Maharashtra University of Health Sciences, Nashik

SYLLABUS

“Fellowship Course in Clinical Embryology”
INTRODUCTION:

Infertility is an inability to conceive and its incidence is rising throughout the world. A recent survey has shown that 15-18% couples of reproductive age group suffer from infertility. According to WHO, infertility is considered to be 1 of the 5 increasing disease in 21st century. India has around 700 IVF centers among which 20% exist in our own state. India is having only 200-300 embryologists whereupon our country needs atleast 1000 embryologists. Thus there is an acute shortage of qualified embryologists. Hence, specially in clinical embryology this fellowship course is being offered.

This programme will provide the student essential theoretical knowledge and practical skills required to competently handle human IVF laboratory. This course will be offered to Post Graduates in Medicine and Post Graduates in Basic Sciences. Upon completion these students can undertake employment as a clinical embryologist in diverse field of reproductive medicine.

OBJECTIVES:

The objectives of this course are to provide:
• Up-to-date knowledge in the areas of human and animal embryology.
• The skills required for working in IVF and micromanipulation laboratories.
• An appreciation of the laboratory ethics towards human assisted reproduction.
• Integration of the clinical and scientific aspects of ART.
• Project work/Thesis /Dissertation

NAME OF COURSE:

Fellowship in Clinical Embryology

COURSE STRUCTURE:

The fellowship programme is a full time laboratory based training course, with no patient contact. Mice oocytes will be used as models for practical work. The fellowship programme is designed to provide students with comprehensive academic, clinical and hands-on laboratory skills in the field of reproductive embryology. The course will comprise lectures, practicals, journal club, presentation and project work. It provides both didactic and self-directed teaching at both clinical and research laboratory.

COURSE DURATION:

This is a 1 year course.
ELIGIBILITY CRITERIA:

This fellowship course is available to Post Graduates in Medicines, Post Graduates in Basic Sciences.

1. M.S. / M.D. (Republic of India and MCI accredited) – Gynaecology, Anatomy, Physiology, Pathology, Microbiology.
2. Post Graduates in Biochemistry, Microbiology, Zoology, Botany, Biotechnology, etc.
3. Possession of Foreign Qualification (M.D. in Gynaecology, Post Graduates in Basic Sciences) which enables the student to practice in any form of medical practice in his country/ departments as per Association of Indian University Rules.

LECTURES:

The lectures will be mainly confined to the detailed scientific aspect of human embryology and general clinical aspects of applied human assisted reproduction as per modules. The course consists of eleven modules comprising of theoretical and practical work. Lectures are delivered by experts from disciplines in, and related to, IVF field.

PRACTICALS:

The student will be exposed to variety of laboratory skills that will ensure that he or she will be equipped to carry out independently all the procedures required in IVF and ICSI lab. The student will be rotated in IVF, andrology, micromanipulation, endocrinology, tissue culture and genetics lab. Each student is expected to perform at least 30 murine ICSI procedures and 50 murine IVF procedures. And is also expected to assist faculty embryologists in 20 ICSI and 50 IVF procedures in human laboratory. Student is expected to maintain certified Log book indicating number of cases assisted under the guidance of faculty for each module.

JOURNAL CLUB:

A journal club will be held every four weekly to provide students experience of reviewing, discussing and presenting journal articles. The student will have opportunity of analyzing and criticizing such articles in a tutorial format among peers and the teaching staff.

PRESENTATION AND PROJECT WORK:

The module topics will be distributed among the students and they are expected to present detailed presentation covering information regarding recent published articles in the respective topics. A project work in the topic of student’s interest will be expected to be completed by the students.

CLASS TIME:

As the course will closely associate with service at the IVF centre, lectures will be held in the late afternoon and practicals in the morning and afternoons. Students will be encouraged to use the libraries for self enrichment.
ASSESSMENT:

The assessment will be by written and oral presentation on the theoretical aspects and practical aspects. The student is expected to obtain a Pass in the various assignments before being awarded the degree.

