

**JSS Academy of Higher Education & Research**

( Deemed to be University )

Re-Accredited "A+" Grade by NAAC

Sri Shivarathreeshwara Nagara Mysuru - 570015, Karnataka

# Regulation & Syllabus

## MSc Clinical Embryology

2021

## **M.Sc. CLINICAL EMBRYOLOGY**

### **GOAL**

The goal of M.Sc. in Clinical Embryology postgraduate course shall be to produce competent clinical embryologists and leaders in reproductive medicine.

### **OBJECTIVES**

1. Demonstrate comprehensive knowledge and understanding of gross and microscopic structure of the human cell and its organelles.
2. Comprehend normal anatomy and physiology of the male and female reproductive system.
3. Demonstrate knowledge of basic and systemic embryology including human genetics, genetic inheritance, gene regulation, immunology and stemcell therapy.
4. Develop a basic understanding of biochemistry, endocrinology and pharmacology.
5. Independently handle semen and its processing for Intra Uterine Insemination (IUI), In-vitro fertilization (IVF) and Intracytoplasmic sperm insemination (ICSI).
6. Should be able to identify and handle human oocyte in the embryology laboratory.
7. Competently handle human gametes in the scenario of IVF and ICSI.
8. Assess viability of embryos and their developmental competence with fair accuracy.
9. Cryopreserve human gametes and embryos; and thaw them and subsequently develop them to transfer into the uterus.
10. Understand the basic concepts of ART IVF.
11. Should be well versed in setting up of ART laboratory according to standards available and well versed in quality control measures and legislation.

### **OUTCOMES**

After completing two years of MSc clinical embryology, the post graduate should be able to:

- Work as a competent embryologist
- Acquire knowledge and skills in educational technology and conduct research in biomedical sciences.

### **COMPONENTS OF THE COURSE CURRICULUM:**

The major components shall be:

- Theoretical knowledge
- Practical skills
- Thesis skills.
- Attitudes including communication skills.
- Training in research methodology.

#### **1. Branch of Study:**

Postgraduate Degree Courses

#### **2. Postgraduate Degree Courses offered in Biomedical Sciences**

M.Sc. in

- Anatomy
- Biochemistry

- Microbiology
- Pharmacology
- Physiology
- Clinical Embryology

### 3. Eligibility for Admission

A candidate seeking admission to the Postgraduate Degree Courses must have passed B. Sc. with at least one subject of biological Sciences or B. Sc. Biotechnology or MBBS from a recognized Deemed to be University.

### 4. Duration of the Course

The duration of the course shall be for a period of 2 years.

### 5. Medium of Instruction

The medium of instruction and examination shall be in English.

### 6. Method and Place of Training

Students will be trained in JSS Medical College and Hospital, Mysuru for the first six months. Later they will be trained at Gunasheela Assisted Reproduction Centre (GARC) **OR** Milann Assisted Reproduction Centre **OR** Femiint Fertility centre at Bengaluru. Training includes involvement in laboratory and experimental work; and research studies. The postgraduate students shall actively participate in departmental seminars and journal reviews.

### 7. Attendance

Candidates shall have attended at least 80% of the total number of classes conducted from the date of commencement of the term to the last working day, as notified by the JSS AHER, in theory and clinical training jointly, to be eligible to appear for the JSS AHER examinations. Candidate lacking in prescribed percentage of attendance in theory and clinical training jointly will not be eligible to appear for final examination in that subject. However candidate shall put in required attendance in subsequent term and appear for JSS AHER examination.

### 8. Subjects and hours of teaching for theory and practical:

**Table I: Distribution of subjects and teaching hours in I Term**

| Sl. No. | Modules  | Subjects                                           | Theory Hours |
|---------|----------|----------------------------------------------------|--------------|
| 1       | Module 1 | Section A: Anatomy<br>Section B: Physiology        | 30<br>30     |
| 2       | Module 2 | Section A: Biochemistry<br>Section B: Pharmacology | 30<br>30     |
| 3       | Module 3 | Section A: Microbiology<br>Section B: Statistics   | 30<br>30     |

The classes for I term will be conducted at JSS Medical College and Hospital, Mysuru.

**Table II: Distribution of subjects and teaching hours in II, III and IV Term:**

| Sl. No. | Modules  | Subjects                                     | Theory Hours | Clinical Training |
|---------|----------|----------------------------------------------|--------------|-------------------|
| 1       | Module 4 | Infertility                                  | 60           | 200               |
| 2       | Module 5 | Laboratory Techniques                        | 60           |                   |
| 3       | Module 6 | Good Laboratory Practice and Recent Advances | 60           |                   |

The classes for II, III and IV term will be conducted at Gunasheela Assisted Reproduction Centre (GARC) **OR** Milann Assisted Reproduction Centre **OR** Femiint Fertility centre at Bengaluru.

