

THE TAMIL NADU Dr. M.G.R. MEDICAL UNIVERSITY, CHENNAI-32

REGULATIONS OF THE UNIVERSITY

In exercise of the powers conferred by Section 44 of the Tamil Nadu Dr.M.G.R.Medical University, Chennai Act 1987 (Tamil Nadu Act 37 of 1987) the Standing Academic Board of the Tamil Nadu Dr.M.G.R.Medical University, Chennai hereby makes the following regulations:-

1. SHORT TITLE AND COMMENCEMENT:-

These regulations shall be called as “THE REGULATIONS FOR THE MASTER OF SCIENCE (**REGENERATIVE MEDICINE**) OF THE TAMIL NADU Dr. MGR MEDICAL UNIVERSITY, CHENNAI”.

They shall come into force from the academic year 2013-2014 onwards.

The Regulations and the Syllabus framed are subject to modification by the Standing Academic Board from time to time.

2. ELIGIBILITY:

The candidates who possess Degree in the following are eligible to get admitted into the course of M.Sc. (Regenerative Medicine):

1. MBBS from Medical Council of India recognized Institutions.
2. BDS from Dental Council of India recognized Institutions.
3. B.V.Sc from Veterinary Council of India recognized Institutions.
4. B.E Biotechnology/ B. Tech Biotechnology from UGC Recognized Universities with atleast one year experience in Regenerative Medicine and one publication in Regenerative Medicine in a peer reviewed journal.
5. B.Sc/ Undergraduate degree with Biological Science subject as the major subject from UGC Recognized Universities with atleast two year experience and two publications in Regenerative Medicine in peer reviewed journals. Preference will be given for B. Sc (Zoology/ Microbiology/Genetics/ Immunology/ Molecular Biology / Biotechnology/Biochemistry/Bioinformatics/Biomedical Sciences).
6. M.Sc/ Post Graduate degree with Biological Science subject as the major subject from UGC Recognized Universities with atleast one year experience in Regenerative Medicine or two publications in Regenerative Medicine in peer reviewed journals. Preference will be given for M.Sc., (Anatomy/Physiology/Pharmacology/Microbiology/ Biotechnology/Molecular Biology/Zoology/ Genetics/ Immunology/ Biochemistry/Bioinformatics/Biomedical Sciences)

Candidates must possess a minimum of 55% marks in aggregate.

3. PHYSICAL FITNESS CERTIFICATE:

Every candidate before admission to the course shall submit to the Institution, a Certificate of Medical Fitness from an Authorised Medical Officer that the candidate is physically fit to undergo the academic course and does not suffer from any disability or contagious disease.

4. ELIGIBILITY CERTIFICATE

The candidate who has passed any qualifying examination as stated in Regulation No.2 above other than the Tamil Nadu Dr. MGR Medical University shall obtain an "Eligibility Certificate" from this University by remitting the prescribed fee along with the application form and required documents before seeking admission to anyone of the affiliated medical institutions.

5. REGISTRATION:

A Candidate admitted in the Master of Science (Regenerative Medicine) course in any one of the affiliated institutions of this University shall register his / her name in the prescribed application form for registration duly filled, along with the prescribed fee and declaration taking in the format, as in Annexure

I. The application for registration is to be submitted to the Controller of Examinations through the affiliated institutions within 30 days from the cut off date prescribed for admission.

6. DURATION OF THE COURSE:

a. The period of certified study and training of the M.Sc., (Regenerative Medicine) course shall be two academic years for award of degree.

b. No exemption shall be given from this period of study and training for any other experience gained prior to the admission of the course.

7. COMMENCEMENT OF THE COURSE:

The course shall commence from May 1st and October 1st of the academic year and the candidates admitted upto May 31st and October 31st will be registered for the course.

8. COMMENCEMENT OF THE EXAMINATIONS:

15th April/ 15th October

If the date of commencement of examination falls on Saturdays / Sundays or declared Public Holidays, the examination shall begin on the next working day. The University paper will be awarded for 100 marks and Internal 50 marks.

9. CUT-OFF DATE FOR ADMISSION TO EXAMINATIONS:

The candidates admitted upto 31st May and 31st October shall be registered to take up their First Year examinations after fulfilment of the regulations from April of the next year.

All kinds of admissions shall be completed on or before 31st May and 31st October of the academic year. There shall not be any admissions after 31st May and 31st October , even if seats are vacant.

10. CURRICULUM:

The Curriculum and the syllabus for the course shall be as prescribed by the Standing Academic Board from time to time.

11. MEDIUM OF INSTRUCTION:

English shall be the Medium of Instruction for all the Subjects of study as for examinations of the M.Sc., (Regenerative Medicine) course.

12. WORKING DAYS IN THE ACADEMIC YEAR:

Each academic year shall consist of not less than 270 working days

Total No. of days in a year	365 days
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No. of weekly off (Sundays) - 52 days	
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No. of Government Holidays - 22 days	
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No. of Holidays - 21 days	
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-----95 days	
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Total No. of working	
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days including	
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examination period	
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270 days

13. ATTENDANCE REQUIRED FOR ADMISSION TO EXAMINATIONS:

(a) No candidate shall be permitted to appear in any one of the parts of M.Sc. (Regenerative Medicine) course in Examinations unless he/she has attended the course in all the subjects for the prescribed period in an affiliated institution recognized by this University and produce the necessary certificate of study, attendance and satisfactory conduct from the Head of the institution.

