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 (BLOOD BANKING TECHNOLOGY)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.OBJECTIVES: -

To render quality Blood Transfusion service to the patient.

To render safe blood Transfusion

To implement advance technology

3. ELIGIBILITY CRITERIA:-

Candidates have a degree in B.Sc. Medical Laboratory Technology (MLT)

4. ELIGIBILITY CERTIFICATE:

Candidates who have passed any qualifying examination, as specified in Regulation No.3 above from any other Universities other than the Tamil Nadu Dr. M.G.R. Medical University before seeking admission to the affiliated institutions shall obtain an Eligibility Certificate from the University by remitting the prescribed fees along with the application form which shall be downloaded from the University website (www.tnmgrmu.ac.in).

5. DURATION OF THE COURSE:- Two years

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

Total No. of days in a year		**365 days**
No. of weekly off(Sundays)	- 52 days	
No. of Government Holidays	- 22 days	
No. of Holidays	- 21 days	
	----------	95 days

Total No. of working days including		270 days
examination period		----------

6. AGE LIMIT FOR ADMISSION :-

40 years. For SC/ST candidates age relaxation is for 5 years.

7. PHYSICAL FITNESS CERTIFICATE:

Every candidate before admission to the course shall submit to the Director of the Institution a certificate of medical fitness from an authorized medical officer that the candidate is physically fit and mentally sound to undergo the academic course.

8. CUT OFF DATES FOR ADMISSION TO THE COURSE

Candidates admitted up to 31st May/31st October shall be registered to take up their first year examination from April / October of the next year, after fulfilment of the regulations.

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

*** It was resolved XXXX111 S.A.B. Dated 19.12.2011.**

9. REGISTRATION:

A candidate admitted to the Post Graduate Degree in Blood Banking Technology shall register his/ her name by submitting the prescribed application form for registration duly filled in by remitting the prescribed fee to the Tamil Nadu Dr. M.G.R. Medical University within 30 days from the cut off date prescribed for Post Graduate Degree in Blood Transfusion Technology.

10**. COMMENCEMENT OF THE COURSE**:

1st May/1st October

- It was resolved XXXX111 S.A.B. Dated 19.12.2011.

11**. MIGRATION/TRANSFER OF CANDIDATES**

Request for Migration/Transfer of candidates during the course of study from one recognized Institution to another recognized Institution of this University or from other University shall not be granted under any circumstances.

12. **RE-ADMISSION AFTER BREAK OF STUDY**

As per the procedure laid down in a common regulation for all the courses of the Tamil Nadu Dr. M.G.R. Medical University.

13. **POSTING AND TRAINING IN OUTSIDE CENTRES:**

The head of the postgraduate Department shall make necessary arrangements for the postgraduate candidates to undergo training in various skills in other centres.

14. MAINTENANCE OF LOG BOOK:-

a) Every Post Graduate Degree candidate shall maintain a record of skills (Log Book) he / she has acquired during the two years training period, certified by the various Heads of Department, where he / she undergone training including outside the institution.

b) The candidate should also be required to participate in the teaching and training programme in the cadre of undergraduate and post-graduate.

c) In addition, the Head of the Department shall involve their Post-graduate Degree course candidates in Seminars, Journal Clubs, Group Discussions and participation in clinical.

d) Every Post- graduate Degree course candidate should be encouraged to present short title papers in conferences and improve on it and submit them for publication in reputed medical journals. Motivation by the Heads of Departments is essential in this area to sharpen the research skills of the post-graduate candidates.

e) The Head of the Department shall scrutinize the Log Book once in every three months.

f) At the end of the course, the candidate should summaries the contents and get the Log Book certified by the Head of the Department.

g) The Log Book for each years should be submitted 3 months prior to the final year examinations.

15.<u>DISSERTATION & EVALUATION</u>:-

The topic of the dissertation should be submitted at the end of the first year and obtain the ethical clearance of the same. The candidate should also inform the name of the guide for the dissertation to the University while submitting the dissertations topic.