### **9. Project**

Every candidate pursuing M. Sc. degree course is required to carry out work on a selected research project under the guidance of a recognized postgraduate teacher in their respective subject. The result of such work shall be submitted in the form of a project.

The project is aimed to train a postgraduate student in research methods and techniques. It includes identification of a problem, formulation of a hypothesis, search and review of literature, getting acquainted with recent advances, designing of a research study, collection of data, critical analysis and comparison of results and drawing conclusions.

Every candidate shall submit a synopsis in the prescribed format containing particulars of proposed project work within nine months from the date of commencement of the course and on or before the dates notified by the JSS AHER. The synopsis shall be sent through the proper channel. Such synopsis will be reviewed and the project topic will be registered by the JSS AHER. No change in the project topic or guide shall be made without prior approval of the JSS AHER. The candidates shall report the progress of the project work to the concerned guide periodically and obtain clearance for the continuation of the project work.

The Project should be written under the following headings

- i. Introduction
- ii. Aims and objectives of the study
- iii. Review of literature
- iv. Material and methods
- v. Results
- vi. Discussion
- vii. Conclusion
- viii. Summary
- ix. References
- x. Tables
- xi. Annexure

Four copies of project report/ dissertation thus prepared shall be submitted three months before final examination on or before the dates notified by the JSS AHER.

The project shall be valued by examiners appointed by the JSS AHER. Approval of project work is an essential precondition for a candidate to appear for the final examination.

A co-guide may be included provided the work requires substantial contribution from a sister department or from another medical institution recognized for teaching/ training by JSS AHER.

### **10. Internal Assessment:**

There shall be minimum two periodical tests in theory for modules 1, 2 and 3 spread over evenly

in first term. The average of the two tests will be calculated and submitted to the JSS AHER.

One theory and one practical internal assessment examination will be conducted in second, third and fourth term for modules 4, 5 & 6 at Bengaluru. Average of the three internal assessments shall be submitted to the JSS AHER at least 15 days before the commencement of final exam. The records and marks obtained in such tests will be maintained by the head of the respective departments.

A mock exam will be held one month before the final exam for modules 4, 5 & 6 to see if the students are eligible to attend the final exams. Students shall secure 35% marks to appear for the final exam.

Candidates who have failed in the final examination shall be given an internal assessment improvement test and the best marks shall be submitted to JSS AHER.

### 11. Schedule of Examinations

The JSS AHER examination for M.Sc. Clinical Embryology shall be held at the end of I term and IV term.

#### I Term

| Sl. No. | Modules  | Subjects                | Theory Paper | Internal Assessment |
|---------|----------|-------------------------|--------------|---------------------|
| 1       | Module 1 | Section A: Anatomy      | 40           | 10                  |
|         |          | Section B: Physiology   | 40           | 10                  |
| 2       | Module 2 | Section A: Biochemistry | 40           | 10                  |
|         |          | Section B: Pharmacology | 40           | 10                  |
| 3       | Module 3 | Section A: Microbiology | 40           | 10                  |
|         |          | Section B: Statistics   | 40           | 10                  |

#### IV Term

| Sl. No. | Modules  | Subjects                                     | Theory Paper | Internal Assessment Theory | Internal Assessment Practicals | Final Practicals | Viva-voci on project and subjects |
|---------|----------|----------------------------------------------|--------------|----------------------------|--------------------------------|------------------|-----------------------------------|
| 1       | Module 4 | Infertility                                  | 80           | 20                         | 40                             | 160              | 20+80                             |
| 2       | Module 5 | Laboratory Techniques                        | 80           | 20                         |                                |                  |                                   |
| 3       | Module 6 | Good Laboratory Practice and Recent Advances | 80           | 20                         |                                |                  |                                   |

**12. Question paper pattern for 40 marks**

| Marks              | No of questions | Total marks |
|--------------------|-----------------|-------------|
| 10                 | 01              | 10          |
| 05                 | 03              | 15          |
| 03                 | 05              | 15          |
| <b>Total marks</b> |                 | <b>40</b>   |

**13. Question paper pattern for 80 Marks**

| Marks              | No of questions | Total marks |
|--------------------|-----------------|-------------|
| 10                 | 02              | 20          |
| 05                 | 06              | 30          |
| 03                 | 10              | 30          |
| <b>Total marks</b> |                 | <b>80</b>   |

**14. Practical Examination:**

Practical examination shall be aimed at assessing competence and skills of techniques and procedures as well as testing student's ability to make relevant and valid observations, interpretations and inference of laboratory or experimental work relating to his/ her subject.

**Pattern for Practical examination**

| Subjects     | Particulars          | Marks      |
|--------------|----------------------|------------|
| Andrology    | Semen analysis       | 30         |
|              | Sperm preparation    | 30         |
| Embryology   | Dish preparation     | 20         |
|              | Needle alignment     | 20         |
|              | Viability assessment | 20         |
| Spotters     |                      | 40         |
| <b>Total</b> |                      | <b>160</b> |

**Appointment of Examiners:** There shall be at least two examiners in practical examination. Out of them one shall be external examiner and one shall be internal examiner. Postgraduate teacher with MD/ MS /PhD degree with 5 years of experience shall be appointed as examiner.