(b) A candidate is required to put in a minimum of 90% of attendance out of 270 working days in both theory and practical separately in each subject before admission to the examinations. This 270 working days of attendance is required for Non clinical specialities

(c) A candidate lacking in the prescribed attendance and progress in any one subject in theory and practical wherever necessary in the first appearance shall not be permitted for admission to the entire examinations.

14. CONDONATION OF LACK OF ATTENDANCE:

There shall be no condonation of lack of attendance.

15. SCHEME OF EXAMINATION

I year									
S.No	Subject Name	Internal Assessment (IA)		Theory		Practical		Viva	
		Max	Min	Max	Min	Max	Min	Max	Min
1	Basics in Human Biology	50	25	100	50	100	50	50	25
2	Cell and Molecular Biology	50	25	100	50	100	50	50	25
3	Microbiology, pathology and Immunology	50	25	100	50	100	50	50	25
4	Genetics, Bioinformatics and Nanotechnology	50	25	100	50	100	50	50	25
Four Journal Club and Four Seminar presentations (One in each subject) compulsory for Internal Assessment									
II year									
S.No	Subject Name	Internal Assessment (IA)		Theory		Practical		Viva	
		Max	Min	Max	Min	Max	Min	Max	Min
1	Cell Culture basics and Protocols	50	25	100	50	100	50	50	25
2	Stem Cells and Tissue Engineering	50	25	100	50	100	50	50	25
3	BioStatistics and Research Methodology, Ethics and Regulatory Approvals	50	25	100	50	100	50	50	25
4	Applied Regenerative Medicine and Recent Advances in Regenerative Medicine	50	25	100	50	100	50	50	25

Four Journal Club and Four Seminar presentations (One in each subject) compulsory for Internal Assessment Thesis/ Project- 200 Marks; Viva Voce/presentation - 100 marks

EXAMINATIONS :- THEORY AND PRACTICALS

Candidate needs to get a pass mark separately in Theory, Internal Assessment and Practical Exams in each subject. If the student fails in any of the subject, he/she has to appear for that subject in the consecutive October Examinations. Only on passing all the subjects in the first year will the student be eligible to continue the second year. Degree Certificate and Course Completion Certificates will be awarded only when the student passes in all the subjects.

16. INTERNAL ASSESSMENT MARKS:

Marks for Internal Assessment for each subject will be given by the H.O.D. three times a year.

17. DISSERTATION

- a. A candidate shall present and defend his/her dissertation at the end of the second year of his/her study and shall be subjected to a Viva-Voce on his/her dissertation.
- b. "The Dissertation/thesis shall be a bound volume of minimum 50 pages and not exceeding 75 pages of typed matter(Double line spacing and on one side only) excluding certification, acknowledgments, annexures and Bibliography.
- c. 4 copies of dissertation shall be submitted 2 months prior to the commencement of the examination on the prescribed date to the Controller of Examination of this University.

18. EVALUATION OF DISSERTATION:

Evaluation will be at the time of examination during which marks are given. 200 Marks for dissertation, 100 marks for Viva/Presentation. Minimum passing mark is 150.

19. MARKS QUALIFYING FOR A PASS:

A candidate shall be declared to have passed the examination if he/she obtains the following qualifying marks:-

Theory : 50%

Practical : 50%

IA: 50%

Overall: 50%

20. REVALUATION OF ANSWER PAPERS:

Revaluation of the answer papers of the failed candidates in any Post-Graduate examination is not permitted.

21. TRAINING IN OUTSIDE CENTRES:

During the second year, the candidates shall work on their Dissertation/Thesis, after approval of the protocol by the Guide and the Head of the Institute/Course Director. The Head of the Institute/ Head of the Institute/Course Director shall write to the Colleges/Institutions having facilities for Project Work and get their consent in writing and then make necessary arrangements for deputing the students under intimation to the Controller of Examinations. Such Project Work done by a student shall be certified by the Supervisor and Head of the Institution who will send it to the Controller of Examinations through proper channel.

The attendance will be forwarded directly to the Controller of Examinations

22. MAINTENANCE OF LOG BOOK:

- a) The candidate should participate in the teaching and training programme of Under-graduate students.
- b) In addition, the Head of the Department shall involve their Postgraduate candidates in Seminars, Journal club meets, Conferences, Group Discussions, etc.
- c) During the second year, the candidate shall maintain a log book of activities in connection with the dissertation
- d) The Head of the Department shall scrutinize and certify the Log Book once in every three months
- e) At the end of the course, the candidate should summarize the contents and get the Log Book certified by the Head of the Department
- f) The Log Book should be submitted at the time of practical examination for the scrutiny of the Examiners.

