing possible complications**: Clinician in-charge should be satisfied that the centre where the OR is performed has the necessary facilities and is adequately equipped to manage any potential complications that might arise during or after the OR procedure. This includes promptly addressing issues like bleeding, infection, or any adverse reactions to anaesthesia or medications used during the process.

4.1.4 Embryo transfer:

A. Recommendation on embryo transfer:

i. **Fresh embryo transfer:** Recommending whether a fresh embryo transfer is suitable based on the treatment plan and individual circumstances.

ii. Frozen Embryo Transfer (FET):

- **Natural Cycle FET**: Advising on FET within a natural menstrual cycle without additional hormonal medications.
- **Modified Natural FET**: Providing guidance on FET within a partially controlled cycle.
- **Medicated FET**: Recommending FET within a hormonally controlled cycle.

B. Recommendation on number of embryos to be transferred:

i. **Advocacy for single embryo transfer**: Recommend single embryo transfer as the safest approach to minimize the risks associated with multiple pregnancies.

Limitation on number of embryos: Transfer of more than two embryos on a single occasion, is not recommended. This is to reduce the likelihood of higher order multiple pregnancies and associated complications.

ii. **Exceptional circumstances for consideration of three embryos**: In specific exceptional cases, such as older women with a history of recurrent implantation failures or with suboptimal embryos deemed unsuitable for freezing and thawing, considering up to three embryos might be justifiable. However, meticulous records justifying such decisions should be maintained.

iii. In cycles where donor eggs or donor embryos are used it is recommended not to transfer more than two embryos in any given cycle.

C. Luteal hormonal support:

Providing guidance and recommendations regarding hormonal support during the luteal phase following embryo transfer to optimize the chances of successful implantation and early pregnancy maintenance.

D. Pregnancy test and follow-up in IVF:

i. **Timing of pregnancy testing**: Advising the appropriate timing for the pregnancy test after the embryo transfer, typically around 12-14 days post-transfer.

ii. **Type of pregnancy test**: Recommending the type of pregnancy test (blood test or urine test) based on clinic protocols and patient needs for accurate confirmation of pregnancy.

E. Counselling for patients with failed cycles:

i. Discuss possible factors that may have contributed for failed cycle.

ii. Discuss management options and measures that could be tried to improve the outcome in a future cycle.

F. Follow-up care for pregnancy:

i. Monitoring Early Pregnancy: Scheduling follow-up appointments for monitoring to assessment.

ii. Support and Guidance: Providing guidance and support to patients during the early stages of pregnancy, addressing concerns, and offering appropriate advice on diet, lifestyle, and medications.

G. Continued monitoring and care:

i. Continued Assessments: Planning and scheduling regular check-ups and assessments to monitor the progress of the pregnancy.

ii. Addressing Complications or Concerns: Being available to address any complications or concerns that may arise during the course of the pregnancy, providing necessary medical interventions or referrals as required.

H. Patient education:

Educating Patients: Providing comprehensive information to patients about what to expect during early pregnancy, common symptoms, warning signs that require immediate attention, and guidance on medications or lifestyle adjustments.

I. Fertility add-ons:

In the event where any kind of treatment or procedure that is considered as an add-on (e.g. endometrial scratching) is included in the treatment cycle, the patent should be provided with up to date and evidence-based information regarding its efficacy and safety.

4.2 Embryologist/embryology team

The Embryologist or the person in charge of an embryology laboratory is entrusted with full responsibility for the laboratory's operations.

4.2.1 Mandatory qualifications

i. Degree in medical, veterinary, or biological sciences, coupled with a postgraduate qualification specifically focused on human embryology from a recognized university.

ii. The individual should demonstrate competence in embryology laboratory management and possess a minimum of three years practical training under supervision of a fully qualified clinical embryologist. This training should encompass ART and related procedures, andrology and cryopreservation procedures. The training should be endorsed and certified by the supervisor concerned before become qualified to practise independently as an embryologist.

4.2.2 Responsibilities

The responsibilities of the Embryologist or Embryology team encompass a range of crucial

tasks within the realm of ART, including:

i. Performing conventional IVF: Overseeing and conducting the process of IVF by fertilizing retrieved eggs with sperm in a laboratory setting.

ii. Performing Intracytoplasmic Sperm Injection (ICSI): Administering the specialized technique of ICSI, where a single sperm is injected directly into an egg to facilitate fertilization.

iii. Egg freezing: Managing the cryopreservation process of unfertilized eggs (oocytes) for potential future use.

iv. Sperm freezing: Preserving sperm samples through cryopreservation methods for future use in ART procedures.

v. Embryo freezing: Handling and freezing viable embryos for storage and potential later use in Frozen Embryo Transfer (FET) procedures

vi. Biopsy for Pre-implantation Genetic Testing (PGT): Conducting biopsies on embryos to collect cells for genetic testing before their transfer into the uterus.

vii. Embryo preparation for fresh/frozen embryo transfer: Preparing embryos for transfer in either fresh or frozen cycles, ensuring optimal conditions for successful implantation."

viii. Record keeping and maintaining statistics on fertilization, embryo quality, freezing records etc. This record should be available for inspection by the FSGB.

ix. Maintaining the optimal laboratory standards

4.3 The person in charge of Andrology laboratory

4.3.1 Mandatory qualifications

i. Degree in medical, veterinary or biological sciences from a recognized university.

ii. Minimum of two years (24 months) of specific experience in Andrology laboratory procedures, quality control, equipment handling, staff management, and overall laboratory management practices, thereby enabling them to competently lead and oversee operations within the laboratory. This training should be endorsed and certified by the supervising qualified andrologist before becoming qualified to practise independently as an andrologist.

4.3.2 Responsibilities of the Andrologist/ andrology team

i. Laboratory Management: Taking charge of the day-to-day operations within the andrology laboratory, ensuring adherence to quality control measures, maintaining equipment, and managing inventory and supplies.

ii. Performing tests related to andrology: Overseeing and conducting various andrological tests, including seminal fluid analysis, sperm morphology assessments, sperm viability tests, and sperm function tests, ensuring accuracy and reliability of results.

iii. Sperm Processing: Supervising procedures related to sperm preparation for use in medically assisted reproduction techniques including IUI and IVF/ICSI.

iv. Cryopreservation of sperms: Managing the freezing and storage of sperm samples for future use, ensuring proper protocols are followed for successful cryopreservation.

v. Quality Assurance: Implementing and monitoring quality assurance and quality control measures to maintain high standards of laboratory procedures and accuracy of results.

vi. Documentation and Record-keeping: Maintaining accurate records of test results, laboratory procedures, and patient information documents in compliance with regulatory standards.

vii. Staff Training and Supervision: Providing training to laboratory staff, ensuring they adhere to standardized protocols, and overseeing their work to maintain quality and efficiency.

viii. Compliance and Regulation: Ensuring the andrology laboratory complies with all relevant regulations, guidelines, and ethical standards set forth by regulatory bodies.

4.4 Medical Officers engaged in ART treatment services

4.4.1 Mandatory qualifications

Full registration as medical practitioners with SLMC.

4.4.2 Responsibilities

A. **Conducting ART** related tasks under the close supervision of the consultant in charge. Registration of the couple MAR at the centre for fertility treatment including medical history, clinical examination and documentation of relevant investigations. Their work and decisions must align with the guidance and oversight provided by the overseeing consultant.

i. **Relevant medical history**: Gathering comprehensive medical histories of both partners to assess any existing conditions, previous treatments, surgeries, or health issues pertinent to fertility and pregnancy.

ii. **Physical assessment**: Conducting a thorough physical examination to evaluate overall health, fitness to through a pregnancy and to identify any physical factors that might affect fertility.

iii. **Relevant fertility investigations**, other medical investigations and screening for

infections such as Hepatitis B, C and HIV.

B. **Coordination of MAR cycle** - Liaise with the Embryology team, Andrology team, Nursing team, Counsellors and the administrative team to ensure smooth progression of the MAR cycle.

C. **The ultimate responsibility *for clinical decisions and patient care lies with the consultant overseeing the MAR treatments*.** As such the medical officers should communicate with the consultant in charge at all times with regard to the management of the couple.

4.5 Counselling Staff

4.5.1 Mandatory qualifications

i. Should hold qualifications in counselling and/or clinical psychology at a diploma level or higher from a recognized university or University Grants Commission recognized higher education centres.

ii. Counsellors should work closely with the medical staff at least for a period of six months to understand the process of MAR prior to commencing fertility counselling on their own.

iii. Counselling staff must demonstrate evidence of membership in a professional body relevant to their qualification/qualifications.

4.5.2 Responsibilities

i. **Providing emotional Support and Counselling**: Offering emotional support and counselling to individuals or couples navigating the complexities and challenges of fertility treatments. This includes addressing their concerns, fears, and emotional well-being throughout the ART process. The counsellor should look into safeguarding issues related to the well-being of the unborn child especially with couples with Physical and/or Psychological and/ or social issues.

ii. **Assessment and Guidance**: Conducting thorough assessments of the patient's emotional and psychological state to understand their needs better.

iii. **Support in Decision-Making through implications counselling:** Assisting individuals or couples in making difficult decisions, understanding the implications, and coping with the emotional stress associated with these choices.

iv. **Couples and Family Dynamics**: Addressing issues related to relationships, communication, and family dynamics that may arise during fertility treatments, ensuring that both partners are equally supported.

v. **Counselling for failed procedure and early pregnancy loss**: Offering counselling and

support in case of failed procedures, early pregnancy loss, or any other emotionally distressing events during the MAR procedure.

vi. **Referral and Collaboration**: Collaborating with other healthcare professionals or specialists when necessary and making referrals for additional support, such as mental health professionals or support groups, if needed.

vii. **Ethical and Legal Guidance**: Providing guidance on the ethical and legal aspects of procedures, ensuring that patients are aware of their rights and responsibilities.

viii. **Documentation and Confidentiality**: Maintaining accurate and confidential records of counselling sessions while adhering to ethical guidelines and ensuring patient confidentiality.

4.6 Nursing Staff

4.6.1 Mandatory Qualifications

i. Registered with the Sri Lanka Nursing Council (for Nursing and Midwifery) or registered in Private Health Service Regulatory Council (PHSRC) as a Listed Nursing Officer.

ii. All MAR centres should undertake training of recruited nursing staff with regard to MAR procedures including ART at least for a period of three months.