**15. Criteria for declaring as pass in JSS AHER Examination:**

**I Term Examination:** A candidate shall secure not less than 50% marks in Theory of each section in Modules 1, 2 & 3. A candidate securing less than 50% of marks as described above shall be declared to have failed in the examination. Failed candidate may appear in any subsequent examination upon payment of fresh fee. Those candidates who fail in one or more subjects shall have to appear only in the subject so failed, in the subsequent examinations.

**IV Term Examination:** A candidate shall secure not less than 50% marks in each head of passing which shall include (1) Theory, (2) Practical and viva voce examination.

A candidate securing less than 50% of marks as described above shall be declared to have failed in the examination. Failed candidate may appear in any subsequent examination upon payment of fresh fee.

Those candidates who fail in one or more subjects shall have to appear only in the subject so failed, in the subsequent examinations

#### **16. Declaration of Class:**

**Distinction:** A successful candidate passing the JSS AHER examination in first attempt will be declared to have passed the examination with distinction, if the grand total aggregate mark is **75% and above**.

**First class:** If the grand total aggregate mark is between **65% and 74%**.

**Pass class:** If the grand total aggregate mark is between **50% and 64%**

Distinction and 1st class will not be awarded for candidates passing the examination in more than one attempt.

**17. Carry over:** A candidate who fails in any subject of modules 1, 2 and 3 shall be permitted to carry those subjects up to IV term. However the candidate must pass the carry over subjects before appearing for the IV term JSS AHER examinations.

**18. Award of Degree:** A candidate who has passed all the subjects of I term and IV Term shall be eligible for award of the degree.

#### **19. Duration for completion of the course of study:**

The duration for the completion of the course shall be fixed as double the actual duration of the course and the students have to pass within the said period. Otherwise they have to get fresh registration.

#### **20. Revaluation/ Retotaling of answer papers:**

There is no provision for revaluation of the answer papers of failed candidates in any examination. However, the failed candidates can apply for retotaling.

#### **21. Re-admission after break of study:**

Candidate who seeks re-admission to the course after break of study has to get the approval from the JSS AHER by paying a condonation fee.

No condonation is allowed for the candidate who has more than 2 years of breakup period and he/ she has to rejoin the course by paying the required fees.

## **MODULE 1 - Section A**

### **ANATOMY**

#### **I. The cell:**

**2H**

- Structure and organelles
- Internal organization
- Cell cycle control
- Mitosis and meiosis

#### **II. Gross anatomy and histology of the reproductive system**

**6H**

##### **Male reproductive system:**

- Development of male reproductive system
- External genital organs

- Internal genital organs
- Anatomy of sperm

**Female reproductive system:**

- Development of female reproductive system
- External genital organs
- Internal genital organs
- Anatomy of oocyte

**III. Urinary system 1H**

- Urinary bladder
- Urethra

**IV. Endocrine system 2H**

- Hypothalamus
- Pituitary
- Thyroid
- Suprarenal

**V. Fundamentals of reproduction 5H**

- Gametogenesis (Oogenesis, spermatogenesis)
- Fertilisation
- Implantation
- Decidua, chorion and chorionic villi
- Development of inner cell mass

**VI. Early embryonic development:****6H**

- Cleavage
- Implantation
- Formation of germ layers
- Notochord and neural tube development
- Fate of germ layers and derivatives of germ layers
- Folding of embryo

**VII. Trophoblast and twinning:****2H**

- Development of trophoblast and its derivatives
- Development of placenta
- Twinning

**VIII. Practicals:****6H**

- Demonstration of Embryology models:  
General embryology (models and charts)
  - Introduction: Cell division
  - Gametogenesis, ovarian cycle, Sperm, ovum
  - Menstrual cycle
  - 1<sup>st</sup> week: Fertilization, implantation
  - 2<sup>nd</sup> week: amniotic cavity, yolk sac, Bilaminar germ disc
  - 3<sup>rd</sup> week: Primitive streak and three germ layers, Notochord, Neural tube
  - 4<sup>th</sup> week: Folding of embryo
  - Trophoblast and twinning: Placenta, TwinningSystemic embryology (models and charts)
  - Male reproductive system: Gonad, mesonephric duct, descent of testis
  - Female reproductive system: Gonad, paramesonephric duct, descent of ovary
- Histology slides: Testes, uterus, ovary and fallopian tube
- Prosection of male and female pelvis