23. NUMBER OF APPEARANCES:

- a) A candidate registered for Two Years Post Graduate Degree Course must qualify in the Examinations within four years of the date of his/her admission.
- b) The Candidate should submit a certificate of study and training from the Course Director to the Controller of Examinations along with his/her application for every subsequent examination.
- c) However, a candidate may be permitted to undergo a further period of study and training of minimum six months duration in a recognized Post- Graduate Department in the Speciality in an Institution affiliated to this University.
- d) Part – II can be attempted only one year after appearing for Part – I. The candidate must have cleared Part – I before appearing for thesis defence.
- e) If the candidate does not complete Part – I in three years, he/she will not be eligible to continue.
- f) The candidates will not be permitted to appear for more than 5 attempts in the final examinations and shall be discharged from the course if he/she fails to pass Examination in the said number of attempts.

24. DURATION FOR COMPLETION OF THE COURSE OF STUDY:

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

25. AWARD OF DISTINCTION AND RANKS:

Distinction will be awarded to successful candidates who secure 75% marks or more as a course aggregate without any failure.

The names of these candidates at the end of the course will be published in the Tamil Nadu Govt. Gazette. Also the details will be published in the University website.

26. RE-ADMISSION AFTER BREAK OF STUDY:

Please refer to the Separate Regulations for Re-admission after break of study for all courses.

27. MIGRATION/TRANSFER OF CANDIDATES:

Migration/Transfer of candidates from one recognized college to another recognized college of this University or from another University shall not be granted.

28. VACATION:

There is no vacation.

29. AWARD OF MEDALS AND PRIZES:

The University shall award at its Convocation, Medals and prizes to outstanding candidates as and when instituted by the donors as per the schedule prescribed for the award.

30. AUTHORITY TO ISSUE TRANSCRIPT:

The University shall be the Authority for issuing Transcript after remitting the prescribed fee or as may be prescribed from time to time.

CURRICULUM & SYLLABUS FOR MSc., (REGENERATIVE MEDICINE)

I year

PAPER I - BASICS IN HUMAN BIOLOGY

Section A:

Basics in Human Anatomy and Physiology

- Scope of anatomy, physiology and basic terminology.
- Cell physiology: Different type of cells, cell membrane physiology, development of action potential, impulse transmission, cardiac and skeletal muscles electrophysiology, cell stimulation and neuronal functions.
- Tissues: Epithelial, connective, muscular and nervous tissues, their types and characteristics.
- Bones and Joints: Structure and function of skeleton, types of joints and their disorders.
- Blood and Lymph: Composition and functions of blood including their disorders. Blood grouping and its significance, mechanism of coagulation, bleeding and clotting disorders. Formation of lymph and its composition. Reticule-endothelial system and its functions.
- Cardiovascular system: Anatomy and physiology of heart, blood circulation - systemic, hepatic, pulmonary, fetal and circle of Willis, cardiac cycle, heart rate, blood pressure and its regulation, ECG and heart sounds.
- Digestive system: Gross anatomy of the Gastrointestinal system and its physiology with special reference to liver, pancreas and stomach. Digestion, absorption, movements of intestine and disorders of digestive system- constipation, diarrhoea and vomiting.
- Respiratory system: Anatomy of respiratory tract, mechanism of respiration, lung volumes, transport of oxygen and carbon dioxide. Disorders like cyanosis, mountain sickness and Caisson's disease. Cough and sneezing reflex.
- Urinary system: Structure and functions of kidney and urinary tract. Physiology of urine formation and acid-base balance.
- Reproductive system: Structure and functions of male and female reproductive systems, sex hormones, physiology of menstruation, coitus and fertilization. Spermatogenesis and oogenesis, pregnancy and parturition.

- Endocrine system: Basic anatomy and physiology of pituitary, thyroid, parathyroid, adrenal and pancreatic hormones and disorders of these glands.
- Central nervous system: Structure and functions of brain and spinal cord. Functions of cerebrum, cerebellum, vital centres of medulla oblongata, cerebral ventricles, cranial nerves and their functions. Reflex arc, cerebrospinal fluid and its functions, meninges.
- Autonomic nervous system: Anatomy, physiology and divisions. Motor and sensory pathways.
- Sense organs: Physiology of vision, audition, olfaction, taste and skin.

Human Embryology and Development Basics

Human Reproductive Cycle, Pregnancy, Implantation, Placenta, Embryonic Developmental Stages, Germ Layers, Somitogenesis, Neuralation, Birth, Common Developmental Anomalies

Section B:

Basics of Human Histology

- The Cell - Components, Protoplasm, Cytoplasmic Organelles, Cytoskeleton, Nucleus
- Microscopy – Types of Microscopy
- Cell Division - Mitosis and Meiosis
- Epithelium- Classification and Cell attachments
- Connective Tissue - Organization and Classification, Histology of Cells and Tissues of Cartilage, Bones and Joints,
- Hematopoietic System Components
- Muscle – Classification – Histology of Skeletal Muscle , Cardiac Muscle, Smooth Muscle
- Nervous Tissue –organization of Neuron and Spinal Cord
- Skin – Structure of Epidermis, Dermis
- Respiratory System- Cells and Tissues of the Nose, Pharynx and Larynx, Trachea, Bronchi relevant to Regenerative Medicine
- Digestive System –Histology of Cells and Tissues of the Stomach, Small Intestine and Large Intestine, Liver and Pancreas.
- Urinary System –Histology of Cells and Tissues of the Kidney and Urinary Bladder
- Histology of Male and Female Reproductive Tissues
- Special Senses –Histology of Eye and Ear