4.6.2 Responsibilities

i. Patient Assessment and Care: Conducting initial assessments, monitoring patient progress throughout the ART cycle and providing personalized nursing care tailored to the patient's needs.

ii. Medication Administration: Administering medications as prescribed by the Clinical team, including fertility medications, hormonal therapies, and medications for ovarian stimulation or preparation for procedures.

iii. Prior to administration of all medications, a careful history should be taken to exclude any history of allergies to food and medication. In the presence of any allergic history the clinical team should be alerted immediately.

iv. Procedure Assistance: Assisting in various ART procedures such as egg retrieval, embryo transfer, and IUI, ensuring proper preparation of patients and the environment for these procedures.

v. Patient Education: Providing comprehensive education to patients regarding their treatment protocols, medications, procedures, and post-procedure care to ensure patient compliance and understanding.

vi. Monitoring and Documentation: Monitoring patients for any adverse reactions or complications, documenting observations, vital signs, and treatment administration accurately in medical records.

vii. Emotional Support: Offering emotional support, guidance, and reassurance to patients and their families throughout the ART process, addressing concerns and providing empathetic care.

viii. Collaboration and Coordination: Collaborating with other healthcare team members, including physicians, embryologists, counsellors, and administrative staff, to ensure seamless coordination of care and treatment protocols.

ix. Adherence to Protocols and Safety Standards: Following established protocols, safety measures, and infection control practices to maintain a safe and sterile environment within the ART facility.

x. Post-Procedure Follow-up: Conducting follow-up assessments after procedures, providing post-procedure care instructions, and addressing any patient queries or concerns.

xi. Ensure maintenance of sterility: Nursing staff should take all necessary steps to ensure sterility when administering medication, performing procedures including oocyte retrieval and embryo transfers.

xii. Patient Advocacy: Serving as advocates for patients, ensuring their rights, preferences and concerns are addressed and respected throughout the ART process.

xiii. Considering the sensitivity nature of fertility treatment and emotional status of the couples undergoing MAR, the nursing staff should take extra care in communicating and maintaining strict confidentiality.

4.7 Administrative lead

Administrative lead should have a degree in management or a similar educational qualification from a higher education institute recognized by the university grants commission.

4.7.1 Responsibilities

i. **Overall responsibility for centre services**: Ensuring that the centre operates efficiently and effectively.

ii. **Licensing and approvals**: Managing the process of obtaining necessary licenses, permits, and regulatory approvals required for the operation of the MAR centre. This includes ensuring compliance with local regulations and guidelines.

iii. **Human resource management**: Overseeing the recruitment, training, scheduling and management of staff working in various roles within the centre. This involves maintaining staffing levels, addressing Human Resource issues, and fostering a positive work environment.

iv. **ART equipment**: Supervising the acquisition, maintenance, and management of specialized ART equipment necessary for various procedures such as IVF, ICSI, and

embryo transfer. Ensuring the equipment is functional, calibrated, and meets quality standards.

v. **Consumables and supplies**: Managing the inventory of consumables and supplies essential for ART procedures, including fertility medications, laboratory supplies, disposables, and other materials required for daily operations.

vi. **Sterility maintenance**: Ensuring adherence to stringent sterilization and hygiene protocols within the centre to maintain aseptic conditions, critical for procedures involving gametes and embryos.

vii. **Compliance and quality assurance**: Ensuring compliance with ethical, legal, and quality standards related to ART services. Implementing quality control measures, audits, and continuous improvement initiatives to maintain high standards of care.

viii. **Coordination and collaboration**: Facilitating communication and collaboration among different departments within the centre, promoting teamwork, and ensuring seamless coordination for efficient service delivery.

ix. **Patient and stakeholder relations**: Maintaining positive relations with patients, stakeholders, regulatory bodies, and other external parties. Addressing patient concerns, ensuring satisfaction, and fostering a positive reputation for the centre.

5. Clinical Management of Medically Assisted Reproduction Including Assisted Reproduction

5.1 Age limitation for MAR/ART treatment

Females seeking MAR/ART treatment should not exceed 50 years of age. No embryo transfer should be done on a woman after her fiftieth birthday. This age restriction is in place considering the potential impact on maternal health and the well- being of the unborn child. This limitation aims to ensure the safety and health of both the mother and the child during and after pregnancy.

5.2 Civil status

i. For citizens of Sri Lanka undergoing MAR/ART treatment, it is mandatory that they are legally married.

ii. The ART centre should collect and maintain marriage certificates and identity documents of the couple seeking treatment. True copies of these documents should be included in the patient records as part of the verification process.

iii. Foreign citizens who are legally married, in a civil partnership or a stable relationship can be offered MAR/ART treatment.

5.3 Wellbeing of the unborn child

i. Clinician in charge should be satisfied about the 'Wellbeing of the Unborn Child' before the commencement the IVF treatment.

This is a mandatory requirement and should be recorded.

ii. If not satisfied (e.g. Couple with Physical and/or Psychological and/ or social issues), the relevant stakeholders (e.g. medical professionals, counsellors or any other relevant stakeholder) should be consulted in order to reach a conclusion on fitness of the couple to raise a child.

These referrals and feedbacks should be comprehensively recorded and should be submitted when requested by the FSGB.

iii. In the event the clinician is still not satisfied, the clinician should exercise his/her right to refuse fertility treatment or consult the FSGB for advice.

5.4 Consents

Ensure that both partners are well-informed and actively participate in decision-making throughout the MAR/ART procedures, maintaining transparency, and respecting individual choices and autonomy.

5.4.1. **Consent for ovarian stimulation and fertilization by IVF/ICSI**: Informed written consents from both Partners, are necessary for ovarian stimulation, whether using them own gametes or donor gametes.

5.4.2. **Counselling:** The Consultant in charge of the cycle and/or the MAR/ART centre is bound to explain the IVF cycle (stimulation protocols and the possible risks and complications) to the patient and answer any queries. The consent forms (Annex 4a, 4b & 4c) should be explained to both partners before signing.

5.4.3. **Consent for oocyte retrieval**: Both partners must provide informed written consent specifically for the process of oocyte (egg) retrieval.

5.4.4. **The consultant in charge of the cycle and/or the MAR/ART centre** is bound to explain the oocyte retrieval procedure and possible risks and complications and explain to both partners. The consent form should be explained to both partners before signing the form.

5.4.5. **Consent for embryo/gamete freezing and storage duration**: Both partners need to provide written consent for the freezing and storage of embryos or gametes. This should include the duration for which the storage is agreed upon.

5.4.6. **Consent for embryo and or gamete donation**: In cases where embryo donation is involved, written consent from both partners is mandatory for donating embryos.

A. This could be for following indications;
   i. Gamete donation or embryo donation for fertility treatment of another subfertile couple
   ii. Gamete donation or embryo donation for research work (Annex 4d)
   iii. Gamete donation or embryo donation for training purposes.

B. The gamete donor could be single or married. For a married gamete donor, it is recommended both partners are aware of the gamete donation and should be taken from both partners.

C. For an embryo donation it is mandatory that both partners give written consent for the donation. Embryo donation cannot take place when one partner has not consented for donation.

D. If one partner is deceased without consenting for donation, the embryo donation cannot take place even when the living partner has consented for donation.

5.4.7. **Consent for embryo biopsy:** If embryo biopsy is part of the procedure, written consent is required from both partners for this process.

5.4.8. **Consent for discarding embryos**: Before discarding (disposing) It is mandatory to take written consent from both partners.

5.5 Screening

Screening tests and investigations are crucial in assessing the health status of the individuals involved and identifying any potential factors that might impact the success of MAR/ART procedures, ensuring better outcomes and minimizing risks during the treatment process.

5.5.1. **Infections screening**: It is mandatory screening for infections such as syphilis, hepatitis B and C, HIV, and other potential microorganisms are performed to ensure the safety of the individuals undergoing MAR/ART procedures.

5.5.2. **Immunological investigations**: Appropriate investigations should be conducted, especially when indicated, to exclude any immunological factors in the couple that might interfere with the success of MAR/ART procedures.

5.5.3. **Karyotyping**: Karyotyping, which involves examining an individual's chromosomes, is recommended in specific situations:

i. Family history of chromosomal disorders

ii. Recurrent pregnancy loss

iii. Recurrent implantation failures

iv. Persistent severe oligozoospermia (low sperm count), asthenozoospermia (poor sperm motility), or teratozoospermia (abnormal sperm morphology) in the male partner.

5.6 Collection of sperm

The primary goal is to maintaining high standards and transparency throughout the collection and utilization of sperm for MAR/ART procedures, accommodating exceptional situations, ensuring meticulous documentation, and adhering to ethical considerations as outlined below.

5.6.1. **Collection of seminal fluid sample at a licensed centre**: Generally, it is preferable that sperm production for assisted reproduction procedures takes place within a licensed MAR/ART centre to ensure proper handling and quality control.

5.6.2 **Exceptional Circumstances for collection of seminal fluid sample outside the centre:**
In exceptional cases or circumstances, when attempts at within the centre have failed, the centre may allow to collect a seminal fluid sample at home or elsewhere, outside the centre. This should only occur under specific circumstances and following proper documentation of failed attempts within the centre.

5.6.3. **Requirement for counselling and declaration**: In cases where seminal fluid sample is collected outside the centre, counselling of both the husband and wife is essential. Both partners should submit a signed declaration confirming that the sample obtained from the husband is genuine and obtained under appropriate conditions.

5.6.4. Consideration for embryo donation: If embryos are created using partner where the seminal fluid sample is collected outside the licensed centre and there's a consideration for donation of excess embryos, it is important to note and record that the seminal fluid sample was not collected at the licensed centre. This information should be duly documented and taken into account, if excess embryos are considered for donation.

5.7 Ovarian Stimulation for MAR/ART

This section outlines the consultant's role in patient consultations, treatment planning, ensuring safety during ART stimulation, and handling potential complications like OHSS, ensuring high standards of care and patient safety throughout the IVF stimulation process (Refer 4.1).

5.7.1. Patient consultation and assessment: The consultant is responsible for conducting patient consultations and assessing both partners comprehensively through appropriate investigations.

5.7.2. Planning ovarian stimulation: Primary responsibility lies with the consultant in charge for planning ovarian stimulation for MAR/ART.