Candidate will be evaluated by credit points system:

The credit based system is a scientifically accepted system which allows different weightage to different courses in a program based on its utility in the overall program structure.

The Advantages of credit based evaluation system are (1) Skilled fellows can always go for the maximum credits (2) Students can learn at their own pace. (3) Students get the freedom to choose and identify (4) Fellows can translate their innate capabilities to credits and get the know-how of more than one discipline increasing their horizons

Since the entire course is Credit System based, for each Module, the candidates will be assigned credits for their work by respective Faculty. The candidates may finish their modules and earn credits in respective sessions within a certain stipulated time in any order depending upon their availability of time and convenience. The fellows may be rotated with different expert faculties of a specific module so as to learn maximum from the respective experts in their actual operative module.

Allotment of Credits:

Total Credits: -300
Minimum Number of Credits for successful completion of programme:- 240 credits and not less than 80% in each module (1 to 9).

The credits points are distributed among the eleven modules as follows. Credit points assigned to a module are equally divided per topic within that module. -

<table>
<thead>
<tr>
<th>Module</th>
<th>Title</th>
<th>Credit points allotted</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td><strong>Introduction to Embryology</strong> – It covers the theoretical concepts of Human Embryology</td>
<td>10</td>
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<tr>
<td>2</td>
<td><strong>Infertility and its clinical management</strong> – It covers concepts in infertility, its diagnosis and treatment strategies.</td>
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<td>3</td>
<td><strong>Andrology</strong> – It covers concepts in male infertility, theoretical as well as practical knowledge of andrology lab.</td>
<td>25</td>
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<td>4</td>
<td><strong>IVF procedure: Fertilisation, Embryo production &amp; Cryopreservation techniques (theory)</strong> – This unit introduce the students with the skills and techniques used in the IVF lab</td>
<td>20</td>
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<tr>
<td>5</td>
<td>IVF procedure: Fertilisation, Embryo production &amp; Cryopreservation techniques (practical) – It involves extensive practical training in IVF lab. Student are expected to complete 50 murine IVF cycle as well as assist faculty embryologist in 50 IVF human cases efficiently.</td>
<td>75</td>
</tr>
<tr>
<td>6</td>
<td>Intracytoplasmic sperm injection (ICSI) - It involves extensive practical training in ICSI. Student are expected to complete 30 murine ICSI cycle as well as assist faculty embryologist in 20 ICSI human cases efficiently.</td>
<td>75</td>
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<tr>
<td>7</td>
<td>QC, QA and Record keeping in ART – It covers the total quality management principles involved in ART lab.</td>
<td>5</td>
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<td>8</td>
<td>Ethics and regulation in ART - It covers the knowledge about the regulation and ethical issues involved in ART.</td>
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<td>9</td>
<td>Cytogenetics – It covers the theoretical knowledge and understanding of techniques used in cytogenetics. Students will have practical exposure to essential techniques like FISH, karyotyping, etc.</td>
<td>10</td>
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<tr>
<td>10</td>
<td>Project Work, Presentation &amp; Publications</td>
<td>15</td>
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<tr>
<td>11</td>
<td>Fellowship Examination- Terminal Exam by MCQs</td>
<td>50</td>
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</table>

**COURSE CONTENT:**

**MODULE 1: INTRODUCTION TO EMBRYOLOGY – 10 Credit points**

1. Basic Human Embryology
2. Gametogenesis
3. Meiosis
4. Implantation and placentation
5. Preimplantation embryo development
6. Development of various organs
7. Anatomy of Male Reproductive System
8. Anatomy of Female Reproductive System
9. Anatomy of Brain
10. Anatomy of Sperms