Staining Techniques - Fixing, Processing - dehydration, clearing, and infiltration, Embedding, Sectioning and Staining, Common laboratory stains and Alternative techniques

Laboratory Exercises:

1. Representative Human tissue Histology Slides Identification
2. Hemocytometer and Microscope Basics; Identification of parts. Cleaning and Maintaining the Microscope
3. Blood Cell counts- Total Leucocyte counts, Differential Leukocyte counts
4. Physiological Cell and Tissue Preservation Methodologies including cryopreservation and Thawing
5. Tissue Processing and Staining Methods

Recommended Books:

Section A: Basics of Human Anatomy and Physiology

1. Gray's Anatomy: The Anatomical Basis of Clinical Practice, 40th Ed (2008), 1576 pages, Churchill-Livingstone, Elsevier.
2. R.M.H McMinn et al: Concise Handbook of Human Anatomy, 1998 Book Power.
3. Orban's Oral Histology & Embryology - S.N.Bhaskar
4. Best and Taylor's "Physiological basis of Medical Practice".
5. Guyton A.C. Hall J.E. Text book of Medical Physiology.
6. Human Physiology by C.C. Chatterjee.
7. Samson Wright's Applied Physiology by Cyril A. Keek, Eric Neil and Norman Joels. Choudhari; Concise Medical Physiology, 2nd edition

Section B: Human Histology

1. D.W. Fawcett and R.P. Jensen, Bloom's Concise Histology, 2002, 2nd Ed, Oxford University Press.
2. I. Singh, Text Book of Human Histology, 2008, Jaypee Brothers Medical Publishers (P) Ltd.

For Laboratory Exercise:

1. Hutchison's; Clinical Methods, 20th edition
2. Hewitson, Tim D.; Darby, Ian A. (Eds.). Histology Protocols. Series: Methods in Molecular Biology, Springer Vol. 611 2010, 2010, X, 230 p.
3. Mohan Harsh. Pathology Practical Book 2/e. Jaypee, 2007

4. John G. Day (Editor), Mark R. McLellan (Editor). Cryopreservation and Freeze-Drying Protocols (Methods in Molecular Biology). Humana Press; 1 edition (March 24, 1995)

PAPER II - CELL AND MOLECULAR BIOLOGY

- An overview of Biological Molecules, Energy, Enzymes, and Biological Reactions.
- The Cell: An Overview, Cell Communication and Cellular Respiration
- Cell Membranes and Transport.
- Cell Division- Mitosis and Meiosis
- Genes and Inheritance.
- Chromosomes – Structure and Arrangement
- DNA Structure, Replication, and Organization.
- Protein Synthesis
- Control of Gene Expression
- Bacterial and Viral Genetics

Techniques in Molecular Biology

- DNA Preparation, Polymerase Chain Reaction, and Molecular Cloning
- Protein Expression, Purification, and Analysis
- Oligonucleotide-Directed Mutagenesis
- DNA Sequencing
- Southern Blot
- Northern Blot

Laboratory Exercises:

1. To study living matter under phase contrast microscope.
2. To study the parts of phase contrast microscope and its maintenance.
3. Density gradient separation of human blood cells.
4. Isolation of DNA
5. DNA electrophoresis
6. PCR analysis.

Recommended Text Books:

1. B. Alberts A. Johnson, J. Lewis, M. Raff, K. Roberts, and P. Walter, Molecular biology of cell, 2008, Garland Science, Taylor & Francis Group.

2. P. J. Russell, P.E. Hertz, C. Starr, S. L. Wolfe and B. McMillan, Cell and Molecular Biology, 1st edition 2009 Cengage Learning.
3. K. Wilson & J. Walker., Principle & Techniques of Practical Biochemistry and Molecular Biology, 2006, Cambridge University Press.
4. D. Friefielder, Physical Biochemistry: Applications to Biochemistry and Molecular Biology, 1982 W. H. Freeman.
5. Walt Ream Katharine G. Field . Molecular Biology Techniques: An Intensive Laboratory Course. Academic Press (November 26, 1998)

PAPER III - MICROBIOLOGY , PATHOLOGY AND IMMUNOLOGY

Section A:

Microbiology

- History, Introduction, Scope, Aims and Objectives.
- Morphology and Physiology of bacteria.
- Sterilization and Disinfection.
- Culture media and Culture techniques.