If there are changes in the dissertation topic, the same has to be informed six months prior to the final year examination.

The dissertation should be submitted duly signed by the Professor and the same has to be forwarded to the Controller of Examination through the Head of the Institution two months prior to the Examination.

For dissertation marks 200, Viva/Presentation 50 and IA 50– Minimum mark to pass 150.

* It was resolved XXXX111 S.A.B. Dated 19.12.2011.

If the dissertation is not approved (Failed) by the majority of the examiners, the results shall be withheld till the resubmitted dissertation is approved (Passed).

If the candidate fails in the Written / Practical Examination, but his / her dissertation is approved(Passed), the approval of the dissertation shall be carried over to the subsequent examination.

16. **ATTENDANCE REQUIREMENT FOR ADMISSION TO EXAMINATION**

a) No candidate shall be permitted to appear in any one of the parts of M.Sc., (Blood Banking Technology) Course 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 has to produce the necessary certificates of study, attendance, satisfactory conduct and progress from the Head of the Institution.

b) A candidate is required to put in a minimum of 90% of attendance (of 270 days) each in theory and practical classes in each subject before admission to the examination.

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

17. **CONDONATION OF LACK OF ATTENDANCE:**

There shall be no condonation of lack of attendance in Post Graduate degree programme.

18.**COMMENCEMENT OF EXAMINATION:**

15th April/15th October

* It was resolved XXXX111 S.A.B. Dated 19.12.2011.

There shall be two University examinations in an academic year. The I Batch Examinations will commence from 15th April and the IInd Batch Examinations will commence from 15th October. If the date of commencement of the examination falls on Saturdays, Sundays or declared Public Holidays, the examination shall begin on the next working day.

19. **MEDIUM OF INSTRUCTION:**

The medium of instruction for all subjects shall be English.

20. **AWARD OF DEGREE** :-

The degree shall be awarded by the University only after the successful completion of the course.

21. **AWARD OF MEDALS / 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.

22. **PASSING MINIMUM:**

A candidate shall be declared to have passed in each paper/subject if he / she secures NOT LESS THAN 50% of the marks prescribed for the examinations.

23. **RETOTALLING OF ANSWER PAPERS:-**

Re-totalling is allowed in the failed subjects. Revaluation is not allowed.

24. **NUMBER OF APPEARANCE/COMPLETION OF THE COURSE OF STUDY**

The duration for completion of the course is double the duration of the course i.e. 4 years to pass the examination, from the date of joining the course. Otherwise he / she has to be discharged from the course.

25**. <u>CURRICULUM</u>:- FIRST YEAR:**

Paper - I	MICROBIOLOGY & BIOCHEMISTRY
Paper - II	HEMATOLOGY
Paper - III	GENERAL IMMUNOLOGY
Paper – IV	IMMUNOHAEMATOLOGY

SECOND YEAR:

Paper - I	BLOOD DONATION
Paper - II	BLOOD COMPONENTS
Paper - III	TRANSFUSION THERAPY
Paper - IV	QUALITY CONTROL DOCUMENTATION AND LEGAL ASPECTS OF BLOOD BANKING
Paper - V	RECENT ADVANCES IN BLOOD BANKING TECHNIQUES

Dissertation is to be submitted three months before the final year examination.

26**. <u>INTERNAL ASSESSMENT</u>:**

The Internal Assessment should consist of the following points for Evaluation:-

<u>INTERNAL ASSESSMENT – SCHEME</u> : 50 MARKS

Theory	Practical
30 Marks	20 Marks

The Internal Assessment of the candidate has to be assessed on the above points and a report has to be submitted by the institution as detailed below:-

The aggregate of Final Internal Assessment Marks should be submitted 2 months before the commencement of the exam as per scheme of examination shall be taken by the University as Internal Assessment Marks and minimum of 50% marks is mandatory for permitting the candidates to sit for the University examinations.