**Recommended Books/ Reading Material:**

1. Larsen's Human Embryology 6th edition by Gary C. Schoenwolf, Steven B. Bleyl, Philip R. Brauer, Philippa H. Francis-West
2. Langman's Medical Embryology 13th edition by Ph.D. Sadler, T. W
3. Human Embryology and Developmental Biology 6th Edition - November 26, 2018  
Author: Bruce Carlson
4. Netter's Atlas of Human Embryology: Updated Edition (Netter Basic Science) Paperback – by  
Larry R. Cochard PhD
5. B. D. Chaurasia's Human Anatomy 8<sup>th</sup> Edition
6. Text Book of Anatomy by Vishram Singh 3<sup>rd</sup> Edition

## **MODULE 1 - Section B**

### **HUMAN PHYSIOLOGY**

#### **I. Physiology of endocrine glands 10H**

- Hypothalamus
- Pituitary
- Thyroid
- Parathyroid
- Endocrine pancreas
- Adrenal

#### **II. Sex determination and differentiation, physiology of puberty 2H**

#### **III. Physiology of the male reproductive system 6H**

- Functional anatomy
- Spermatogenesis and its regulation
- Testosterone- Synthesis, functions & its regulation
- Semen- Composition

#### **IV. Physiology of the female reproductive system 12H**

- Functional anatomy
- Oogenesis and its regulation
- Ovarian hormones
  - Oestrogen- Synthesis, functions & its regulation
  - Progesterone- Synthesis, functions & its regulation
- Female reproductive cycle
  - Ovarian cycle
  - Uterine cycle
  - Cervical and vaginal changes
- Hormonal regulation of menstrual cycle
- Ovulation and tests for ovulation
- Abnormalities of menstrual cycle
- Menopause
- Fertilization and implantation
- Placenta- Hormones, feto-placental unit
- Physiology of pregnancy with tests for pregnancy

#### **Recommended Books/ Reading Material:**

- Guyton, Text Book of Medical Physiology, 12th edition (2011), Elsevier publication.
- Prof Dr G K Pal, Text book of medical physiology, 2nd edition (2015), Ahu-ja publications.
- Indu khurana, Medical physiology, 1st edition (2012), Elsevier publications.
- AK Jain: Text book of physiology, Prof A.K. Jain, 6th edition vol I & II, Avichal publishing company, 2016.
- Williams, Text book of Endocrinology, 10th edition (2002), W.B. Saunders publications.

## **MODULE 2 - Section A**

### **BIOCHEMISTRY**

- |                                                                                                                                                                                                                                                                                                                                                                                                                                       |           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| <b>I. Embryonic stem cells and basics of stem cell therapy</b>                                                                                                                                                                                                                                                                                                                                                                        | <b>2H</b> |
| <ul style="list-style-type: none"><li>• Origins, definitions, characteristics</li><li>• Immunology concerning reproductive tract: Embryo &amp; endometrial dialogue</li></ul>                                                                                                                                                                                                                                                         |           |
| <b>II. Lipid metabolism</b>                                                                                                                                                                                                                                                                                                                                                                                                           | <b>4H</b> |
| <ul style="list-style-type: none"><li>• Definition, classification, properties and biological importance</li><li>• Fatty acids, steroids, eicosanoids - chemistry, distribution, classification and functions</li><li>• Synthesis of cholesterol (only crucial intermediates), fate of cholesterol and other compounds derived from cholesterol</li><li>• Dyslipidemia and associated syndromes associated with infertility</li></ul> |           |
| <b>III. Steroid metabolism</b>                                                                                                                                                                                                                                                                                                                                                                                                        | <b>2H</b> |
| <ul style="list-style-type: none"><li>• Classification of hormones, mechanism of action of steroid hormone</li></ul>                                                                                                                                                                                                                                                                                                                  |           |
| <b>IV. Genetics</b>                                                                                                                                                                                                                                                                                                                                                                                                                   | <b>2H</b> |
| <ul style="list-style-type: none"><li>• Basic genetics of the cell</li><li>• DNA chromatin chromosomes</li><li>• Concept of a gene.</li><li>• Mutations</li><li>• Epigenetics</li></ul>                                                                                                                                                                                                                                               |           |
| <b>V. Basic gene regulation</b>                                                                                                                                                                                                                                                                                                                                                                                                       | <b>3H</b> |
| <ul style="list-style-type: none"><li>• Translation</li><li>• Transcription</li><li>• Expression</li><li>• Imprinting</li></ul>                                                                                                                                                                                                                                                                                                       |           |
| <b>VI. Basic genetics</b>                                                                                                                                                                                                                                                                                                                                                                                                             | <b>3H</b> |
| <ul style="list-style-type: none"><li>• Genotype, phenotype</li><li>• Basic Mendelian inheritance patterns</li><li>• Monogenic diseases</li><li>• Chromosomal abnormalities: numerical, structural</li><li>• Interpretation of a pedigree</li></ul>                                                                                                                                                                                   |           |
| <b>VII. Metabolism of sperm cell</b>                                                                                                                                                                                                                                                                                                                                                                                                  | <b>1H</b> |
| <b>VIII. Genetic analysis</b>                                                                                                                                                                                                                                                                                                                                                                                                         | <b>2H</b> |
| <ul style="list-style-type: none"><li>• Basic methods: Cytogenetics (karyotyping, FISH)</li><li>• Molecular genetics (PCR, ELISA, PCR)</li></ul>                                                                                                                                                                                                                                                                                      |           |
| <b>IX. Prenatal diagnosis and genetic counseling:</b>                                                                                                                                                                                                                                                                                                                                                                                 | <b>5H</b> |
| <ul style="list-style-type: none"><li>• Genetic counseling</li><li>• Prenatal diagnosis and treatment of genetic disease</li><li>• Preimplantation genetic testing, embryo biopsies</li><li>• Role of genetics in infertility</li><li>• Role of genetics in recurrent pregnancy loss</li><li>• Chromosomal and genetic analysis in assisted reproduction</li></ul>                                                                    |           |