**MODULE 2: INFERTILITY AND ITS CLINICAL MANAGEMENT– 10 Credit points**

1. Physiology of Ovulation
2. Folliculogenesis
3. Physiology of Menses
4. Hormonal control of human
5. Investigating male and female patients
6. Infertility and its management
7. Ultrasound
8. Elderly Patients
5. Natural Cycle
6. Various stimulation protocols
7. Ovarian Hyperstimulation syndrome (OHSS)
8. Complication of stimulation
9. Monitoring of patients
10. Reproductive function and causes of subfertility

MODULE 3: ANDROLOGY – 25 Credit points

1. Physiology of Sperm
2. Spermatogenesis
3. Male Factor
4. Lab Set-up for andrology
5. Sperm separation
6. Semen analysis
7. Semen analysis as per WHO criteria
8. Sperm morphology assessment according to Strict (Kruger) criteria.
10. Grading of Sperms
11. Sperm preparation for IUI
12. Sperm preparation for IVF
14. Semen cryopreservation-both neat and processed sample.
15. Sperm freezing
16. Donor Sperm Programme

MODULE 4: IVF PROCEDURE: FERTILISATION, EMBRYO PRODUCTION & CRYOPRESERVATION TECHNIQUES (THEORY) – 20 Credit Points

1. Lab Set-up for IVF
2. Requirements and Protocols
3. Quality Control and Quality Assurance
4. Health and safety in the laboratory
5. Introduction to culture media
6. Handling and culture techniques
7. Preparation of media and buffer
8. Sequential culture media
9. Blastocyst culture –technique
10. Embryo transfer technique
11. USG guided embryo transfer
12. Embryo Reduction
13. Complication of IVF
14. Anesthesia
15. Patient Counseling
16. History of cryobiology
### Module 5: IVF Procedure: Fertilisation, Embryo Production & Cryopreservation Techniques (Practical) – 75 Credit Points

<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Introduction to lab</td>
<td>15.</td>
<td>Ferti-check on day 1</td>
</tr>
<tr>
<td>2.</td>
<td>Lab ethics</td>
<td>16.</td>
<td>Classification of 2PN</td>
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<tr>
<td>3.</td>
<td>Aseptic precaution</td>
<td>17.</td>
<td>Growth of embryo on day 2</td>
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<td>4.</td>
<td>Introduction to instruments</td>
<td>18.</td>
<td>Shifting of embryos</td>
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<tr>
<td>5.</td>
<td>Handling of instruments</td>
<td>19.</td>
<td>Quality of embryo on day 3</td>
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<tr>
<td>6.</td>
<td>Insemination technique</td>
<td>20.</td>
<td>Grading of blastocyst</td>
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<td>7.</td>
<td>Identification of oocyte</td>
<td>21.</td>
<td>Selection of blastocyst for embryo transfer</td>
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<td>8.</td>
<td>Grading of oocyte</td>
<td>22.</td>
<td>Vitrification of blastocyst</td>
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<tr>
<td>9.</td>
<td>Insemination of oocyte</td>
<td>23.</td>
<td>Vitrification of cleaving embryos</td>
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<td>10.</td>
<td>Denuding</td>
<td>24.</td>
<td>Retrieval of vitrified embryos</td>
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</table>