Bacteriology:

- Common Bacteria Encountered in Cell Culture Contamination - Distinguishing features of each , Mode of Spread, Laboratory Diagnosis
- Mycoplasma

Virology:

- Introduction, General properties, cultivation, host - virus interaction, Laboratory diagnosis, Classification of Viruses, Chemotherapy and immuno prophylaxis in general.
- Hepatitis Virus, HIV, Epstein Barr Virus and Cytomegalovirus - Distinguishing features of each , Mode of Spread, Laboratory Diagnosis

Mycology:

- Brief Introduction
- Common Fungi encountered in Cell Culture contamination - Distinguishing features of each , Mode of Spread, Laboratory Diagnosis

Section B: Pathology

Introduction

- **General pathology – cell injury, causes**
- **Reversible injury – Types, morphology, swelling, hyaline, fatty change**
- **Irreversible injury – Types of necrosis, apoptosis, calcification, dystrophic,**
- **Metastasis**
- **Concepts of disease**

B. Inflammation and repair

- **Acute inflammation – causes, features, examples**
- **Inflammatory cell and mediators**
- **Chronic inflammation – causes, features, examples**
- **wound healing**
- **Regeneration and repair.**

C. Circulatory disturbance

- **Edema**
- **Chronic venous congestion**
- **Thrombosis**
- **Embolism**
- **Infarction**
- **Gangrene**
- **Shock**

D. Growth disturbance

- **Atrophy**
- **Neoplasia – benign & malignant**

E. Specific pathology

- **Cardiovascular system – atherosclerosis, Ischemic Heart Disease, Myocardial Infarction, Hypertension, Congestive Cardiac Failure, peripheral vascular diseases.**

- **Respiratory System – COPD, Pneumonia, Tuberculosis, Asthma**
- **Nervous System – Cerebrovascular Accident, Coma, Polio, Parkinsonism, Myasthenia Gravis, Spinal Cord Injury, Multiple Sclerosis, Cerebral Palsy**
- **Bone and joint – Arthritis, Osteomyelitis, Autoimmune Disease, Spondylosis, Osteomalacia,, Tenosynovitis**
- **Muscle – Muscular Dystrophy, Polio, Myopathies.**

Section C:

Immunology:

- Infection - Definition, Classification, Source, Mode of transmission and types of Infectious disease.
- Immunity - Structure and functions of Immune system, The Complement System – Pathways, Antigen - Antibody reactions - with reference to clinical utility.
- Immuno deficiency disorders, Hypersensitivity reactions and Autoimmune disorders
- Immunology of Transplantation and Malignancy
- Immunehaematology

Laboratory Exercises:

1. Blood group typing.
2. Separation of WBC from blood by Density gradient centrifugation and Identification of various types of cells
3. Methods for Identification of different microbes
4. Methods for Aerobic and Anaerobic Microbial Culture
5. Representative Pathological slides identification
6. Pathological cell, tissue and organ preservation and identification protocols
7. Immunological Methods

Recommended Text Books:

1. John M. Davis. Animal Cell Culture: Essential Methods.Wiley; 1 edition (June 13, 2011)
2. Textbook of Microbiology by R. Ananthanarayan and C.K.Jayaram Paniker (Nov 1990)
3. Robbins. Basic Pathology, 8/e 2007. Saunders 2007
4. Parakrama Chandrasoma. Concise Pathology. McGraw-Hill Publishing Co; 3rd edition (June 25, 1997)

- Drug Discovery: Drug databases, Identification of drug validation, Optimization, Target Identification, Docking, Results Visualization and Results Interpretation.
- Applications of Bioinformatics in Regenerative Medicine

Section C: Nanotechnology

- Nanotechnology – Introduction and History
- Biomimetics
- Synthesis of Nanomaterials
- Nanopolymers, Nanocomposites, Nanoengineered Thin Films, Hydrogels and other nanomaterials used in Tissue Engineering and Regenerative Medicine
- Surface Engineering of Biomaterials
- Imaging using Nanoparticles
- Biofunctionalization of surfaces with peptides, proteins or sub cellular organelles
- Pharmacogenomics and nanotechnology, personalized medicine.
- Optical Cell Manipulation
- Overview of Applications of Nanotechnology in Regenerative Medicine

Laboratory Exercises:

1. Karyotyping
2. Mitosis cell division
3. Conjugation
4. Bio-informatics Tools: Online tools, Databases, Online Servers, Macromolecules Visualization software and Docking software
5. Gene Transfection Methods

Recommended Books:

1. B. S. Gardener and D. P. Smaustad, Principles of Genetics., 5th edition, 2009 John Wiley & Sons Ltd.
2. Ricki Lewis. Human Genetics: Concepts and Applications. McGraw-Hill Science/Engineering/Math; 9 edition (October 5, 2009)
3. U. W. Goodenough: Genetics 3rd Ed., 1984 Saunders (W.B.) T Strachen & A. Read, Human Molecular genetics, 1999, Wiley-Liss.
4. R. L. Nussbaum, R.R., McInnes & H. F. Willard, Genetics in Medicine, 2007, W. B. Saunders Company.
5. Current Protocols in Human Genetics. John Wiley & Sons, Inc. 1994
6. Christopher G. Mathew (Author) . Protocols In Human Molecular Genetics (Methods in Molecular Biology (Cloth)) (Vol.9).Humana Press; 1 edition (January 1, 1991)
7. Nicolas C. Dracopoli et al. Short Protocols in Human Genetics .Wiley; 1 edition (October 13, 2004)