## **X. Practicals**

**6H**

- Different test for hormones
- Instrument and Principles of hormone assays (ELISA, Immunofluorescence and chemiluminescence)
- Specimen collection and handling calibration for hormonal assay
- Preparation of reagents
- Specificity and sensitivity of different hormonal assays
- Quality control
- Trouble shooting in clinical biochemistry laboratory

### **Recommended Books/ Reading Material:**

1. Clinical chemistry, Michael L. Bishop and Edward P. Fody 7th edition Publisher: LWW
2. Harpers Biochemistry-Robert Murray, 27th Edition, Publisher : McGraw-Hill Companies
3. Principles of Biochemistry, Voet & Voet 4th Edition, Publisher :John Wiley and Sons Inc
4. Human stem cell manual- Jeanne F Loring, Publisher :Academic Press
5. Teitz text book of Clinical Chemistry and Molecular Diagnosis, Carl A Burtis & Edward R Ashwood 5th Edition, Publisher :Elsevier

## **MODULE 2 - Section B**

### **PHARMACOLOGY**

#### **I. General pharmacological principles**

**8H (3+3+2)**

- Introduction to Pharmacology
  - Routes of drug administration
  - Novel drug delivery systems
  - Drug dosage forms
- Pharmacokinetics
  - Absorption
  - Distribution
  - Metabolism
  - Excretion of drugs
- Pharmacodynamics
  - Receptors and transducer mechanisms
  - Adverse drug reactions (including teratogenicity)

#### **II. Hormones and related drugs**

**22H (12+10)**

- Introduction to hormones
  - Pituitary hormones
  - Ovarian hormones
  - Testicular hormones
  - Other hormones: Thyroid, adrenal, placental hormones

- Drugs used in treatment of infertility
  - Male infertility
  - Female infertility

### **Recommended Books/ Reading Material:**

1. Essentials of Medical Pharmacology. 7th edition. K.D Tripathi. JAYPEE Publishers
2. Sharma & Sharma's Principles of Medical Pharmacology. 3rd edition. HL Sharma & KK Sharma. Paras Medical Publishers.
3. Medical Pharmacology. 5th edition. Padmaja Udaykumar. CBS Publishers & Distributors Pvt Ltd.
4. Drug screening methods. 3rd edition. SK Gupta. JPB

## **MODULE 3 - Section A**

### **MICROBIOLOGY**

|                                                                                                                                                                                                                                                                                 |            |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|
| <b>I. Sterilization</b>                                                                                                                                                                                                                                                         | <b>03H</b> |
| <ul style="list-style-type: none"> <li>• Autoclave</li> <li>• Hot air oven</li> <li>• Incineration</li> <li>• Plasma sterilization</li> <li>• ETO Sterilization</li> <li>• CSSD</li> </ul>                                                                                      |            |
| <b>II. Disinfection</b>                                                                                                                                                                                                                                                         | <b>03H</b> |
| <ul style="list-style-type: none"> <li>• Low level disinfectants</li> <li>• Intermediate level disinfectants</li> <li>• High level disinfectants</li> <li>• Testing of disinfectants</li> <li>• Sterilization and disinfection practices in a tertiary care hospital</li> </ul> |            |
| <b>III. Culture</b>                                                                                                                                                                                                                                                             | <b>02H</b> |
| <ul style="list-style-type: none"> <li>• Basics of culture media and culture techniques</li> <li>• Semen culture and sensitivity</li> <li>• Vaginal swab culture and sensitivity</li> </ul>                                                                                     |            |
| <b>IV. Hospital infection control</b>                                                                                                                                                                                                                                           | <b>05H</b> |
| <ul style="list-style-type: none"> <li>• Nosocomial infections</li> <li>• Biomedical waste management</li> <li>• Hand wash technique</li> </ul>                                                                                                                                 |            |
| <b>V. Sexually transmitted infections</b>                                                                                                                                                                                                                                       | <b>05H</b> |
| <ul style="list-style-type: none"> <li>• STI- Bacterial, fungal (candidiasis), parasitic (trichomoniasis)</li> <li>• STI-Viral (HIV, HBV, HCV, HPV, HSV, Molluscum)</li> <li>• Genital ulcers, bubo and pustules</li> </ul>                                                     |            |
| <b>VI. Immunology</b>                                                                                                                                                                                                                                                           | <b>06H</b> |
| <ul style="list-style-type: none"> <li>• Antigen, antibody</li> <li>• Vaccines</li> <li>• ELISA, PCR</li> </ul>                                                                                                                                                                 |            |