A. Responsibilities include:

i. Counselling the couple about the treatment plan.

ii. Providing guidance on the potential need for using donor eggs, sperm, or embryos if indicated.

iii. Counselling on the potential need for genetic assessment of embryos (PGT), if available at the centre. If PGT facilities are unavailable, Fertility Specialist must counsel the couple regarding PGT and its advantages during the consultation so the couple can look for alternative ART centre with this facility if they wish to have embryos tested.

B. Treatment protocol and management: The consultant decides on the treatment protocol, including determining the medication, overseeing follicular tracking, and managing the triggering process.

C. Ensuring patient safety during stimulation: Ensuring patient safety is paramount; the consultant should take all precautions to use correct drug dosage for ovarian stimulation without compromising patient safety.

D. Management of ovarian hyperstimulation syndrome (OHSS):

i. In situations where there are indications of possibility of OHSS the consultant should take adequate precautions to prevent such occurrence for the safety of patients. (e.g. cancellation of the cycle)

ii. The consultant should possess competence in managing OHSS should it occur during the stimulation process.
iii. Reporting severe or critical OHSS cases to the supervising authority within 24 hours, is mandatory.

5.8 Oocyte retrieval

Delineate the roles and responsibilities of medical professionals involved in Oocyte Retrieval, ensuring proper patient care, documentation, and handling of retrieved oocytes for further ART procedures.

i. **Performing oocyte retrieval**: Oocyte retrieval should be performed by a specialist in Subfertility/ a competent specialist Gynaecologist with Expertise in ART.

ii. **Patient consent and explanation**: The procedure and possible complications should be thoroughly explained to the patient by the Specialist, before starting the Oocyte Retrieval, and informed written consent should be obtained.

iii. **Documentation and reporting**: Notes regarding the Oocyte Retrieval should be documented by the performing specialist. These notes should be signed and dated.

iv. **Anaesthesia and sedation**: A consultant anaesthetist should provide adequate anaesthesia or sedation during the procedure and is responsible for relevant documentation related to this aspect.

v. **Post-retrieval responsibilities**: After the procedure, the specialist who performed the oocyte Retrieval is expected to inform the patient about the number of oocytes retrieved and any complications encountered during the process. It is preferable that a member of the embryology team also take part in the post retrieval counselling session.

vi. **Responsibility of the embryology team**: The embryology team is responsible for handling the retrieved oocytes, performing procedures like IVF/ICSI, monitoring embryo growth, and overseeing embryo freezing processes.

vii. Embryology team is responsible for storing the frozen embryos and gametes maintaining the traceability of origin.

viii. **Quality assurance and facility maintenance**: The embryology team is expected to ensure that the facilities for embryo freezing meet the required standards. They should take necessary steps to maintain these standards and promptly inform the clinical and administrative teams if any issues arise.

5.9 Fertilization

This section emphasizes the importance of a well-justified and medically appropriate selection of fertilization procedures in assisted reproduction, ensuring the best possible outcomes for patients while considering their individual fertility profiles and medical conditions.

i. **Justifiable reasons for fertilization procedures**: The choice between different fertilization procedures (e.g., Conventional IVF, ICSI, or other advanced technologies) should be based on justifiable and medically sound reasons.

ii. **Individualized selection**: The decision-making process for selecting a specific fertilization method should consider individual patient factors, the couple's fertility history, and any underlying medical conditions that may impact the success of the procedure.

5.10 Donor eggs/sperms/embryos

Following recommendations are aimed at regulating and ensuring the responsible usage of donor sperm in assisted reproduction, considering both the health aspects and confidentiality of the donor, as well as establishing limits to prevent excessive offspring from a single donor.

5.10.1 All donors of Embryos, oocytes and Sperms should be registered at the FSGB.

All ART centres should have a separate register of donors (oocytes and Sperms and Embryos) and submitted to the FSGB to maintain a Master registry of all types of donors.

5.10.2 All donors should be comprehensively assessed and investigated by a qualified specialist or Medical Officer before registering as a donor. (Significant Medical or Genetic conditions and Infectious screening)

5.10.3 All donor cycles (Egg /Sperm/Embryo) performed at a centre should be reported to the FSGB on a quarterly basis which should include the outcome of each treatment cycle. This should be done according to the 'Quarterly Return for Donor Cycles' (Annex 5)

5.10.4 All centres should promptly inform the ART Authority if a donor treatment cycle results in foetal anomalies/ congenital anomalies or any other genetically related adverse pregnancy outcomes. In such instances the suitability of the donor should be reassessed. Until such time use of gametes from the respective donor/donors should be withheld. The samples from the investigated donor can be used for treatment cycles only after clearance by FSGB.

5.10.5 Payments to donors

A. Commercial egg donation, Sperm donation or embryo donation is considered inappropriate and no fertility centre shall be engaged in obtaining such gametes on a commercial basis. However, it is acceptable to reimburse the expenditure incurred by the donor.

B. Reimbursement of Expenditures - sperm, ova or embryo donation. The following expenditures incurred by a donor in the course of donating sperm or ova may be reimbursed.

i. travel expenditures, including expenditures for transportation, parking, meals and accommodation;
ii. expenditures for the care of dependents;
iii. expenditures for counselling services;
iv. expenditures for legal services related to gamete/embryo donation;
v. expenditures for obtaining any medicine;
vi. expenditures for obtaining products or services that are provided or recommended by the fertility centre;
vii. expenditures for health, disability related to egg donation or travel to obtain treatment;
viii. expenditures for obtaining or confirming medical or other records;

Such expenditure reimbursement should not exceed a maximum of Rupees one hundred fifty thousand (Rs. 150,000/-) per egg donation and Rupees ten thousand per sperm donation. If any extra reimbursement is required approval should be obtained from the FSGB.

5.10.6 Donation of sperms

A. **Limitation on number of donations**: Donors providing sperm can father a maximum of 10 children through sperm donation cycles and thereafter should be noted in the master registry at the FSGB and informed to all the fertility centres. This limit aims to prevent excessive number of offsprings related to a single donor and mitigate potential genetic relationships between half-siblings.

B. **Routine screening for STIs**: Donors must undergo screening for sexually transmitted infections (STIs) such as HIV 1 and 2, Hepatitis B and C and Syphilis. These tests should show negative results before the samples are obtained. The donor should be rechecked after the window period of 3 months before using the samples.

C. **Disclosure of blood group**: The blood group of the sperm donor should be disclosed to the recipient and adequately explained.

D. **Donor characteristics** could be disclosed without revealing identity.

E. **Confidentiality of donor identity**: The identity of the sperm donor must be maintained with strict confidentiality. It should never be disclosed to the recipients unless mandated by legal provisions.

F. **Age criteria for donors**: The recommended age for sperm donors is between 20 and 45 years. However, in exceptional circumstances where a suitable young donor is not available, an older person may be considered for sperm donation, after careful assessment and relevant implication counselling.

G. **Absence of significant medical and inherited illnesses**: Sperm donors should not have any known significant medical conditions or inherited illnesses that could pose potential risks or complications to the recipient or the offspring.

H. Donor can receive **reasonable compensation** for each donation cycle as recommended by the FSGB.

I. Following **information should be given** to the donors by a specialist or a trained counsellor prior to consenting for sperm donation.

J. **If donated at a licensed MAR/ART centre as an anonymous donor**,

the sperm donor **will not:**

i. be the legal parent of the child,
ii. have any parental responsibilities to the child, be named on the birth certificate,
iii. have any rights over how the child will be brought up, or
iv. be required to support the child financially.

K. **Donating through a private arrangement**

i. At present only anonymous sperm donations are recommended and donation by a known donor is discouraged.

ii. Some donors decide to donate in a private arrangement. If you donate through a private arrangement, the fertility centre will not be responsible regarding the legality of parenthood.

iii. The woman who gives birth is always the legal mother.

5.10.7 Donor eggs

A. **Limitation on number of Donations**: Donors providing Oocytes can mother a maximum of 10 children through oocyte donation cycles and thereafter should be taken off from the Registry maintained at the FSGB and informed to the fertility centres. This limit aims to prevent excessive number of offsprings related to a single donor and mitigate potential genetic relationships between half-siblings.

B. Maximum number of egg donation cycles from a single donor should **not be more than four** cycles.

C. **Minimum Gap Between Donation Cycles**: There should be a minimum gap of six months between consecutive egg donation cycles by a single donor. This time frame allows for sufficient recovery and reduces potential risks associated with multiple donations.

D. **Routine Screening for infections**: Donors must undergo routine screening for infectious diseases such as HIV 1 and 2, syphilis, Hepatitis B, and C. These tests should indicate negative results within the last three months before donation.

E. **Confidentiality of donor identity**: The identity of the egg donor should be strictly confidential and not disclosed to the recipients unless required by legal provisions.

F. In situations where eggs of a known donor are used the centre will not responsible regarding the **identification of the donor** or any subsequent issues related to the egg donation from a known donor.

G. Consultant and the MAR/ART centre/hospital are responsible for the **safety of the donor** and any complication arising in a donor due to ART should be completely looked after by the respective MAR/ART centre/hospital or make suitable arrangements to look after the health of the donor.

H. **Other Criteria of eligibility**

Additional criteria aim to ensure the suitability and health of egg donors, considering factors such as age, previous reproductive history, and absence of significant medical or inherited conditions, thus contributing to safer and more successful assisted reproduction procedures.

i. **Age range:** Ideal age range for egg donors is generally less than 35 years and above 20 years old. However, under exceptional circumstances where a suitable young donor is not available, consideration may be given to older individuals.

ii. **Preferable to have a living child**: It is preferable for an egg donor to have at least one living child of her own. This criterion may vary based on individual clinic policies and preferences.

iii. **Absence of significant medical and inherited illnesses**: Egg donors should not have any known significant medical conditions or inherited illnesses that could pose potential risks or complications to the recipient or the offspring.

5.10.8 Egg sharing

Egg sharing arrangements in assisted reproduction, allowing women to donate eggs while undergoing IVF treatment themselves, maintaining confidentiality. In such situations recipients are expected to cover part of the associated costs as decided by the centre.

A. **Age criteria**: Women participating in egg sharing programs should generally be between 20 years and 35 years.

B. **Absence of any gynaecological pathologies and medical comorbidities**: The sharing donor should not have any gynaecological or medical disorder that adversely affect egg donation, safety of the donor or offspring.