SCHEME OF EXAMINATION – **FIRST YEAR**

S.N	Paper - Subject	Internal Assessment (IA)		Theory		Practical		Viva	
		Max	Min	Max	Min	Max	Min	Max	Min
1.	Microbiology & Biochemistry	50	25	100	50	100	50	-	-
2.	Haematology	50	25	100	50	100	50	-	-
3.	General Immunology	50	25	100	50	-	-	-	-
4.	Immunohaematology	50	25	100	50	100	50	-	-

SECOND YEAR

S.N	Paper - Subject	Internal Assessment (IA)		Theory		Practical		Viva	
		Max	Min	Max	Min	Max	Min	Max	Min
1.	Blood Donation	50	25	100	50	100	50	-	-
2.	**B**lood Components	50	25	100	50	100	50	-	-
3.	Transfusion Therapy	50	25	100	50	-	-	-	-
4.	Quality Control Documentation and legal Aspects of blood Banking	50	25	100	50	100	50	-	-
5.	Recent advances in Blood Banking Techniques	50	25	100	50	-	-		

EVALUATION OF DISSERTATION :

Evaluation of Dissertation	200
Viva/Presentation	50
IA	50
Total	**300**
Passing Minimum	150

** Resolved in the 43rd SAB Dated 19.12.2011.

SYLLABUS FOR MSC., (BLOOD BANKING TECHNOLOGY)

FIRST YEAR

PAPER - I - MICROBIOLOGY & BIOCHEMISTRY

1. Introduction to Microbiology, Fundamentals of microscopy, sterilization and disinfection
2. Groups of Micro organisms, Micro organisms staining techniques
3. Bacteriological media, Pure cultures and cultural characteristics, Bacteria of medical importance
4. Transfusion transmitted infections, HCV, HBV, malaria, syphilis
5. ELISA, rapid and other tests for diagnosis of transfusion transmitted infections
6. Nucleic acid testing
7. Biosafety, Management of Biomedical waste
8. Instrumentation principles: PH meter, colorimeter, Spectrophotometer, Electrophoresis equipment

PAPER - II. HEMATOLOGY

1. Collection of blood samples, types of anticoagulants
2. Complete hemogram, Different methods of haemoglobin screening/estimation: Copper sulphate, haematology analysers, Sahli's, Cyanmethhemoglobin and Hemocue methods, Red cell indices
3. Normal erythropoiesis, Leucopoiesis, Formation and function of platelets
4. Classification of anaemia, their laboratory diagnosis, Hemoglobinopathy: Beta Thalassemia and Sickle cell disease, G6PD deficiency, polycythemia
5. Autoimmune hemolytic anaemia, classification, diagnosis, specificity of autoantibodies
6. Coagulation Mechanism, Hemostasis, laboratory tests for coagulation, Platelet Disorders
7. Haematological malignancies
8. Bone marrow transplantation, peripheral stem cells, cord blood stem cells, cord blood banking

PAPER - III. GENERAL IMMUNOLOGY

1. Introduction to Immunology, History, Immunity
2. Antigens : Immunogen, allo-antigen, soluble antigen, Red cell antigen, Epitopes
3. Antibodies: Polyclonal antibodies, development of antibodies, structure of immunoglobulins, characteristics of immunoglobulins
4. Monoclonal antibodies: Hybridoma technology, Human monoclonal antibodies, Applications of MAb
5. Antigen antibody reaction: Antigen concentration, antibody concentration, enhancing media, other factors influencing antigen antibody reaction, Immunoassays: ELISA,
6. Cells of immune system: Phagocytic cells, Antigen presenting cells, T cells, T cell subsets, B cells, CD Markers, Flowcytometry for counting T & B cells
7. Autoimmune disorders
8. Complement System
9. HLA antigens, HLA antibodies, HLA Serology, Histocompatibility matching: Molecular methods
10. Molecular methods in Immunology