- Immunology of pregnancy

**VII. Congenital infections** **04H**

- Toxoplasmosis, Rubella, Cytomegalovirus, Herpes virus, Syphilis

**VIII. Genital tuberculosis and infertility** **01H**

**IX. Quality control and quality assurance in lab** **01H**

- Biosafety cabinet
- Laminar airflows
- Incubator
- Refrigerator
- Microscope

**Recommended Books/ Reading Material:**

1. Textbook of Microbiology by Ananth Narayan & Jayaram Paniker
2. Jawetz medical Microbiology
3. Essentials of Medical Microbiology by Apurba Shankar Shastri
4. Textbook of Parasitology by Chatterjee
5. Infectious diseases essentials by Mandell & Bennett

**MODULE 3 - Section B**

**Biostatistics and research methodology**

**I. Introduction and Presentation of data** **3H**

- Meaning
- Branches of Statistics
- Uses of statistics in medicine
- Basic concepts
- Scales of measurement
- Collection of data
- Presentation of data
- Tabulation
- Frequency Distribution
- Diagrammatic and Graphical Representation of Data.

**II. Measures of central tendency and Measures of Variation**  
**3H**

- Arithmetic mean (mean), median, mode
- Partition values, Range, Interquartile range, Mean Deviation, Standard
- Deviation, Coefficient of Variation.

**III. Probability and standard distributions** **3H**

- Definition of some terms commonly encountered in probability
- Probability distributions
- Binomial distribution
- Poisson distribution
- Normal distribution
- Divergence from normality
- Skewness and kurtosis

#### **IV. Census and Sampling Methods** **3H**

- Census and sample survey
- Common terms used in sampling theory
- Non-probability (Non-random) Sampling Methods: Convenience sampling, Consecutive Sampling, Quota sampling, Snowball sampling, Judgmental sampling or Purposive sampling, Volunteer sampling
- Probability (Random) Sampling methods: Simple random sampling, Systematic Sampling, Stratified Sampling, Cluster sampling, Multi-stage sampling
- Sampling error
- Non-sampling error

#### **V. Inferential statistics** **3H**

- Parameter and statistic
- Estimation of parameters; Point estimation, Interval Estimation
- Testing of hypothesis; Null and alternative hypotheses, Type-I and Type-II Errors.

#### **VI. Introduction to research methodology** **3H**

- Types of research: Descriptive vs. Analytical, Applied vs. Fundamental, Quantitative vs. Qualitative, Conceptual vs. Empirical, Other Types of Research

#### **VII. Study Designs- Observational Studies** **3H**

- Epidemiological study designs
- Observational studies
- Descriptive studies; Case reports, Case series
- Analytical studies; Case control studies, Cohort studies, Cross sectional

#### **VIII. Experimental Studies** **3H**

- Experimental studies (Intervention studies); Randomized control trials (Clinical trials), Field trials, Community trials.

#### **IX. Uses of Epidemiology**

**3H**

#### **X. Application of study Designs in Medical Research**

**3H**

#### **Recommended Books/ Reading Material:**

1. K.R.Sundaram, S.N.Dwivedi and V Sreenivas (2010): Medical statistics, principles and methods, BI Publications Pvt Ltd, New Delhi
2. NSN Rao and NS Murthy (2008): Applied Statistics in Health Sciences, Second Edition, Jaypee Brothers Medical Publishers (P) Ltd.
3. J.V.Dixit and L.B.Suryavanshi (1996): Principles and practice of biostatistics, First Edition, M/S Banarsidas Bhanot Publishers.
4. GetuDegu and Fasil Tessema (2005): Biostatistics, Ethiopia Public Health Training Initiative.
5. Essentials of Community Medicine for Allied Health Sciences, JSS AHER, 20
6. Park K. Park's Textbook of Preventive and Social Medicine. 23rd ed. Jabalpur: Banarsidas Bhanot Publishers; 2015. p.135-141
7. Suryakantha. Textbook of Community medicine with recent advances. 3rd edition.
8. Bhalwar R. Textbook of Public Health and Community Medicine. 2nd Edition.