C. **Childbearing status**: Egg donors in sharing programs may be women with or without living children.

D. **Simultaneous IVF treatment**: Women participating in egg sharing programs might undergo IVF treatment simultaneously, allowing them to donate eggs while receiving IVF treatment themselves.

E. **Confidentiality of donor/recipient identities**: The identities of both the egg donor and recipient should be kept strictly confidential. Disclosure to recipients should only occur when mandated by legal provisions.

F. **Financial responsibility**: Recipients participating in egg sharing should cover part of the costs of the IVF treatment for the donor, up to the point of egg retrieval.

5.10.9 Donor embryos

These guidelines aim to regulate the usage of donor embryos in assisted reproduction, emphasizing the necessity of written consent from biological parents, ensuring no financial gains for the centre from recipients, and maintaining traceability of embryos for accountability and proper record-keeping.

A. **Consent of biological parents**: Obtaining the written consent of the both biological parents of the embryo is mandatory before utilizing donor embryos. This consent should be documented and recorded.

B. **Payment to donor**: Embryo donation should be voluntary and commercial donation is discouraged

C. **Financial transactions with the recipient**: The centre should not derive any financial benefit from the recipient for providing surplus donor embryos. This practice ensures that the usage of embryos is not driven by financial gain for the centre.

D. **Traceability of embryos:**

i. All surplus or frozen embryos used in assisted reproduction procedures should be traceable back to their biological parents or to the couple who use donor gametes.

ii. The centres should not be creating embryos using donor gametes without identifying a recipient couple. Any such practice for commercial gain with embryo donation is unacceptable.

iii. This traceability ensures accountability and proper records regarding the origin and usage of embryos.

5.10.10 Sex selection of embryos

Sex selection in assisted reproduction shall be limited to only medically justified reasons (e.g. Family history of Haemophilia, Duchenne muscular dystrophy), ensuring that the practice is employed solely for addressing specific genetic or medical concerns rather than for non- medical or social preferences.

A. **Prohibition for social reasons:** Treatment centres should refrain from selecting the sex of embryos for non-medical or social reasons. This means that sex selection solely for family balancing or personal preferences unrelated to medical concerns is not permissible.

B. **Medical justification for sex selection:** Sex selection of embryos may be offered only when there are specific medical reasons. These could include cases where there is a risk of inheriting genetic disorders that are linked to a particular sex chromosome (e.g. Y chromosome linked genetic disorders, X-linked dominant diseases).

5.11 Embryo transfer

Regulate and standardize the procedures and circumstances surrounding embryo transfer in assisted reproduction, ensuring appropriate techniques, cycle choices, and ethical considerations.

5.11.1 **Performing embryo transfer**: Embryo transfer should be performed by a specialist in subfertility or a specialist gynaecologist with expertise in ART.

5.11.2 **Types of transfers:** Embryo transfer can be conducted as either a fresh embryo transfer or a frozen embryo transfer (FET).

5.11.3 **Options for Frozen Embryo Transfer (FET):** Frozen embryo transfer (FET) can occur in different cycles: natural cycle, modified natural cycle, or medicated cycle.

5.11.4 **Recommendation for medicated FET**: Medicated FET is recommended for patients with conditions such as Endometriosis or Adenomyosis, or in cases where menstrual cycles are highly irregular.

5.11.5 **Avoidance of mixing gametes or embryos**: Women should not be treated with embryos derived from the gametes of more than one man and/or one woman during any treatment cycle. The practice of embryo mixing or sperm mixing is considered highly unethical.

5.11.6 **Number of embryos**: Regulation of the number of embryos transferred during assisted reproduction, emphasizing the preference for single embryo transfer to mitigate the risks associated with multiple pregnancies, while considering individual patient factors and history of previous treatments is discussed in this section.

A. **Factors influencing number of embryos**: The decision on the number of embryos to transfer should consider the patient's age, embryo quality, and outcomes of previous embryo transfers.

B. **Preference for Single Embryo Transfer (SET):** Single embryo transfer (SET) is considered the optimal choice as it minimizes the risks associated with multiple pregnancies while maintaining the chance of a successful pregnancy.

C. **Limitation on number of embryos**: Not more than two embryos should be transferred due to the higher likelihood of multiple pregnancies.

D. **Rare consideration for triple embryo transfer**: In exceptional cases, a clinician may consider triple embryo transfer for older patients, patients with poor-quality embryos and in patients with a history of multiple unsuccessful Embryo Transfers (FETs).

E. **Prevention of multiple pregnancies**: It is crucial to minimize the risk of multiple pregnancies by using the minimum number of embryos necessary for a successful pregnancy.

F. **Reporting and investigation of higher order pregnancies**: Any triplet or higher order pregnancies resulting from assisted reproduction should be reported to the FSGB. Investigation by the FSGB is necessary to provide recommendations or appropriate actions (warnings, cancellation of registration etc).

5.12 Transfer of gametes and embryos

Transfer of gametes and embryos between licensed treatment centres must be done in accordance with the directions made by the FSGB. This will ensure that the transfer of gametes and embryos between licensed treatment centres in assisted reproduction follows strict directives laid down by the supervising authority, maintaining regulatory compliance and standardized procedures to safeguard the integrity and safety of these biological materials during transportation.

5.12.1 **Compliance with FSGB directions:** The transfer of gametes (sperm or eggs) and embryos between licensed treatment centres should strictly adhere to the directions provided by the FSGBSL overseeing assisted reproduction practices.

5.12.2 **Regulatory compliance**: Any movement or transfer of gametes or embryos between centres must comply with the specific guidelines, regulations, and protocols set forth by the FSGB responsible for overseeing assisted reproductive treatments.

5.13 Disposal of embryos

It is essential to ensure that the decision-making process and procedure for the disposal of embryos in assisted reproduction are handled sensitively, ethically, and in accordance with established guidelines, promoting transparency and proper communication with the involved parties.

5.13.1 Decision-making for disposal: In cases where an embryo is no longer required for treatment or storage, the treatment centre is responsible for determining the method and procedure for allowing the embryo to perish.

5.13.2 Sensitive procedure for disposal: The procedure for disposal should be sensitively developed and clearly described by the centre. It should take into account ethical considerations and be communicated to the individuals or parties for whom the embryo was originally being stored and obtain their written consents.

5.13.3 Disposal of embryos: The disposal process should align with the guidelines and directives outlined by the FSGB, ensuring adherence to ethical standards and proper protocols for handling perished embryos.

5.14 Embryo research

Any embryo research conducted in the field of assisted reproduction is subjected to rigorous oversight and ethical considerations, requiring explicit approval from the FSGB and Ethics Committee recommended by the FSGB while referencing established guidelines related to embryo donation.

5.14.1 Need for FSGB approval: Embryo research is only permitted upon receiving explicit approval from the FSGB, along with the involvement and approval from its Ethics Committee (Refer section 6).

5.14.2 Decision-making process: The FSGB, with inputs from its Ethics Committee, will evaluate and consider all relevant details before granting approval for any proposed embryo research activities.

5.14.3 Reference to embryo donation guidelines: Specific guidelines or procedures for obtaining embryos for research purposes should align with the section dedicated to embryo donation.

5.15 Gestational Surrogacy

5.15.1 Gestational surrogacy is only utilized/allowed for medical reasons, and the legal ownership of the baby follows a defined procedure, acknowledging the birth mother's initial ownership while allowing for subsequent transfer to the biological/intended parents through legal procedures.

5.15.2 Medical indication: Gestational surrogacy should be permitted only for patients for whom it would be physically or medically impossible/undesirable to carry a baby to term.

5.15.3 Ownership of Baby:

A. The mother who physically delivers the baby through gestational surrogacy is considered the rightful owner of the child initially.

B. The existing country law should be followed for the transfer of ownership to the Biological or intended parents, post-delivery.

5.15.4 Payments to surrogate mothers should cover all genuine expenses associated with the pregnancy. Documentary evidence of the financial arrangement for surrogacy must be available.

5.15.5 Advertisements regarding surrogacy should not be made by the ART centre. The responsibility of finding a surrogate mother, through advertisement or otherwise, should rest with the couple.

5.15.6 A surrogate mother should not be over 45 years of age.

5.15.7 Before accepting a woman as a possible surrogate for a particular couple's child, the ART centre must ensure (and put on record) that the **woman satisfies all the testable criteria** to go through a successful full-term pregnancy.

5.15.8 The health of the surrogate should be carefully assessed by the specialist to confirm her fitness to go through the pregnancy and she and her husband should be counselled regarding the associated possible risks of surrogacy.

5.15.9 A relative, a known person, as well as a person unknown to the couple may act as a surrogate mother for the couple. In the case of a relative acting as a surrogate, the relative should ideally belong to the same generation as the women desiring the surrogate.

5.15.10 A prospective surrogate mother must be **tested for HIV, Syphilis, Hepatitis B and C** and shown to be seronegative for these viruses just before embryo transfer. The surrogate should also be immune to Rubella.

5.15.11 No woman may act as a surrogate more than thrice in her lifetime. The specialist should assess the risk of going through the pregnancy when there are obstetric or medical risk factors before selecting the surrogate.

6. Ethics Committees

6.1 FSGB should have **a central ethics committee** comprising of ART practitioners, scientists who are knowledgeable in developmental biology or in clinical embryology, a social scientist and a member of the legal community.

6.2 Each **ART clinic must have its own ethics committee** constituted according to SLMC Guidelines, comprising ART practitioners, scientists who are knowledgeable in developmental biology or in clinical embryology, a social scientist and a member of the legal community.

7. Reporting Incidents Related to Fertility Treatment

It is important to report any fertility treatment adverse incident to the FHSGB for efficient supervision of the fertility services in Sri Lanka.

7.1 Reporting incidents by the fertility centre

The BoD/Unit Head and the Administrative Lead are responsible to report following incidents to the FSGB.

A. Severe or Critical OHSS should be reported within 24 hours.

B. Surgical complications related to Oocyte retrieval.

C. Triplet or higher order pregnancies following fertility treatment.

7.2 Reporting incidents by other parties

7.2.1 Obstetricians and Gynaecologists

A. When a triplet or higher order ongoing pregnancy as a result of MAR/ART is diagnosed.

B. When triplets or higher number of babies resulting of MAR/ART are delivered in the unit.

C. When severe or critical OHSS is diagnosed in a patient undergoing fertility treatment.

D. Any other significant event, related to fertility treatment which the consultant thinks should be reported.

7.2.2 Neonatologist/ paediatricians/ neonatology units

Any triplet or higher number of babies resulting from MAR/ART, coming under their care should be reported.

