Syllabus for Two-Year

MASTER OF SCEINCE (M. Sc.) MEDICAL BIOTECHNOLOGY SYLLABUS

Module/Semester	Module-1 Theory/Practical	Module-2 Theory/Practical	Module-3 Theory/Practical	Module-4 Theory/Practical
I semester	Molecular Cell Biology	Basic Biochemistry	Immunology, Immunotechnology & Immunogenetics	Biostatistics & Research Methodology & Scientific Writing
II Semester	Analytical Instrumentation	Bioinformatics,	Molecular Biology	Recombinant DNA Technology
III Semester	Human Genetics	Medical Microbiology	Plant Biotechnology	Animal Biotechnology
IV Semester	Biosafety, Introduction to quality assurance, accreditation & SOP writing		PROJECT	

INTRODUCTION TO THE CURRICULUM

This curriculum is developed for the course leading to the award of M.Sc degree in Medical Biotechnology. This manual is provided to assist you in integrating important elements of the content with the selection of effective teaching strategies.

The curriculum is presented in three main sections:

CORE CURRICULUM: These modules are defined as essential base information about Biotechnology that all post graduate professionals need to kno

SEMESTER-1		Lecturers (Hrs)	Practicals (Hrs)
Module-1	Molecular Cell Biology (Theory & Practical)	30	50
Module-2	Basic Biochemistry (Theory and Practical)	40	60
Module-3	Immunology, Immunotechnology& Immunogenetics (Theory and Practical)	30	50
Module-4	Biostatistics &Research Methodology (Theory &Practical)	40	30
	Evaluation	30	30
	Seminars : LCD, tutorial, Group discussion	190	-
	Semester total hours	360	220

Syllabus for Two-Year

MASTER OF SCEINCE (M. Sc.) MEDICALGENETICS SYLLABUS

DURATION: Four Semesters (Two Years)

Module/ Semester	Theory/ Practical	Theory/ Practical	Theory/ Practical	Theory/ Practical
I Semester	Molecular Cell Biology	Biochemical Genetics	Immunology, Immunotechnology & Immunogenetics	Biostatistics and Research Methodology & Scientific Writing
II Semester	Analytical Instrumentation	Bioinformatics	Molecular Biology	Recombinant DNA Technology
III Semester	Principles of Genetics and Population Genetics	Clinical Genetics, Genetic Counseling & Prenatal Diagnosis	Cancer Genetics & Pharmacogenomics	Developmental & Environmental Genetics
IV Semester	Biosafety, Introduction to quality assurance, accreditation & SOP writing	PROJECT		

INTRODUCTION TO THE CURRICULUM

This curriculum is developed for the course leading to the award of M.Sc degree in Medical Biotechnology. This manual is provided to assist you in integrating important elements of the content with the selection of effective teaching strategies.

The curriculum is presented in three main sections:

CORE CURRICULUM: These modules are defined as **essential base** information about Biotechnology that all post graduate professionals need to know

	SEMESTER-1	Lecturers (Hrs)	Practicals (Hrs)
Module-1	Molecular Cell Biology (Theory & Practical)	30	50
Module-2	Biochemical Genetics(Theory and Practical)	40	60
Module-3	Immunology, Immunotechnology & Immunogenetics (Theory and Practical)	30	50
Module-4	Biostatistics & research methodology(Theory & Practical)	40	30
	Evaluation	30	30
	Seminars : LCD, tutorial, Group discussion	190	-
	Semester total hours	360	220

Semester II							
	Syllabus Ref. No.	**Subject**	**Credits**	**Teaching hours**	**Marks**		
	Theory				**Internal Assessment**	**Semester Exam**	**Total**
	GEN 105 T	Molecular Biology & Genomics	4	4	20	80	100
	GEN 106 T	Recombinant DNA Technology	4	4	20	80	100
	GEN 107 T	Bioinformatics	4	4	20	80	100
	CC 001 T	Research Methodology & Biostatistics (Core Course)	4	4	20	80	100
	Practical						
	GEN 105 P	Molecular Biology & Genomics	2	4	10	40	50
	GEN 106 P	Recombinant DNA Technology	2	4	10	40	50
	GEN 107 P	Bioinformatics	2	4	10	40	50
	CC 001 P	Research Methodology & Biostatistics (Core Course)	2	4	10	40	50
		Total	24	32	120	480	600