## **MODULE – 4**

### **INFERTILITY**

- |                                                                                                                                                                                                                                                                                                                                                                                        |            |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|
| <b>I. History of assisted reproductive techniques</b>                                                                                                                                                                                                                                                                                                                                  | <b>3H</b>  |
| <b>II. Infertility, causes, work-up and treatment</b>                                                                                                                                                                                                                                                                                                                                  | <b>10H</b> |
| <ul style="list-style-type: none"><li>• Infertility: Introduction, definition and classification</li><li>• Causes in male and female partner</li><li>• Investigations and Evaluation: Male and female partner</li><li>• Basics of management: Role of antibiotics, surgery, hormone therapy, basics of ART</li><li>• Counseling and consent for various fertility treatments</li></ul> |            |
| <b>III. Patient screening</b>                                                                                                                                                                                                                                                                                                                                                          | <b>3H</b>  |
| <ul style="list-style-type: none"><li>• Physical Examination</li><li>• Investigations</li><li>• Screening for donors</li></ul>                                                                                                                                                                                                                                                         |            |
| <b>IV. Ovarian stimulation</b>                                                                                                                                                                                                                                                                                                                                                         | <b>6H</b>  |
| <ul style="list-style-type: none"><li>• Basic principles</li><li>• Types of medication and monitoring</li><li>• Stimulation regimes (types, rationale)</li><li>• Endometrial receptivity</li><li>• Complications: OHSS, multiple pregnancy, ectopic pregnancy, heterotopic pregnancy, miscarriage</li><li>• Luteal phase support</li></ul>                                             |            |
| <b>V. Introduction to IVF laboratory</b>                                                                                                                                                                                                                                                                                                                                               | <b>10H</b> |
| <ul style="list-style-type: none"><li>• Setting up of ART lab</li><li>• Essential equipment and maintenance (incubators, microscopes, micromanipulators, laminar air flow etc)</li><li>• Essential qualification of ART team</li><li>• Air purification system in ART lab</li><li>• Troubleshooting</li></ul>                                                                          |            |
| <b>VI. Andrology</b>                                                                                                                                                                                                                                                                                                                                                                   | <b>10H</b> |
| <ul style="list-style-type: none"><li>• Semen analysis as per WHO criteria (hands-on experience)</li><li>• Sperm chromatin assays</li><li>• Sperm cryopreservation – both neat and processed sample</li></ul>                                                                                                                                                                          |            |
| <b>VII. Artificial insemination</b>                                                                                                                                                                                                                                                                                                                                                    | <b>10H</b> |
| <ul style="list-style-type: none"><li>• Indications</li></ul>                                                                                                                                                                                                                                                                                                                          |            |

- Sperm preparation techniques (hands-on experience)
- Pre and post-wash semen sample, insemination time, methods and procedure

### **VIII. Azoospermia and surgical retrieval techniques 8H**

- Classification of azoospermia
- Evaluation and treatment of azoospermia
- Indication- PESA, TESA, TESE, micro-TESE

### **Recommended Books/ Reading Material:**

1. Human Embryology & Developmental Biology, 2013 Bruce Carlson
2. Essential Reproduction (6th edn) Johnson, M (2007), Blackwell Scientific
3. In vitro fertilization (3rd edition) Elder and Dale, Cambridge University Press, 2011
4. Textbook of Assisted Reproductive Techniques, Fifth Edition, 2018 David K. Gardner, Ariel Weissman, Colin M. Howles, Zeev Shoham
5. WHO laboratory manual for the examination and processing of human semen World Health Organization, 5th ed., 2010

## **MODULE – 5**

### **LABORATORY TECHNIQUES**

#### **I. Sperm sample: preparation methods for IUI and IVF/ ICSI 8H**

- Indications, advantages and disadvantages of density gradient, swim-up and wash methods.
- Advanced techniques (MACS, cell sorter)

#### **II. Practicals from ovum pick up to transfer 12H**

- Anaesthesia
- Ovum pick up
- Oocyte screening
- Denudation
- Insemination techniques: IVF, ICSI
- Embryo transfer: catheters used, ultrasound guided techniques
- Embryo loading techniques
- GIFT, ZIFT

#### **III. Oocyte to embryo grading: day 1 – 6 6H**

- Oocyte grading- quality and dysmorphism
- Pn scoring
- Embryo grading- cleavage stage, blastocyst

#### **IV. Culture condition 8H**

- Culture media, types, equilibration.
- Ideal incubators for embryo culture

- Maintenance of ideal gas levels, temperature, pH, osmolarity.
- Quality control for embryo culture system (cold chain maintenance)

**V. Assisted hatching techniques** **5H**

**VI. Biopsy** **6H**

- Types and methods (number of cells)
- Zona opening (pros and cons)

**VII. Cryopreservation programme: freezing and thawing** **10H**

- Basics and principles of freezing and thawing of cells
- Methods of cryopreservation
- Cryoprotectants
- Slow freezing and vitrification, timing
- Advantages/ disadvantages
- Sperms
- Oocytes and embryos
- Ovarian and testicular tissue (cancer patients)