7.2.3 Judicial medical officers

Any medicolegal event which may have resulted due to fertility treatment E.g. Maternal deaths.

7.2.4 Other medical professionals

Any significant event, related to fertility treatment which the consultant considers should be reported FSGB.

8. References

1. Sri Lanka Medical Council. A Provisional Code of Practice for Assisted Reproductive Technologies 2005

2. Human Fertilization and Embryology Authority (HFEA) Code of Practice, 9th edition (Version 4) – revised October 2023.

3. Presented to Parliament pursuant to section 26 of the Human Fertilisation and Embryology Act 1990. The Human Fertilization and Embryology Authority, 21 Bloomsbury Street, London WC1B 3HF, admin@hfea.gov.uk, http://www.hfea.gov.uk

4. The assisted Reproductive Technology (Regulation) Act of India, 2021

5. Assisted Human Reproduction Act of Canada (S.C. 2004, c. 2)

6. Guideline of Ethical Conduct of Medical and Dental Practitioners Registered with the Sri Lanka Medical Council, 2003

Annexes

Application Format for MAR/ART Centre Registration

This format should be used for the Initial License Application (ILA) for Fertility Centers providing Fertility Treatment including Intra Uterine Insemination (IUI) and Assisted Reproduction Technologies (ART).

The Fertility Services Governing Body (FSGB) of Sri Lanka oversees and regulates all activities to provide medically assisted reproduction (MAR) services to couple seeking parenthood, including IUI and ART services. This will cover the use of sperms, oocytes/ova and embryos for human application, and research involving human gametes and viable as well as admixed human embryos.

General considerations

Before applying for a license, you are expected to familiarize yourself with the guidance and the legal framework surrounding MAR procedures in Sri Lanka. For this purpose, make sure that you go through the Code of Conduct laid down by the Ministry of Health in collaboration of the Family Health Bureau (FHB) and Sri Lanka College of Obstetricians and Gynaecologists (SLCOG).

You must have all the facilities required to provide services licensed under the provision of medically assisted reproduction services for IUI only or IUI and IVF. These include state-of-the-art laboratories and with appropriate storage facilities and air quality, clinical as well as counseling services and individual areas/rooms for counseling.

You also need to make sure that your premises have a duly approved consent from the relevant local government authority conforming to the specified safety and environmental health requirements.

Type of license

For all centers providing ART services including in-vitro fertilization, Intra-cytoplasmic sperm injection (ICSI), and gamete and embryo cryopreservation the license should cover both the treatment and storage aspects. This will cover all the specified laboratory services generally provided by an ART center, if you are planning to use a novel process or modality for either therapeutic or research purposes, you need to apply for special permission from the FSGB.

The validity period

As a new clinic, your facility will be issued a two-year license that needs to be renewed biannually. However, once established you will become eligible to apply for a license that will be valid for a period of three years.

Annex - 1

The licensing process

You need to initiate the licensing process by submitting an initial enquiry form containing the details of the fertility services you are planning to offer and the therefore the type of license you would like to apply for.

You are required to download the Initial License Application (ILA) from the following websites.

1. Private Health Services Regulatory Council (https://www.phsrc.lk/)
2. Family Health Bureau (https://fhb.health.gov.lk/)
3. Sri Lanka College of Obstetricians and Gynaecologists (https://slcog.lk/)

Once completed, you may e-mail or hand over the printed version of the ILA to;

Director, Private Health Sector Development, Ministry of Health, Colombo 10 (Email: dphsd@health.gov.lk). Once the initial enquiry form is received the FSGB will contact you and provide guidance and support through the rest of the licensing process.

Annex - 1

Initial License Application (ILA)

This form is for clinics to register their interest in applying for a license to carry out fertility treatment or research.

Please ensure the language on this enquiry form is clear and understandable to non-specialist, lay members and staff.

All abbreviations must be explained.

Complete the following sections;

1. For Treatment and/or Storage License, complete sections A and B.
2. For a Research License, complete sections A and C.
3. For IUI ONLY centres Complete sections A and D.

For information on licensing and inspection see the ***FHB/SLCOG/Private Health Services Regulatory Council websites***.

Please email or hand over the completed form to; ***Director, Private Health Sector Development, Ministry of Health, Colombo 10*** (Email: dphsd@health.gov.lk).

Section A:

Name of the Centre:	
Address:	
Contact Details:	

Contact details for correspondence prior to licensing

Name of Contact:	
Telephone Number:	
Email Address:	

Annex - 1

A. Human Resources

1. Name/S of The Unit in Charge or Board of Directors

Name	Position	Email	Mobile Number

2. Fertility Specialists practising in the centre

Name	SLMC registration No	Qualifications*	Email	Mobile number

* Attach certified copies

3. Clinical Embryology Team (<u>Not applicable for IUI only centres)</u>

Name	SLMC registration No (or alternative body)	Qualifications*	Email	Mobile number

* Attach certified copies

4. Clinical Andrology Team

Name	SLMC registration number (Or Alternative Body)	Qualifications*	Email	Mobile number

* Attach certified copies

5. Nursing Team

Name	SLMC/Nursing Council registration number (or alternative body)	Qualifications*	Email	Mobile number

* Attach certified copies

6. Administrative Team

Name	Position	Qualifications*	Email	Mobile number

* Attach certified copies

Annex - 1

Section B: Proposed Treatment and/or Storage License for ART related Activities

N.B. *Only complete this section if you intend to apply for a license to provide treatment and/or to store gametes or embryos. If you intend to apply for a research license, please only complete the 'Proposed Research License Activities - Section C below.*

Please indicate from the list below, the treatment and/or storage activities you wish to license.

Licence Activity	**Autorised processes**
☐ 1. Procuring gametes	☐ Egg collection
	☐ Surgical sperm collection
	☐ Ovarian tissue collection
	☐ Testicular tissue collection
☐ 2. Keeping gametes	☐ Culture of eggs
	☐ Culture of sperm
☐ 3. Processing gametes	☐ Semen preparation (including the use of reagents to increase sperm motility)
	☐ Egg preparation
	☐ Grading of gametes
	☐ In vitro maturation
	☐ Cryopreservation of gametes
	☐ Thawing/re-warming gametes
	☐ Polar body biopsy
	☐ Egg activation using Calcium Ionophore (only in selected patients or in accordance with professional body guidelines)
☐ 4. Distribution of gametes	☐ Transfer of sperm between centres
	☐ Transfer of eggs between centres
	☐ Supply of sperm from a licenced centre to unlicenced premises in thawed or thawing state for home insemination
☐ 5. Use of gametes	☐ IUI
	☐ GIFT
	☐ IVF
	☐ ICSI
☐ 6. Srorage of gametes	☐ Cryopreservation of eggs
	☐ Cryopreservation of sperm
	☐ Cryopreservation of testicular tissue (HTA licence may be required depending on the reason for storage and intended use)
	☐ Cryopreservation of ovarian tissue (HTA licence may be required depending on the reason for storage and intended use)
☐ 7. Srorage of embryos	☐ Cryopreservation of embryos (including at the pro nucleate and blastocyst stage)
☐ 8. Creation of embryos	☐ IVF
	☐ ICSI

Annex - 1

☐ 9. Procuring embryos	☐ Lavage
☐ 10.Keeping embryos	☐ Culture system
☐ 11.Testing embryos	☐ PGT-M
	☐ PGT-A
	☐ PGT-SR
☐ 12.Processing embryos	☐ Culture
	☐ Biopsy
	☐ Assisted hatching
	☐ Embryo grading (including non-invasive assessments, see T91 for limitations)
	☐ Manipulation
	☐ Thawing/re-warming of blastocysts and embryos
	☐ Intrauterine culture of gametes and embryos (including insertion and removal of device, followed by transfer of embryo(s) to the same person)
☐ 13.Distribution of embryos	☐ Transfer of embryos between centres
☐ 14.Placing permitted embryo inside a woman	☐ Embryo transfer
☐ 15 Using embyos in training	☐ Embryo biopsy
	☐ Blastocyst biopsy
	☐ Cryopreservation and thawing/re-warming techniques
	☐ Assisted hatching
	☐ Embryo handling and manipulation
	☐ Assessment of embryos

Please provide an estimated start date for providing treatment: DD/MM/YYYY

**Please note this date cannot be guaranteed and you should liaise with your assigned inspector regarding timelines for processing license applications.*

Annex - 1

Section C: Proposed Research License Activities

N.B. *Only complete this section if you intend to apply for a license to carry out research.*

Please indicate from the list below, what research activities you wish to carry out.

Select proposed activities	Licence Activity
☐	Creation of embryos
☐	Keeping embryos
☐	Use of embryos
☐	Storage of embryos
☐	Storing gametes to be used to create embryos for use in research
☐	Creation of admixed embryos
☐	Keeping admixed embryos
☐	Use of admixed embryos
☐	Storage of admixed embryos
☐	Storing gametes to be used to create admixed embryos for use in research
☐	Derivation of stem cells for human application
☐	Derivation of stem cells NOT for human application
☐	Other: Please specify

1. Proposed title of research project:	
2. Lay summary describing the research project:	
3. Please provide an estimated start date for research:	
**Please note this date cannot be guaranteed and you should liaise with your assigned inspector regarding license application timescales.*	

Section D: For centres intending to provide IUI only

1. Private area for semen collection	Yes ☐	No ☐
2. Andrology laboratory for sperm processing	Yes ☐	No ☐
3. Area for performing IUI	Yes ☐	No ☐
4. Facilities for Cryopreservation and sperm storage	Yes ☐	No ☐

Annex - 2

Annual Feedback Report

The report should include details from 1st January to 31st December every year.

The report should be submitted before the 31st of January the following year.