Semester II							
	Syllabus Ref. No.	**Subject**	**Credits**	**Teaching hours**	**Marks**		
	Theory				**Internal Assessment**	**Semester Exam**	**Total**
	CE 105 T	Infertility & Ovulation induction methods	4	4	20	80	100
	CE 106 T	Quality assessment, statistics, handling data, ethics, legislation	4	4	20	80	100
	CE 107 T	IVF procedure	4	4	20	80	100
	CC 001 T	Research Methodology & Biostatistics(Core Course)	4	4	20	80	100
	Practical						
	CE 105 P	Infertility & Ovulation induction methods	2	4	10	40	50
	CE 106 P	Quality assessment, statistics, handling data, ethics, legislation	2	4	10	40	50
	CE 107 P	IVF procedure	2	4	10	40	50
	CC 001 P	Research Methodology & Biostatistics (Core Course)	2	4	10	40	50
		Total	24	32	120	480	600

Semester II							
	Syllabus Ref. No.	**Subject**	**Credits**	**Teaching hours**	**Marks**		
	Theory				**Internal Assessment**	**Semester Exam**	**Total**
	MB105 T	Gene and Protein Science	4	4	20	80	100
	MB106 T	Bioinformatics &Computational biology	4	4	20	80	100
	MB 107 T	DNA Recombinant Technology	4	4	20	80	100
	CC 001 T	Research Methodology and Biostatistics (Core Course)	4	4	20	80	100
	Practical						
	MB 105 P	Gene and Protein Science	2	4	10	40	50
	MB 106 P	Bioinformatics &Computational biology	2	4	10	40	50
	MB 107 P	DNA Recombinant Technology	2	4	10	40	50
	CC 001 P	Research Methodology and Biostatistics (Core Course)	2	4	10	40	50
		Total	24	32	120	480	600

OUTLINE OF COURSE CURRICULUM

M.Sc. Clinical Nutrition

Semester II														
Code No.	**Core Subjects**	**Credits/Week**					**Hrs/Semester**					**Marks**		
		Lecture (L)	**Tutorial (T)**	**Practical (P)**	**Clinical Posing/ Rotation**	**Total Credits (C)**	**Lecture (L)**	**Tutorial (T)**	**Practical (P)**	**Clinical Posing/ Rotation**	**Total hrs.**	**Internal Assessment**	**Semester Exam**	**Total**
Theory														
MCN 106 L	Medical Nutrition Therapy I	4	-	-	-	4	60	-	-	-	60	20	80	100
MCN 107 L	Advance Nutrition	3	-	-	-	3	45	-	-	-	45	20	80	100
MCN 108 L	Food Microbiology and Safety	3	-	-	-	3	45	-	-	-	45	20	80	100
MCN 109 CP	Nutrition Directed Clinical Education-II	-	-	-	21	7	-	-	-	-	315	50	-	50
CC 001 L	Research Methodology & Biostatistics (Core Course)	4	-	-	-	4	60	-	-	-	60	20	80	100
Practical														
MCN 106 P	Medical Nutrition Therapy I	-	-	4	-	2	-	-	60	-	60	10	40	50
CC 001 P	Research Methodology & Biostatistics (Core Course)	-	-	4	-	2	-	-	60	-	60	10	40	50
Total		14	0	8	21	25	210	0	120	0	645	150	400	550

Semester II

	Syllabus Ref. No.	Subject	Credits	Teaching hours	Marks		
	Theory				**Internal Assessment**	**Semester Exam**	**Total**
	MHA 108 T	Hospital Planning and Management	4	4	20	80	100
	MHA 109 T	Organizational Behaviour	2	2	10	40	50
	MHA 110 T	Managerial Communication	2	2	10	40	50
	MHA 111 T	Accounting & Costing	2	2	10	40	50
	MHA 112 T	Management Information System	2	2	10	40	50
	MHA 113 T	Human Resource Management	2	2	10	40	50
	MHA 114 T	Project Management	2	2	10	40	50
	CC 001 T	Research Methodology & Biostatistics (Core Course)	4	4	20	80	100
	Practical						
	MHA 115 P	Hospital Project	8	16	20	80	100
	CC 001 P	Research Methodology & Biostatistics (Core Course)	2	4	10	40	50

OUTLINE OF COURSE CURRICULUM

Master in Public Health (MPH)