**VIII. Non- routine practices** **5H**

- IVM
- Rescue ICSI
- Polar body biopsy

**Recommended Books/ Reading Material:**

1. In vitro fertilization (3rd edition)
2. Elder and Dale, Cambridge University Press, 2011
3. Textbook of Assisted Reproductive Techniques, Fifth Edition, 2018 David K. Gardner, Ariel Weissman, Colin M. Howles, Zeev Shoham
4. ESHRE revised guidelines for good practice in IVF laboratories

## **MODULE-6**

### **GOOD LABORATORY PRACTICE AND RECENT ADVANCES**

**I. Patient data** **4H**

- Identity check, confidentiality, record keeping
- Safety, coding

**II. Legislation** **7H**

- National legislation (ART, Surrogacy, PCPNDT, MTP acts, Regulations related to stem cell)
- International guidelines
- Ethical consideration
- Code of practice

**III. The EU-directive** **1H**

- Examples of what the directive covers, implementation in own country

- IV. Risk in the IVF laboratory** **4H**
- Contaminated samples, processing and storage of sample known/ suspected to be contaminated with contagious agents
- V. Staff protection** **4H**
- Hygiene, rules and regulations, protective measures (gloves, masks etc)
  - Actions upon injury
- VI. Patient counseling** **4H**
- Oocyte retrieval, fresh embryo transfer, frozen embryo transfer
  - Complications of ART
- VII. Innovative techniques in embryo viability assessment** **8H**
- Transcriptomics, proteomics, metabolomics
  - Time lapse monitoring
  - polscope
- VIII. Sperm selection methods** **4H**
- Physical, chemical, physiological (IMSI, PICSI, ROSNI, MACS)
- IX. Adverse events, back - up strategies** **5H**
- How to avoid, what to do? Eg. Mix-up of gametes, loss or damage during handling, transfer of wrong embryos, breakdown of equipment
  - Back-up strategies
- X. Three parental art techniques** **5H**
- Mitochondrial transfer, pro-nuclear, spindle transfer
- XI. Third party reproduction** **8H**
- Sperm donation and banking
  - Oocyte and embryo donation
  - Oocyte sharing
  - Surrogacy
  - Adoption
- XII. Quality control and assurance** **6H**
- Identification procedures
  - Monitoring of performance, index variables (KPI)
  - SOPs
  - Traceability
  - Validations
  - Monitoring ,use of key performance indicators
  - Logbooks
  - If/ how/ when to bring in new methods

**Recommended Books/ Reading Material:**

| Sl. No. | Name of the Book | Authors | Edition and Year |
|---------|------------------|---------|------------------|
|---------|------------------|---------|------------------|

|    |                                                                                                                          |                                                                |                       |
|----|--------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------|-----------------------|
| 1  | A - Z Encyclopedia on Infertility                                                                                        | Sulochana Gunasheela                                           | 2005                  |
| 2  | A Practical Guide to Setting Up an IVF Lab, Embryo Culture Systems and Running the Unit                                  | Alex C Varghese, Peter Sjoblom, K. Jayaprakasan,               | April 2013            |
| 3  | Oogenesis                                                                                                                | Giovanni Coticchio, David Albertini, Lucia De Santis           | December2012          |
| 4  | Sperm Chromatin Biological & Clinical Applications in Male Infertility & Assisted Reproduction                           | Nini, Armand; Agarwal, Ashok (Eds.)                            | September 2011        |
| 5  | Practical Manual of In Vitro Fertilization: Advanced Methods and Novel Devices                                           | Nagy, Zsolt Peter; Varghese, Alex C; Agarwal, Ashok (Eds)      | September 2011        |
| 6  | Preservation of Human Oocytes                                                                                            | Dr. Andrea Borini & Dr. Giovanni Coticchio                     | December2009          |
| 7  | Human Preimplantation Embryo                                                                                             | Kay Elder, Jacques                                             | February              |
| 8  | In Vitro Fertilization: A Practical                                                                                      | David K. Gardner                                               | February Approach     |
| 9  | Textbook of Assisted Reproductive Techniques                                                                             | David K. Gardner, Ariel Weissman, Colin M. Howles, Zeev Shoham | January 2018          |
| 10 | A Textbook of in Vitro Fertilization and Assisted Reproduction: the Bourn Hall Guide to Clinical and Laboratory Practice | Peter Brindsen                                                 | 3rd Edition 200       |
| 11 | Quality & Risk Management in the IVF Laboratory                                                                          | David Mortimer, Sharon T                                       | 2015                  |
| 12 | A Color Atlas for Human Assisted Reproduction: Laboratory & Clinical Insights (Hardcover)                                | Pasquale Patrizio, Michael J Tucker, Vanessa Guelman           | August 2006           |
| 13 | The Developing Human: Clinically Oriented Embryology                                                                     | Keith L. Moore,                                                | 10th edition May 2015 |

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|----|---------------------------------------|----------------------------|------------------------|
| 14 | Vitrification in AssistedReproduction | MJ Tucker/ J<br>Liebermann | Second<br>edition 2016 |
|----|---------------------------------------|----------------------------|------------------------|