Name of the Centre	
Address	
Registration Number	

A. Stimulation cycles

1. Total number of stimulation cycles	
2. Total number of stimulations for egg donations	
3. Total number of on-going cycles	
4. Total number of cycle cancellations	

B. Oocyte Retrievals

1. Total number of oocyte retrievals performed	
2. Complications related to Oocyte retrieval (OR);	
I. Number of bladder injuries	
II. Number of bowel injuries	
III. Number of internal bleedings	
IV. Number of other complications	
(Specify complication)	
3. Number of hospital admissions due to OR related complications	

C. Laboratory

1. Number of conventional IVF cycles	
2. Number of ICSI cycles	
3. Number of egg freezing cycles	
4. Number of embryos freezing	
5. Number of embryo biopsies	
6. Fertilization rate*	
7. Blastocyst rate**	

* Number of oocytes fertilised per person /no of oocytes subjected to IVF/ICSI

** Number of blastocysts /no of fertilised oocytes

D. Total number of embryo transfers

1. Own Oocytes and Sperms (n)	
2. Donor gametes (n)	

E. Number of embryos transferred per cycle

1. Single embryo transfers (n)	
2. Double embryo transfers (n)	
3. Triple embryo or more (n)	

F. Embryo transfer outcomes

	Number	Rate per embryo transfer cycle
1. Biochemical pregnancies		
2. Negative cycles		
3. Clinical pregnancies		
4. Miscarriages		
5. Ectopic pregnancies		
6. Singleton pregnancies		
7. Twin pregnancies		
8. Triplets or higher order		
9. Live births		
10. Congenital anomalies (specify)		

G. Donor IVF

1. Number of donor oocyte retrievals	
2. Number of embryo transfers from donor oocyte IVF	
3. Number of embryo transfers from donor sperm IVF	
4. Number of donor embryo transfers	

…….. ……

Signature, Name and Designation of Reporting Officer Date

Annex - 3

Format for Immediate reporting of complications to FSGB

1. NAME OF THE CENTRE:	
2. ADDRESS:	

	COMPLICATION	REMARKS
☐	Severe Oocyte Hyper Stimulation Syndrome (OHSS)	
☐	Injuries during procedure needing hospital admission	
☐	Higher order pregnancies	
☐	Other	

…… ……

Signature, Name and Designation of Reporting Officer Date

*Please attach necessary documents

Annex - 4a

Consent to donating your sperm

About this form

This form is produced by the Ministry of Health.

Who should fill in this form?

Fill in this form if you are a man donating sperm for the treatment of others or for training purposes (to allow healthcare professionals to learn about, and practice, the techniques involved in fertility treatment).

What do I need to know before filling in this form?
Before you fill in this form, you should have registered as a donor and completed the 'Donor information form'.

You should also be certain that your clinic has given you all the relevant information you need to make fully informed decisions. This includes:

- information about:

– the different options set out in this form
– the implications of giving your consent
– the consequences of withdrawing this consent, and
– how you can make changes to, or withdraw your consent.

- an opportunity to have counselling.

If you are unsure, or think that you have not been given all of this information, please speak to your clinic. There is a declaration at the end of this form which you must sign to confirm you have received this information. If you do not receive this information before filling in this form, your consent may be invalid.

If you are unable to complete this form because of physical illness, injury or disability you may direct someone else to complete and sign it for you.

Why do I have to fill in this form?

By law, you need to give your written consent if you want your sperm, or embryos created outside the body (in vitro) with your sperm, to be used or stored (for example, for in vitro fertilisation (IVF) treatment).

If you are storing your sperm or embryos, you must also state in writing how long you consent to them remaining in storage.

What if I want to donate my sperm for research?

Sperm can also be donated for research purposes, helping to increase knowledge about diseases and serious illnesses and potentially develop new treatments. This form only allows you to consent to

donate sperm for the treatment of others or for training purposes. Your clinic can give you more information about donating for research and provide you with the relevant consent form(s).

What happens to my sperm or embryos if I die?

By consenting to donate your sperm or embryos, you are also agreeing to them being used and stored if you were to die or lose the ability to decide for yourself (become mentally incapacitated). If you do not want your sperm or embryos to be used for the purposes outlined in this form if this were to happen, you can state this as a restriction (at section 2.4 of this form). You may also state here that you only want your sperm or embryos to be donated in the event of your death.

Please note that the clinic can only act on these wishes if they are informed about your death or mental incapacity. If you're unsure of anything in relation to this, please ask your clinic.

When filling in this form, make sure you sign the declaration on every page to confirm that you have read the page and fully agree with the consent and information given. When you have completed the form, you may request a copy of it from your clinic.

Date sperm were placed in storage

D	D	M	M	Y	Y

Date sperm can remain in storage until

D	D	M	M	Y	Y

1. About you

1.1 **Your first name(s)**

1.2 **Your surname**

1.3 **Your date of birth**

D	D	M	M	Y	Y

1.4 **Your National ID number**

2. About your sperm donation

2.1 **Do you consent to your sperm being used for the treatment of others, without the creation of embryos outside the body, i.e. using artificial insemination?**

Examples of artificial insemination include intrauterine insemination (IUI) or gamete intra- fallopian transfer (GIFT), a technique which a small number of clinics use.

☐ Yes ☐ No

2.2 **Do you consent to your sperm being used to create embryos outside the body (e.g., through IVF treatment) and for these embryos to be used for the treatment of others?**

☐ Yes ☐ No

2.3 **How many families may have children using your donated sperm?**

The maximum number is 10 families. This is to minimise the possibility of two children from the same donor having a relationship with each other without knowing they are genetically related. It is also based on the perceived interests of donor-conceived people and their parents in maintaining a relatively small number of siblings. Consenting to 10 families will help the greatest number of families and maximise the potential of your donation. You should think about how many families you are comfortable donating to and the long-term implications of donation.

☐ Families may have children using my donated sperm.

2.4 **Do you have any restrictions that you would like to apply to any of your answers to 2.1 or 2.2?**

You may want to put restrictions on who your sperm or embryos are used by, e.g., a specified named recipient.

☐ Yes ➞ specify your restrictions below then continue to section 2.5.

☐ No ➞ go to section 2.5.

2.5 **Do you consent to your sperm being used for training purposes?**

☐ Yes ☐ No

2.6 **Do you consent to your embryos (already created outside the body with your sperm) being used for training purposes?**

☐ Yes ☐ No

3. Storing sperm and embryos

Please note that sperm donated for the treatment of others needs to be stored.

3.1 **Do you consent to your sperm being stored?**

☐ Yes ☐ No

3.2 **Do you consent to embryos (created outside the body with your sperm) being stored?**

Only complete this section if you answered yes to section 2.2. Please note that embryos can only be stored if the egg provider has also given her consent.

☐ Yes ☐ No

If you have answered no to both 3.1 and 3.2, sign the page declaration on this page and the next page then go to section four.

If you have answered yes to 3.1 or 3.2, or both, sign the page declaration below then continue on the next page.

In this section you must state how long you consent to your sperm and/or embryos being stored for. You may want to think about how far in the future you want others to use your stored sperm and embryos – ask your clinic if you are unsure.

Once your sperm or embryos have been allocated to someone else's treatment, the patient (together with the clinic) will determine how long the sperm and embryos are stored for within the boundaries of what you have consented to in this form.

3.3 **For how long do you consent to your sperm being stored? Only complete this section if you answered yes to section 3.1.**

☐ 10 years

☐ 55 years

☐ A specific period (up to a maximum of 55 years ➡ specify the number of years: ☐ years

3.4 **For how long do you consent to embryos (created with your sperm) being stored?**

Only complete this section if you answered yes to section 3.2.

Please note that the egg provider also has to give her consent to storage.

☐ 10 years

☐ 55 years

☐ A specific period (up to a maximum of 55 years) ➡ specify the number of years: ☐ years

The consent period will start from the date of storage. Remember you can always change the time period you consent to by completing this form again and specifying the new total time period you would like your sperm and embryos to be stored for. For example, if you consented to five years' storage on the original form and wish to consent for a further five years (10 years in total), you would complete another copy of this form but tick the box for 10 years. This second form would supersede the first form you completed.

Declaration

Please sign and date the declaration

Your declaration

• I declare that I am the person named in section one of this form.

• I declare that:

– before I completed this form, I was given information about the different options set out in this form, and I was given an opportunity to have counselling

– the implications of giving my consent, and the consequences of withdrawing this consent, have been fully explained to me, and

– I understand that I can make changes to, or withdraw, my consent at any point until the sperm or embryos have been transferred, used in training, or have been allowed to perish.

• I declare that the information I have given on this form is correct and complete.

• I understand that information on this form may be processed and shared for the purposes of, and in connection with, the conduct of licensable activities under the Ministry of Health, Sri Lanka.

Your signature **Date**

	D	D	M	M	Y	Y

If signing at the direction of the person consenting

If you have completed this form at the direction of the person consenting (because he is unable to sign for himself due to physical illness, injury or disability), you must sign and date below. There must also be a witness confirming that the person consenting is present when you sign the form.

Representative's declaration

I declare that the person named in section one of this form is present at the time of signing this form and I am signing it in accordance with his direction.

Annex - 4a

Representative's name

Representative's signature

Relationship to the person consenting

Date

D D M M Y Y

Witness's name

Witness's signature

Date

D D M M Y Y

Men's consent to treatment and storage form (IVF and ICSI)

This form is produced by the Ministry of Health Sri Lanka.

Who should fill in this form?

Fill in this form you are having fertility treatment using embryos created outside the body (in vitro) with your sperm. This may be in vitro fertilization (IVF) or intra-cytoplasmic sperm injection (ICSI).

What do I need to know before filling in this form?

Before you fill in this form, you should be certain that your clinic has given you all the relevant information you need to make fully informed decisions.

This includes: Information about:

- The different options set out in this form
- The implications of giving your consent
- The consequences of withdrawing this consent,
- How you can make changes to, or withdraw, your consent.
- An opportunity to have counselling.

If you are unsure, or think that you have not been given all of this information, please speak to your clinic.

There is a declaration at the end of this form which you must sign to confirm you have received this information. If you do not receive this information before filling in this form, your consent may be invalid.

If you are unable to complete this form because of physical illness, injury or disability you may direct someone else to complete and sign it for you

Why do I have to fill in this form?

You need to give your written consent if you want your sperm, and embryos created using your sperm, to be used or stored (e.g. for IVF or ICSI treatment). If you are storing your sperm or embryos, you must also state in writing how long you consent to them remaining in storage. You

are also legally required to record what you would like to happen to your sperm and embryos if you were to die or lose the ability to decide for yourself (become mentally incapacitated). While this is perhaps not something you have considered, your clinic needs to know this so that they only allow your sperm and embryos to be used according to your wishes. If you are unsure of anything in relation to this, please ask your clinic.