8. Melba Navarro, Josep A. Planell . Nanotechnology in Regenerative Medicine: Methods and Protocols (Methods in Molecular Biology). Humana Press; 2012 edition (November 1, 2011)
9. Shastri, Venkatram Prasad; Altankov, George; Lendlein, Andreas (Eds.). Advances in Regenerative Medicine: Role of Nanotechnology, and Engineering Principles. 1st Edition., Springer 2010, XIV, 406 p.
10. Harry F. Tibbals . Medical Nanotechnology and Nanomedicine (Perspectives in Nanotechnology). CRC Press; 1 edition (September 29, 2010)
11. Bioinformatics: Tools and Applications. Springer, 22-Sep-2009 - 451 pages
12. Venkatarajan Mathura, Pandjassarame Kanguane. Bioinformatics: A Concept-Based Introduction. Springer, 20-Oct-2008
13. Lukas K. Buehler, Hooman H. Rashidi. Bioinformatics Basics: Applications in Biological Science and Medicine. CRC Press; 2 edition (June 23, 2005)

II Year

PAPER I - CELL CULTURE BASICS AND PROTOCOLS

- Introduction.
- Historical Background.
- Types of Tissue Culture.
- Biology of Cultured Cells and the Culture Environment.
- Cell Adhesion, Cell Proliferation and Differentiation.
- Energy Metabolism, Incubation and Culture.
- Laboratory and Equipments - Design, Layout, and Specifications, Laboratory Maintenance
- Sterility and Standard Procedures to be followed
- Culture Vessels and Substrates.
- Media and Supplements- Preparation, Storage, Physicochemical Properties and Validation.
- Primary Culture- Initiation, Isolation of the Tissue, Types, Sub- Culture, Cell Lines
- Cloning and Selection- Cell Cloning. Plating, Selective Inhibitors
- Cell Separation - Density based separation, Antibody Based Techniques, Fluorescence-Activated Cell Sorting, Magnetic-activated cell sorting
- Cell Characterization- Cell Morphology, Microscopy, Chromosome Content, DNA Analysis, RNA and Protein Expression, Enzyme Activity, Antigenic Markers, Differentiation.
- Cell Differentiation - Stages, Markers and Methods
- Cell Immortalization and Tumorigenicity

- Cryopreservation- Freezing and Thawing Protocols
- Quantization- Cell Counting, cell Proliferation assays, Cell Migration assays, cell weight, DNA content, Protein, cell Cycle time
- Gene Transfection to Cells
- Cytotoxicity and Genotoxicity Assays
- Contamination -Sources, Types of Microbial Contamination, Monitoring and Solutions
- Cell Culture of Specialized Cells- Epithelial Cells, Mesenchymal Cells, Neuroectodermal Cells, Hematopoietic Cells, Germ Cells, Tumour Cells
- Autoradiography, Time-Lapse Recording, Somatic Cell Fusion and Production of Monoclonal Antibodies.
- Biohazards

Laboratory Exercises:

1. Handling Cell culture equipments
2. Lab maintenance
3. Trypan Blue Dye Exclusion Method
4. Preparation of Cell Culture Media
5. MTT Assay
6. Cryopreservation and Retrieval of Cells
7. Isolation of Primary cells
8. Continuous Suspension Cell line Culture and Passaging
9. Continuous adherent Cell line Culture and Passaging
10. Identification of Contamination in Cell culture
11. Gene Transfection to cells

Recommended Text Books:

1. R. Ian Freshney, Culture of Animal Cell; A manual of Basic Technique 5th Ed. 2005, John Wiley.
2. J. M. Davis. Basic Cell Culture, 2nd Ed., 2005, Oxford University Press (OUP).
3. N. Jenkins: Animal Cell Biotechnology; Methods & Protocols, 2005, Humana Press
4. Richard Twyman. Gene Transfer to Animal Cells (Advanced Methods). Taylor & Francis; 1 edition (February 11, 2005)
5. Maureen A. Harrison, Ian F. Rae. General Techniques of Cell Culture. Cambridge University Press 1997

PAPER II - STEM CELLS AND TISSUE ENGINEERING

- Three-Dimensional Cell Culture, Organ Culture, Organotypic Culture.
- Stem Cells – Basics, Properties and Classification
- Types of Stem cells – Hematopoietic Stem Cells, Mesenchymal Stem Cells, Embryonic Stem Cells, Fetal Stem Cells, Stem cells from adult organs-Characteristics, Isolation, Culture and Characterization protocols
- Extra Cellular Matrices
- Morphogenesis and Tissue Engineering
- Principles of Tissue Culture
- Bioreactor Design
- Mechanochemical Regulation of Cell Behaviour
- *In Vitro* and *In Vivo* Synthesis of Tissues and Organs
- Micro-Scale Patterning of Cells and their Environment
- Three-Dimensional Scaffolds
- Tissue Engineering and Transplantation Techniques
- Immunoisolation Techniques
- Modes of Cell and Tissue Delivery
- Regeneration of Bone and Cartilage
- Islet Cell transplantation and Bioartificial Pancreas
- Bioprinting of Organs and Tissues
- Stem Cells in Gastrointestinal , Liver, Pancreas, Kidney, Heart, Spinal Cord and Lung Regeneration
- Stem Cells in Eye Diseases and Disorders