PAPER - IV - IMMUNOHAEMATOLOGY

1. Basic Principles of immunohaematology, Application of Blood groups: Population Genetics, Forensic medicine, Transfusion medicine
2. ABO Blood of Group Systems: History, Genetics, ABH antigens, Biochemical Synthesis of blood group antigens, Antigenic sites, weaker variants, Bombay Phenotype, ABO antibodies,
3. Rh Blood Group System: History, Genetics, Molecular Genetics, Nature of Rh Antigens, Partial D, Week D, other variants of Rh, Rh Null, Rh antibodies, factors influencing Rh immunization, Functional role of Rh antigens
4. Other Blood Group Systems: Lewis, P, Ii, MNSs, Kell, Duffy, Celano, In, Private antigens, Public antigens.
5. Antenatal Serology, Hemolytic disease of the newborn due to ABO Incompatibility, Rh Incompatibility and other allo-antibodies

6. Red cell serology techniques, their advantages and disadvantages, Cell and serum grouping, detection of weak A and B antigens and weak D/Partial D cases, Trouble shooting in red cell serology

7. Pre transfusion testing, Different methods of cross matching, cross matching in special circumstances, emergency cross matching, electronic cross matching

8. Principles of Direct and indirect antiglobulin test, enzyme technique, albumins technique, Detection of blood group antibodies, identification of their Specificity, clinical significance of antibody detection, differentiation between auto and allow-antibodies

9. Gel Technology, Micro plate technique

SECOND YEAR

PAPER - I. BLOOD BANKING - BLOOD DONATION

1. Donor Motivation, Motivational Techniques, Social Marketing, Preparation of IEC Materials

2. Donor recruitment & Retention: Types of blood donors, Donor selection, medical interview and medical examination, screening for haemoglobin estimation, Managing rejected blood donors, technique for conversion of first time donor into regular voluntary donor, donor felicitation

3. Blood collection room equipment, their principles, and use, emergency medicines, Pre donation counselling, Bleeding of the donor, post donation care, post donation counselling

4. Screening of blood units for mandatory tests, Discarding infected units,

5. Blood Donation drive: Awareness programs prior to blood donation drive, Camp site, staff requirement, management of camp, transportation of blood units from camp site to blood bank

6. Preservation of donated blood, blood preservation solutions, Additive solutions

7. Apheresis procedures, Apheresis products, preparation of multiple products on cell separators, Maintenance of cell separator equipment

8. Autologous blood donation

PAPER – II - BLOOD BANKING: BLOOD COMPONENTS

1. Selection of blood bags for component preparation, preparation of red cell concentrate, Fresh Frozen plasma, platelet concentrate, cryoprecipitate, washed red cells, Frozen red cells

2. Plasma Fractionation: Principles, manufacturing of different plasma derivatives
3. Component Testing, Labeling,
4. Transportation and storage of blood components.
5. Preparation of leukoreduced blood products, Leukocyte filters, component extractors.
6. Metabolic changes in blood components during storage, release of cytokine during storage.
7. Inventory management and maintenance of blood stock.
8. Irradiated blood components
9. Blood substitutes
10. Measurement of factor VIII level in FFP
11. Measurement of fibrinogen level in FFP
12. Sterility test on platelet concentrates.
13. Sterility test on Whole blood
14. Measurement of pH and other platelet parameters.

PAPER – III - TRANSFUSION THERAPY

1. Management of Blood Bank Issue Counter, Criteria for acceptance of requisition form, inspection of blood component prior to issue.

2. Blood administration, transfusion filters, post transfusion care, Therapeutic plasma exchange

3. Judicious use of blood; management of different types of anemia, management of bleeding patient, Neonatal transfusion, Transfusion practices in surgery, Transfusion therapy for oncology and trans plantation patents.