Using my sperms and embryos for training purposes?

You may have some sperms and embryos left after treatment which you do not wish to use (e.g. because you do not want future treatment or the sperms and embryos are not viable for treatment). On this form, you can consent to donate these for training purposes to allow healthcare professionals to learn about, and practice, the techniques involved in fertility treatment

What if I want to donate my sperm and/or embryos?

Unused sperm and embryos can also be donated for research purposes, helping to increase knowledge about diseases and serious illnesses and potentially develop new treatments. Your clinic can give you more information about this and provide you with the relevant consent form(s). You could also think about donating viable unused sperm and embryos to another person for use in their treatment. Before doing this, there are lots of issues to consider. If you decide to donate, you will need to complete a separate form: 'Your consent to donating your sperm'

1. Personal information

Your first name(s) :…….

Your surname: ……

Your date of birth: ……..

Your NIC/passport number (please circle) :……..

2. Partners personal information

Your partner's first name(s) :…….

Your partner's surname: ……

Your partner's date of birth: ……..

Your partner's NIC/passport number (please circle) :……..

3. Your treatment

Do you consent to your sperm being used to create embryos outside the body for your treatment (e.g., through IVF treatment)?

In order to create embryos for your treatment you must provide your consent by ticking the yes box below. Please note that the egg provider also has to give his consent for embryos to be created.

YES ☐ NO ☐

4. Storing embryos

4.1 Do you consent to the embryos (created outside the body with your sperm) being stored? Please note that embryos can only be stored if the egg provider has also given his consent.

YES ☐ NO ☐

Embryo storage periods

You may wish to store any embryos left after treatment so they can be used in future treatment. To be stored, embryos are frozen or 'vitrified'. When considering how long to store for, you may want to think about how far in the future you might want/be able to use your stored embryos and the costs of storing – ask your clinic if you are unsure.

Please note that any arrangements you need to make regarding the practicalities of storage with your clinic or funding body are separate from this consent. For example, your clinic may only continue to store your embryos for the period you have specified in this form if you, or your funding provider, continue to pay the storage fees.

4.2 Have you, or your partner, been diagnosed as prematurely infertile or likely to become prematurely infertile?

Causes of premature infertility can include chemotherapy treatment and early menopause. Please speak to your clinic if you are unsure. If your circumstances change and either you or your partner become prematurely infertile, or are likely to become prematurely infertile, you and your partner can change your consent to store your embryos for up to 55 years.

YES ☐ go straight to 4.4. NO ☐ go to 4.3.

4.3 For how long do you consent to store your embryos?

You can consent to store your embryos for up to 10 years. Please note that the egg provider also has to give his consent to storage.

- For 10 years ☐
- For a specific period (up to a maximum of 10 years) specify the number of years:
  ☐ Years

The consent period will start from the date of storage. Remember you can always change the time period you consent to by completing this form again and specifying the new total time period you would like your embryos to be stored for.

4.4 Premature infertility

If you or your partner are prematurely infertile, or likely to become prematurely infertile, you can consent to store your embryos for up to 55 years.

When the criteria have been met, the storage period will be extended by 10 years from the date the criteria are met. The storage period can then be extended by further 10 year periods (up to a maximum of 55 years) at any time within each extended storage period if it is shown that the criteria continue to be met. For more information about this, please ask your clinic.

For how long do you consent to store your embryos?
You do not need to fill in this section if you have completed section 4.3.

Please specify the number of years you consent to store your embryos for (up to a maximum of 55): ☐ years.

(Clinic staff: please attach all relevant medical practitioners' statements to this form)

5. Using sperm and embryos for training

5.1 Do you consent to your sperm being used for training purposes?

YES ☐ NO ☐

5.2 Do you consent to embryos (already created outside the body with your sperm) being used for training purposes?
Please note that embryos can only be used if the egg provider has also given consent.

YES ☐ NO ☐

6. In the event of your death or mental incapacity

As part of your consent, you also need to decide what you would like to happen to your sperm, to decide for yourself (become mentally incapacitated). Please note your embryos may only be used within the storage period you consented to above. If you do not give your consent in the below section, your sperm or embryos must be allowed to perish in the event of your death or mental incapacity and cannot be used for treatment.

6.1 Do you consent to your sperm being used for training purposes?

- If you die YES ☐ NO ☐
- If you become mentally incapacitated YES ☐ NO ☐

6.2 Do you consent to embryos (already created outside the body with your sperm) being used for training purposes?

Please note that embryos can only be used if the egg provider has also given his consent.

- If you die YES ☐ NO ☐
- If you become mentally incapacitated YES ☐ NO ☐

Other uses for your sperm or embryos

If you wish your sperm or embryos to be used in someone else's treatment, if you die or become mentally incapacitated, please speak to your clinic for more information. Depending on your circumstances, you will need to complete one of the following:

- 'Your consent to donating your sperm'
- 'Your consent to donating embryos' or
- 'Men's consent to the use and storage of sperm or embryos for surrogacy'.

7. Declaration

Please sign and date the declaration

Your declaration

- I declare that I am the person named in section one of this form.
- I declare that:

– before I completed this form, I was given information about the different options set out in this form, and I was given an opportunity to have counselling

– the implications of giving my consent, and the consequences of withdrawing this consent, have been fully explained to me, and

– I understand that I can make changes to, or withdraw, my consent at any point until the time of embryo transfer, use of sperm or embryos in training, or the sperm or embryos have been allowed to perish.

- I declare that the information I have given on this form is correct and complete.

Your signature:…….. Date :…….

If signing at the direction of the person consenting

If you have completed this form at the direction of the person consenting (because she is unable to sign for herself due to physical illness, injury or disability), you must sign and date below. There must also be a witness confirming that the person consenting is present when you sign the form.

Representative's declaration

I declare that the person named in section 1 of this form, is present at the time of signing this form and I am signing it in accordance with his direction.

Representative's name:……..

Representative's Signature :…….

Relationship to the person consenting:…… Date:……

Witness's name**:……**

Witness's signature:…….. Date :…….

Annex - 4c

Women's consent to treatment and storage form (IVF and ICSI)

This form is produced by the Ministry of Health Sri Lanka.

Who should fill in this form?

Fill in this form you are having fertility treatment using embryos created outside the body (in vitro) with your eggs. This may be in vitro fertilization (IVF) or intra-cytoplasmic sperminjection (ICSI).

What do I need to know before filling in this form?

Before you fill in this form, you should be certain that your clinic has given you all the relevant information you need to make fully informed decisions.

This includes: Information about:

- The different options set out in this form
- The implications of giving your consent
- The consequences of withdrawing this consent,
- How you can make changes to, or withdraw, your consent.
- An opportunity to have counselling.

If you are unsure or think that you have not been given all of this information, please speak to your clinic.

There is a declaration at the end of this form which you must sign to confirm you have received this information. If you do not receive this information before filling in this form, your consent may be invalid.

If you are unable to complete this form because of physical illness, injury or disability you may direct someone else to complete and sign it for you

Why do I have to fill in this form?

You need to give your written consent if you want your eggs, and embryos created using your eggs, to be used or stored (e.g., for IVF or ICSI treatment). If you are storing your eggs or embryos, you must also state in writing how long you consent to them remaining in storage. You are also legally required to record what you would like to happen to your eggs and embryos if you were to die or lose the ability to decide for yourself (become mentally incapacitated). While this is perhaps not something you have considered, your clinic needs to know this so that they only

allow your eggs and embryos to be used according to your wishes. If you are unsure of anything in relation to this, please ask your clinic.

Using my eggs and embryos for training purposes?

You may have some eggs and embryos left after treatment which you do not wish to use (e.g., because you do not want future treatment or the eggs and embryos are not viable for treatment). On this form, you can consent to donate these for training purposes to allow healthcare professionals to learn about, and practice, the techniques involved in fertility treatment

What if I want to donate my eggs and/or embryos?

Unused eggs and embryos can also be donated for research purposes, helping to increase knowledge about diseases and serious illnesses and potentially develop new treatments. Your clinic can give you more information about this and provide you with the relevant consent form(s). You could also think about donating viable unused eggs and embryos to another person for use in their treatment. Before doing this, there are lots of issues to consider. If you decide to donate, you will need to complete a separate form: 'Your consent to donating your eggs'

1. Personal information

Your first name(s) :…….

Your surname: ……

Your date of birth: ……..

Your NIC/passport number (please circle) :……..

2. Partners personal information

Your partner's first name(s) :…….

Your partner's surname: ……

Your partner's date of birth: ……..

Your partner's NIC/passport number (please circle) :……..

3. Your treatment

Do you consent to your eggs being used to create embryos outside the body for your treatment (e.g., through IVF treatment)?

In order to create embryos for your treatment you must provide your consent by ticking the yes box below. Please note that the sperm provider also has to give his consent for embryos to be created.

YES ☐ NO ☐

4. Storing embryos

4.1 Do you consent to the embryos (created outside the body with your eggs) being stored? Please note that embryos can only be stored if the sperm provider has also given his consent.

YES ☐ NO ☐

Embryo storage periods

You may wish to store any embryos left after treatment so they can be used in future treatment. To be stored, embryos are frozen or 'vitrified'. When considering how long to store for, you may want to think about how far in the future you might want/be able to use your stored embryos and the costs of storing – ask your clinic if you are unsure.

Please note that any arrangements you need to make regarding the practicalities of storage with your clinic or funding body are separate from this consent. For example, your clinic may only continue to store your embryos for the period you have specified in this form if you, or your funding provider, continue to pay the storage fees.

4.2 Have you, or your partner, been diagnosed as prematurely infertile or likely to become prematurely infertile?

Causes of premature infertility can include chemotherapy treatment and early menopause. Please speak to your clinic if you are unsure. If your circumstances change and either you or your partner become prematurely infertile, or are likely to become prematurely infertile, you and your partner can change your consent to store your embryos for up to 55 years.

YES ☐ go straight to 4.4. NO ☐ go to 4.3.

4.3 For how long do you consent to store your embryos?

You can consent to store your embryos for up to 10 years. Please note that the sperm provider also has to give his consent to storage.

- For 10 years ☐
- For a specific period (up to a maximum of 10 years) specify the number of years: ☐ Years

The consent period will start from the date of storage. Remember you can always change the time period you consent to by completing this form again and specifying the new total time period you would like your embryos to be stored for.