### Module 6: Intracytoplasmic Sperm Injection (ICSI) – 75 Credit Points

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<tbody>
<tr>
<td>1.</td>
<td>Historical aspect</td>
<td>13.</td>
<td>ICSI procedure</td>
</tr>
<tr>
<td>2.</td>
<td>Indication for ICSI</td>
<td>14.</td>
<td>Indication and contraindication of ICSI procedure</td>
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<tr>
<td>3.</td>
<td>Philosophy of ICSI</td>
<td>15.</td>
<td>Obstructive azoospermia and ICSI</td>
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<td>4.</td>
<td>Introduction to micromanipulator</td>
<td>16.</td>
<td>PESA, TESA, TESE and ICSI</td>
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<tr>
<td>5.</td>
<td>Physics of micromanipulation</td>
<td>17.</td>
<td>Risk of anomalies in ICSI</td>
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<td>6.</td>
<td>Various equipment required to perform ICSI</td>
<td>18.</td>
<td>Intracytoplasmic morphologically selected sperm injection (IMSI)</td>
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<td>7.</td>
<td>Sperm immobilization</td>
<td>19.</td>
<td>Identification of abnormal sperm</td>
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<td>8.</td>
<td>Selection of sperm</td>
<td>20.</td>
<td>Identification of immature sperm</td>
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<td>9.</td>
<td>Preparation of sperm for ICSI from ejaculates and testicular biopsies</td>
<td>21.</td>
<td>Sperm separation from testicular biopsy</td>
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<td>10.</td>
<td>Various medias required to perform ICSI</td>
<td>22.</td>
<td>Identification of spermatids, spermtocytes and other cells</td>
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<td>11.</td>
<td>Denuding of oocyte</td>
<td>23.</td>
<td>Assessment of fertilization (ferti-check)</td>
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<td>12.</td>
<td>Micropipette handling</td>
<td>24.</td>
<td>Patient Counseling</td>
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**MODULE 7: QC, QA AND RECORD KEEPING IN ART –**  
5 Credit Points

1. Set up of IVF lab  
2. How to establish and equip an IVF lab  
3. QA and AC for IVF lab  
4. QA and QC practices  
5. Precision of IVF procedure  
6. Designing of IVF lab and its location in the clinic  
7. Record keeping  
8. Lab maintenance protocol  
9. Roster of work  
10. Introduction and maintenance of all instruments in IVF lab  
11. Calibration of all instruments  
12. Quality improvement techniques  
13. Review national and international guidelines  
14. Trouble shooting and its solution

**MODULE 8: ETHICS AND REGULATION IN ART –**  
5 Credit Points

1. Current legislation and regulation in ART, India  
2. Requirement for licensing, accrediting and approving ART clinics  
3. National guidelines for accreditation of ART clinics in India  
4. Ethics consideration and legal issues  
5. Ethical policies  
6. Indian Society for Assisted Reproduction (ISAR)  
7. Surrogacy- Ethical and legal issues  
8. Ethical frameworks and principles  
9. Relevant regulatory bodies  
10. Role of ethics in health care  
11. Social and ethical responsibilities with regards to patient care  
12. Patient Consent

**MODULE 9: CYTOGENETICS –**  
10 Credit Points

1. Role of genetics in infertility  
2. Molecular and cellular biology  
3. Chromosomal and genetic analysis in IVF  
4. Genetic techniques  
5. FISH  
6. Embryo biopsies  
7. Preparation of blastomeres for FISH  
8. Karyotyping  
9. Role of genetics in OATS  
10. Genes and RPL (Recurrent pregnancy losses)
EXPECTATION FROM THE FELLOW STUDENTS:

- All Fellows will present and review current literature at Journal Clubs
- Maintain high standards of ethical behaviour.
- Demonstrate sensitivity to age, race, gender, and culture of patients and other health care professional
- Practice high-quality, cost-effective patient care.

These academic activities will be constantly be reviewed by a Senior Faculty.

PORTFOLIO MANAGEMENT:

All Fellows will maintain a Fellowship PORTFOLIO.

Two monthly review of following topics by faculty will include:

- Research/Project
- Log Book
- Presentations
- On-going Publications
- Number of hours spent on hands on practice
- Summaries of case discussions and presentations.
- Synopsis of publications.

Maintaining accurate log book is critical to each fellow. These numbers are vital for hospital privileging. Log book, presentation & project work will be signed & evaluated on a time to time basis by respective faculties.

FELLOWSHIP EXAMINATION:

The examination will be conducted according to the requirement of the course as per module 11.

On successful completion of all modules of the Programme the Fellow will be awarded a Certificate of the Fellow in Clinical Embryology.