4. Hemolytic transfusion reaction immediate and delayed; immune and non immune reaction path physiology; Clinical signs and symptoms Laboratory invigilation for HTR Tests to defect bacterial Contamination in blood,

5. Non- hemolytic transfusion reactions Immediate and delayed, febrile reaction, allergic reaction, clinical signs and symptoms.

6. Acute transfusion related lung injury, alloimmunization, Iron overload, Graft versus host disease.

7. Strategies to prevent transfusion reactions

PAPER - IV QUALITY CONTROL DOCUMENTATION AND LEGAL ASPECTS OF BLOOD BANKING

1. Quality control of blood grouping reagents, QC of anti-human globulin reagent, bovine albumin, Normal saline

2. Quality control of blood bags

3. Quality control of different blood bank Components, sterility test on component.

4. Automation in blood banking

5. Calibration, validation and maintenance of blood bank equipment, QC of blood bank techniques, internal and external QC.

6. Organization of blood bank services, Blood Bank premises and infrastructure, Regional blood transfusion centre and blood storage centres, Blood bank management system

7. Regulations for blood bank operation: Drugs and cosmetics Law, National blood policy, standards in Blood Banking, licensing procedures.

8. Recruitment and training of blood bank personnel, Proficiency testing.

9. Blood Bank Accreditation.

PAPER – **V - RECENT ADVANCES IN BLOOD BANKING TECHNIQUES**

1. Automation in Blood Banking
2. Nucleic Acid Testing
3. Apheresis
4. Stem Cells

Reference Books

1. Modern Blood Banking and Transfusion practices by Denise M Harmening, 5th edi
2. Transfusion Medicine technical manual-DGHS, Ministry of Health and Family Welfare, Govt. of India, Second edition, 2003
3. Blood transfusion in clinical medicine by PL Mollison
4. AABB Technical Manual, 17th ed, AABB
5. Compendium of transfusion medicine, RN Makroo
6. Practical Hematology, J A Dacie and S M Lewis
7. Basic Immunology, A K Abbas and A H Lichtman. Second ed, Saunders Elsevier.
8. Essential Immunology. I Roitt, 8th ed, Blackwell scientific publications
9. Basic molecular and cell biology. David Latchman. BMJ Publishing group, 1997.
10. Voluntary blood donation program NACO, Ministry of Health and Family Welfare, Govt. of India, New Delhi, 2007.
11. National guide book in blood donor motivation. NACO, Ministry of Health and Family Welfare, Govt. of India.
12. Standards for blood banks and blood transfusion services, NACO, Ministry of Health and Family Welfare, Govt. of India, New Delhi 2007.

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—ra nge, 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 a nd Normal distribution – Chi-square test – Hypothesis test - Student's t-tes t – 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 :

- Epidemiology: An Introduction. Kenneth J. J. Rothman. Latest edition / Pub. Date: May 2002. Publisher: Oxford University Press.
- Epidemiology. Leon Gordis. Latest edition / Pub. Date: November 2004. Publisher: Elsevier Health Sciences.
- Diseases and Human Evolution. Ethne Barnes. Latest edition / Latest edition / Pub. Date: March 2005. Publisher: University of New Mexico Press.

15. Epidemiology: Beyond the Basics. F. Javier Nieto, Moyses Szklo. Latest edition / Pub. Date: November 2003. Publisher: Jones & Bartlett Publishers, Inc.

16. Basic and Clinical Biostatistics. Beth Dawson, Robert G. Trapp, Robert Trapp. Latest edition / Pub. Date: March 2004.

17. 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.

h) Sokal & Rohif (1973). Introduction to Biostatistics, Toppan Co. Japan.

i) Stanton A & Clantz, Primer of Biostatistics — T he McGraw Hill Inc., New York.

10.Government of India. Good Clinical Practices for Clinical Research in India. New Delhi: 2001

9. 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

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