4.4 Premature infertility

If you or your partner are prematurely infertile, or likely to become prematurely infertile, you can consent to store your embryos for up to 55 years.

When the criteria have been met, the storage period will be extended by 10 years from the date the criteria are met. The storage period can then be extended by further 10-year periods (up to a maximum of 55 years) at any time within each extended storage period if it is shown that the criteria continue to be met. For more information about this, please ask your clinic.

For how long do you consent to store your embryos?

You do not need to fill in this section if you have completed section 4.3.

Please specify the number of years you consent to store your embryos for (up to a maximum of 55): ☐ years.

(Clinic staff: please attach all relevant medical practitioners' statements to this form)

5. Using eggs and embryos for training

5.1 Do you consent to your eggs being used for training purposes?

YES ☐ NO ☐

5.2 Do you consent to embryos (already created outside the body with your eggs) being used for training purposes?

Please note that embryos can only be used if the sperm provider has also given consent.

YES ☐ NO ☐

6. In the event of your death or mental incapacity

As part of your consent, you also need to decide what you would like to happen to your eggs, to decide for yourself (become mentally incapacitated). Please note your embryos may only be used within the storage period you consented to above. If you do not give your consent in the below section, your eggs or embryos must be allowed to perish in the event of your death or mental incapacity and cannot be used for treatment.

6.1 Do you consent to your eggs being used for training purposes?

- If you die YES ☐ NO ☐
- If you become mentally incapacitated YES ☐ NO ☐

6.2 Do you consent to embryos (already created outside the body with your eggs) being used for training purposes?

Please note that embryos can only be used if the sperm provider has also given his consent.

- If you die YES ☐ NO ☐
- If you become mentally incapacitated YES ☐ NO ☐

Other uses for your eggs or embryos

If you wish your eggs or embryos to be used in someone else's treatment, if you die or become mentally incapacitated, please speak to your clinic for more information. Depending on your circumstances, you will need to complete one of the following:

- 'Your consent to donating your eggs'
- 'Your consent to donating embryos' or
- 'Women's consent to the use and storage of eggs or embryos for surrogacy'.

7. Declaration

Please sign and date the declaration

Your declaration

- I declare that I am the person named in section one of this form.
- I declare that:

– before I completed this form, I was given information about the different options set out in this form, and I was given an opportunity to have counselling

– the implications of giving my consent, and the consequences of withdrawing this consent, have been fully explained to me, and

– I understand that I can make changes to, or withdraw, my consent at any point until the time of embryo transfer, use of eggs or embryos in training, or the eggs or embryos have been allowed to perish.

- I declare that the information I have given on this form is correct and complete.

Your signature:…….. Date :…….

If signing at the direction of the person consenting

If you have completed this form at the direction of the person consenting (because she is unable to sign for herself due to physical illness, injury or disability), you must sign and date below. There must also be a witness confirming that the person consenting is present when you sign the form.

Representative's declaration

I declare that the person named in section 1 of this form, is present at the time of signing this form and I am signing it in accordance with her direction.

Representative's name:……..

Representative's Signature :…….

Relationship to the person consenting:…… Date :……

Witness's name**:……**

Witness's signature:…….. Date :…….

Embryo Biopsy - Informed Consent for Use In Pre-Implantation Genetic Testing

Definitions:

Embryo Biopsy Informed Consent

Preimplantation Genetic Screening (PGS) and Preimplantation Genetic Diagnosis (PGD) are specialized laboratory tests that can identify embryos that have an increased chance for miscarriage or specific types of genetic defects. These tests can identify a genetic problem before an embryo is transferred to the uterus. Examples of chromosomal problems are a disease-causing gene sequence, abnormal chromosome copy number (aneuploidy), structural abnormalities of a chromosome or X-linked disorders. Embryo biopsy is process by which cells are removed from the embryo so they can be sent for testing.

Description:

Embryo biopsy can be performed on embryos that result from IVF or donor egg cycles. If the biopsy is performed at the 6-8 cell cleavage stage, then 1-2 cells (blastomeres) are removed from each embryo. If the biopsy is performed at the blastocyst stage (5-6 days after retrieval), 5-10 trophectoderm (placental) cells are removed. Only the embryos that lack the specific abnormality of interest or genetic disease are suitable for transfer into the uterus. Transfer may take place 5-6 days after retrieval for a cleavage stage biopsy. Embryos biopsied at the blastocyst stage will need to be frozen as the test results can take up to one week. After embryo transfer you will follow routine treatment for an IVF or donor egg patient.

Benefits:

Patients who have an increased risk for miscarriage or conceiving a child with a genetic disorder can benefit from preimplantation genetic testing. For patients with a specific gene defect or chromosomal translocation, PGD will be used to test for the specific genetic area of concern. Sex determination can be performed for patients at risk of X-Linked disorders or genetic disease that affect a specific gender disproportionately. Embryos that carry a disease-causing genetic abnormality or that demonstrate an unbalanced translocation will not be transferred.

Patients at risk for aneuploidy or recurrent miscarriage can benefit from PGS. Embryos that display an abnormal number of chromosomes will not be transferred as they would likely lead to a miscarriage, birth defects or a failed cycle. Identification of normal embryos has been shown to lead to a higher pregnancy rate and a lower miscarriage rate in several studies.

As part of the screening process, any patient at increased risk of heritable genetic disease should confer with a genetic counsellor to discuss your particular risks. You will also learn how preimplantation testing and its alternatives can impact that risk.

Risks of Embryo Biopsy/Adverse Outcomes:

Typically, if an embryo is damaged by the biopsy procedure it will stop growing and not be suitable for transfer. Animal and human studies to date have not shown that embryo biopsy impedes the normal development of an embryo. The procedure is relatively new in human application and there can be additional risks not known at the present time.

Potential risks are;

- Embryo biopsy may not be possible due to technical difficulties or lack of fertilization or suitable embryo development.
- Embryo biopsy may result in damage to the embryo.
- Possible loss or damage to cells during the process of shipping
- Failure of genetic analysis to provide adequate information
- Genetic testing may reveal that there are no suitable embryos for transfer
- Limitations of genetic tests used
- Biopsied embryos that are cryopreserved may not survive the freezing or thawing process.

Alternatives

Attempted conception with no preimplantation genetic testing

Attempted conception with donor eggs, sperm or embryos from a donor that is known not to carry a specific gene Attempted conception with antenatal diagnosis via amniocentesis, CVS or ultrasound

Important Points

In addition to this consent form, you will need to read and sign an IVF consent, an Embryo disposition consent and a PGS and/or PGD consent (provided by the laboratory performing your testing). Each form will address the risks and benefits of the procedure or test. The IVF and Preimplantation Genetic Testing consents address confidentiality issues pertaining to the data obtained as a result of this treatment.

No test is perfect and errors can occur. Contamination, inadequate sample size or errors in processing can lead to test results that are inconclusive/inadequate. There is a possibility of test results producing a wrong diagnosis. Current literature suggests that error rates are less than 1.0 % per embryo. The actual rates depend on the platform being used and will be stated by the laboratory on their consent form. For this reason, we strongly suggest that you consider

antenatal diagnosis (amniocentesis, CVS, NIPT) if pregnancy occurs. PGD/PGS can detect a specific chromosomal problem but it does not detect all problems and it is not intended as a substitute for routine prenatal testing. Birth defects and other problems can occur in pregnancies that are chromosomally normal and would not be detect by PGD/PGS.

When PGD/PGS test results become available we will contact you to review your embryo transfer plans. We will also review disposition of all embryos not transferred. It is our policy to not knowingly transfer any abnormal embryos. The laboratory doing your genetic testing will provide a report of your results. At the time of your embryo transfer we will provide a summary of your embryos and their disposition. It is also possible that you may be told there are no normal embryos available and in that case no embryo transfer would be performed.

We are interested in the outcome of your pregnancy. We request permission to contact your Obstetrician for the results of your chorionic villus sampling or amniocentesis, prenatal care and delivery outcome. We may also need to contact your paediatrician for growth and development information. All of this information is collected for statistical purposes and is treated with strict confidentiality.

Your signature below acknowledges that you have read this consent form in its entirety as well as the IVF consent, embryo disposition consent and the consent for PGS/PGD provided by the outside centre performing that testing. You understand the potential risks and benefits of embryo biopsy and PGS/PGD and that you have had the opportunity to ask questions. You agree that those questions were answered to your satisfaction. You have considered the alternatives and have sufficient information to base your decision.

_____ _____

Patient Name (Please Print and Sign) Date

_____ _____

Partner Name (Please Print and Sign) Date

_____ _____

Physician

Date

Annex - 5

Quarterly Return for Donor Cycles

Time period (Circle as appropriate)	Jan-Mar / Apr-Jun / Jul-Sep / Oct-Dec
Name of the Centre	
Address	
Registration Number	

A. Sperm donation

1. Number of sperm donations	
2. Percentage of donated semen samples screened for HIV, Hepatitis B and C	
3. Number of registered sperm donors donating at the clinic	

List of sperm donors in the specified period

NIC	Number of samples provided	Number of recipients	Number of positive pregnancy test among recipients	Any previous live births from the donor's sperms (Yes/No)	Number of Congenital anomalies*

*Specify anomalies in a separate attachment

B. Oocyte donation

1. Number of oocyte donations	
2. Number of oocyte donations screened for HIV, Hepatitis B and C	
3. Number of registered oocyte donors donating at the clinic	

List of oocyte donors in the specified period

NIC	Number of oocyte donations so far for the clinic	Number of recipients for oocytes	Number of positive pregnancy test among recipients	Any previous live births from the donor's oocytes (Yes/No)	Number of Congenital anomalies

*Specify anomalies in a separate attachment

C. Embryo donation

1. Number of embryo donations	
2. Number of embryo donations screened for HIV, Hepatitis B and C	

Information on embryo donors in the specified period

Embryo donations registration number	Outcome of the embryo donation	Number of Congenital anomalies

*Specify anomalies in a separate attachment

D. Surrogacy

1. Number of registered surrogates attached to the clinic	
2. Number of surrogate cycles performed	

Information on surrogates in the specified period

NIC of the surrogate	Indication for surrogacy	Outcome of the cycle

…….. ……

Signature, Name and Designation of Reporting Officer Date