Laboratory Exercises:

1. Isolation and Culture of Hematopoietic Stem cells
2. Isolation and Culture of Mesenchymal Stem cells
3. Differentiation of Pluripotent stem cells
4. Cell culture in Scaffolds

Recommended Books:

1. R. Lanza, J. Gearhart et al (Eds), Essential of Stem Cell Biology. (2009), Elsevier Academic press.
2. R. Lanza and I. Klimanskaya, Essential Stem Cells Methods. (2009), Academic Press

3. J. J. Mao, G. Vunjak-Novakovic et al (Ed): Translational Approaches in Tissue Engineering & Regenerative Medicine 2008, Artech House, INC Publications.
4. Robert Lanza et al. Principles of Tissue Engineering, 3rd Edition. Academic Press; 3 edition (August 21, 2007)
5. Stein et al. Human Stem Cell Technology and Biology: A Research Guide and Laboratory Manual. Wiley-Blackwell; 1 edition (January 4, 2011)
6. Lanza et al. Handbook of Stem Cells, Two-Volume Set: Volume 1- Embryonic Stem Cells; Volume 2-Adult & Fetal Stem Cells (v. 1). Academic Press (September 28, 2004)

PAPER III - BIOSTATISTICS AND RESEARCH METHODOLOGY, ETHICS AND REGULATORY APPROVALS:

Section A:

Biostatistics

- Mean; Median; Mode; Standard deviation
- Frequency Distributions
- Probability Concepts
- Binomial Probability Distributions and Normal Probability Distributions
- Basics of Hypothesis Testing
- Chi-squared Statistics
- Odds ratio;
- Confidence intervals; P values
- Mann-Whitney and other non-parametric tests;
- Risk reduction
- Correlation; Regression Statistics
- Life tables and Kaplan-Meier plots;
- Comparing Independent Means
- Comparing Several Means One Way ANOVA
- SPSS Software
- The Cox regression model Statistics
- Sensitivity, Specificity and predictive value

Research Methodology

- Clinical Research and Research Methodology - Basics and Scope
- Formulation of Research Question
- Study Design, Conduct and Analysis of Clinical Trials
- Dissertation Writing
- Analysis of Scientific Articles
- Introduction to computer fundamentals in research, hardware, software.
- Patenting of Research

Laboratory Exercises:

1. Handling SPSS software
2. Practical exercises in Biostatistics

Section B:

Ethics and Regulatory Approvals

- Principles of Regenerative Medicine
- Translational Approaches of Tissue Engineering - Animal Study Protocols, Hurdles in Translation of Therapies to the Clinic and Solutions
- Engineered Scaffolds and Matrices
- Principles of Biomedical Ethics
- Morality
- Ethical Theories
- Ethical Principles -Respect for Autonomy, Nonmaleficence, Beneficence, Justice
- Funding of Research
- Regulatory Mechanisms
- Business of Regenerative Medicine

Laboratory Exercises

1. Observing Laboratory Animal Handling
2. Observing In vivo cell and Tissue transplantation

Recommended Text Books:

1. S.W. Smoller: Biostatistics and Epidemiology: A Primer for Health and Biomedical Professionals, 3rd edition.
2. M. Harris, G. Taylor . Medical Statistics Made Easy. Scion Publishing Ltd; 2nd edition (February 15, 2008)
3. Tiwari Poonima ,Tiwari Shashank. Epidemiology Made Easy®. Jaypee 2009
4. Ann Weaver (Author), Stephen Goldberg (Author). Clinical Biostatistics Made Ridiculously Simple. MedMaster Inc; 1 edition (April 1, 2011)
5. Kanan Yelikar . Essentials of Research Methodology and Dissertation Writing. Jaypee 2009
6. Gerstman. Basic Biostatistics: Statistics for Public Health Practice. Jones & Bartlett Learning, 2008 - 557 pages
7. J.J. Mao, G. Vunjak-Novakovic et al (Eds): Translational Approaches In Tissue Engineering & Regenerative Medicine. (2008), Artech House, INC Publications.
8. Tom L. Beauchamp, James F. Childress. Principles of Biomedical Ethics. Oxford University Press; 6th edition (May 23, 2008)
9. Lewis Vaughn . Bioethics: Principles, Issues, and Cases. Oxford University Press, USA; 1 edition (March 13, 2009)
10. IP, King-Tak (Ed.). The Bioethics of Regenerative Medicine. 2009, VIII, 188 p.
11. John I. Gallin, Frederick P Ognibene. Principles and Practice of Clinical Research, Second Edition (Principles & Practice of Clinical Research). Academic Press; 2 edition (May 8, 2007)

PAPER IV – APPLIED REGENERATIVE MEDICINE AND RECENT ADVANCES IN REGENERATIVE MEDICINE

Section A:

Applied Regenerative Medicine:

- **Regenerative Therapy –Introduction**
- **Applications of Regenerative Medicine in the nervous system, eye, heart, lung, liver, kidney, pancreas and kidney**
- **Large scale manufacturing of cells, tissues and organs**
- **Artificial organs**
- **Gene therapy applications**
- **Engineered Tissues and Regenerative Medicine**
- **Molecular therapy for regeneration**
- **Personalized therapies in Regenerative Medicine**

Section B:

Recent Advances in Regenerative Medicine:

As this subject is based on current concepts, the updation of which is beyond the scope of the syllabus, the students are recommended to read the articles from the following journals (issues from January- December of the year of study and the preceding two years) pertaining to latest advances in Regenerative Medicine and applications of Regenerative Medicine:

- **Nature**
- **Nature Biotechnology**
- **Science**
- **Stem Cells**
- **Cell Stem Cell**
- **Journal of Stem Cells and Regenerative Medicine**
- **Journal of Tissue Engineering and Regenerative Medicine**
- **BMJ**
- **Blood**
- **Stem Cells International**
- **Stem Cells Review and Reports**

Laboratory Exercises:

Case Reports in Regenerative Medicine applications - discussion and Journal club presentations weekly.

Recommended Text books:

1. Anthony Atala, James A. Thomson. Principles of Regenerative Medicine. Academic Press; 1 edition (December 4, 2007)
2. Atala A. Foundations of Regenerative Medicine: Clinical and Therapeutic Applications. Academic Press; 1 edition (August 28, 2009)
3. Hossein Baharvand (Editor), Nasser Aghdami (Editor). Regenerative Medicine and Cell Therapy (Stem Cell Biology and Regenerative Medicine). Humana Press; 2013 edition (August 8, 2012)
4. Gustav Steinhoff (Editor) . Regenerative Medicine.Springer; 1st Edition. edition (March 3, 2011)
5. David L. Stocum. Regenerative Biology and Medicine, Second Edition.Academic Press; 2 edition (June 14, 2012)

SYLLABUS

Epidemiology, Biostatistics and Medical Ethics

UNIT I: Epidemiology

Introduction: Historical aspects and evolution of epidemiology, definitions and concepts in Epidemiology.

Approaches in epidemiology: Descriptive and analytical epidemiology, disease burden, natural history of diseases and measures of risk and death.

Study design and sampling: Sample size estimation and introduction to study design in epidemiological investigations.

UNIT II: Biostatistics

Fundamentals of biostatistics: Introduction, types of data, tabular and graphical presentation of data. Measures of location, dispersion and correlation: Measures of central tendency. Mean, mode, median, GM, HM, quartiles Measures of dispersion—range, standard deviation, variance, coefficient of variation.

Probability and statistical inference: Concept and probability distribution. Normal distribution—density curves, applications and statistical tables. Concept of significance tests, parametric and nonparametric tests, standard error and confidence intervals.

Inferential statistics: Probability and distributions – Poisson, Binomial and Normal distribution – Chi-square test – Hypothesis test - Student's t-test – Correlation and Regression – ANOVA.

UNIT III: Medical Ethics

Bioethics and Medical ethics: Historical perspectives & Introduction to Bioethics, Nuremberg Code, Declaration of Helsinki, Principle of essentiality, informed consent, confidentiality, minimisation of risk, accountability and responsibility. Ethics of clinical trials: Drug trials, vaccine trials, Clinical trials with medical devices/surgical procedures/radioactive materials, Research in transplantation and stem cell therapy. Regulatory framework and guidelines for conduction of human research: Review processes, Institutional ethical committees, composition of committees, review procedures, WHO, UNESCO and ICMR guidelines.

References :

7. Epidemiology: An Introduction. Kenneth J. J. Rothman. Latest edition / Pub. Date: May 2002. Publisher: Oxford University Press.

8. Epidemiology. Leon Gordis. Latest edition / Pub. Date: November 2004. Publisher: Elsevier Health Sciences.

9. Diseases and Human Evolution. Ethne Barnes. Latest edition / Latest edition / Pub. Date: March 2005. Publisher: University of New Mexico Press.

- c. Epidemiology: Beyond the Basics. F. Javier Nieto, Moyses Szklo. Latest edition / Pub. Date: November 2003. Publisher: Jones & Bartlett Publishers, Inc.
- d. Basic and Clinical Biostatistics. Beth Dawson, Robert G. Trapp, Robert Trapp. Latest edition / Pub. Date: March 2004.
- e. Discovering Statistics Using SPSS. Andy Field. Latest edition / Pub. Date: April 2005. Publisher: SAGE Publications.
- 7. Arora PN & Malhon PK (1996). Biostatistics Imalaya Publishing House, Mumbai.
- (d) Sokal & Rohlf (1973). Introduction to Biostatistics, Toppan Co. Japan.
- (e) Stanton A & Clantz, Primer of Biostatistics — The McGraw Hill Inc., New York.
- 10. Government of India. Good Clinical Practices for Clinical Research in India. New Delhi: 2001
- d. Indian Council of Medical Research. Ethical Guidelines for Biomedical Research on Human Subjects. New Delhi: 2000
- 12. United Nations Educational, Scientific and Cultural Organisation (UNESCO). Universal Declaration on Bioethics and Human Rights. Paris; 2005