Semester II

Code No.	Core Subjects	Credits/Week					Hrs/Semester					Marks		
		Lecture (L)	Tutorial (T)	Practical (P)	Clinical Posing/ Rotation	Total Credits (C)	Lecture (L)	Tutorial (T)	Practical (P)	Clinical Posing/ Rotation	Total hrs.	Internal Assessment	Semester Exam	Total
Theory														
MPH 106 L	Health Management: Principles and Practices	4	-	-	-	4	60	-	-	-	60	20	80	100
MPH 107 L	Reproductive, Maternal Health, Child Health and Adolescent Health	3	-	-	-	3	45	-	-	-	45	20	80	100
MPH 108 L	Communicable and Non-Communicable Diseases & Nutrition	3	-	-	-	3	45	-	-	-	45	20	80	100
MPH 109 L	Practice of Public Health (Advanced) – Rural Outreach	-	-	-	24	8	-	-	-	360	360	50	-	50
CC 001 L	Research Methodology & Biostatistics (Core Course)	4	-	-	-	4	60	-	-	-	60	20	80	100
Practical														
CC 001 P	Research Methodology & Biostatistics (Core Course)	-	-	4	-	2	-	-	60	-	60	10	40	50
Total		14	0	4	24	24	210	0	60	360	630	140	360	500

OUTLINE OF COURSE CURRICULUM

M.Optometry

Semester II

Code No.	Core Subjects	Credits/Week					Hrs/Semester					Marks		
		Lecture (L)	Tutorial (T)	Practical (P)	Clinical Posing/ Rotation	Total Credits (C)	Lecture (L)	Tutorial (T)	Practical (P)	Clinical Posing/ Rotation	Total hrs.	Internal Assessment	Semester Exam	Total
Theory														
MOPTOM 105 L	Ocular Diseases and Diagnostics II	3	-	-	-	**3**	45	-	-	-	**45**	20	80	**100**
MOPTOM 106 L	Advanced Contact Lenses I	2	-	-	-	**2**	30	-	-	-	**30**	20	80	**100**
MOPTOM 107 L	Binocular Vision and Pediatric Optometry	4	-	-	-	**4**	60	-	-	-	**60**	20	80	**100**
MOPTOM 108 L	Low vision and Geriatric Optometry	2	-	-	-	**2**	30	-	-	-	**30**	20	80	**100**
MOPTOM 109 CP	Optometry Directed Clinical Education-II	-	-	-	15	**5**	-	-	-	**225**	**225**	50	-	**50**
CC 001 L	Research Methodology & Biostatistics (Core Course)	4	-	-	-	**4**	60	-	-	-	**60**	20	80	**100**
Practical														
MOPTOM 105 P	Ocular Diseases and Diagnostics II	-	-	2	-	1	-	-	30	-	**30**	50	-	**50**
MOPTOM 106 P	Advanced Contact Lenses I	-	-	2	-	1	-	-	30	-	**30**	50	-	**50**
MOPTOM 107 L	Binocular Vision and Pediatric Optometry	-	-	4	-	**2**	-	-	60	-	**60**	10	40	**50**
MOPTOM 108 P	Low vision and Geriatric Optometry	-	-	4	-	**2**	-	-	60	-	**60**	10	40	**50**
CC 001 P	Research Methodology & Biostatistics (Core Course)	-	-	4	-	**2**	-	-	60	-	**60**	10	40	**50**
Core Elective Course														
CEC 001 L	Basics of Clinical Skill Learning	3	-	-	-	**3**	45	-	-	-	**45**	100	-	**100**
CEC 002 L	Hospital Operation Management													
Total		**18**	**0**	**16**	**15**	**31**	**270**	**0**	**240**	**225**	**735**	**380**	**520**	**900**

Semester I							
	Syllabus Ref. No.	**Subject**	**Credits**	**Teaching hours**	**Marks**		
	Theory				**Internal Assessment**	**Semester Exam**	**Total**
	BT 101 T	Cell Biology	4	4	20	80	100
	BT 102 T	Immunology &Immunotechnology	4	4	20	80	100
	BT 103 T	Analytical Instrumentation	4	4	20	80	100
	BT 104 T	Basic Biochemistry & Biomolecules ▲ (Multidisciplinary/Interdisciplinary)	4	4	20	80	100
	Practical						
	BT 101 P	Cell Biology	2	4	10	40	50
	BT 102 P	Immunology &Immunotechnology	2	4	10	40	50
	BT 103 P	Analytical Instrumentation	2	4	10	40	50
	BT 104 P	Basic Biochemistry & Biomolecules ▲ (Multidisciplinary/Interdisciplinary)	2	4	10	40	50
		Total	24	32	120	480	600

Semester II							
	Syllabus Ref. No.	**Subject**	**Credits**	**Teaching hours**	**Marks**		
	Theory				**Internal Assessment**	**Semester Exam**	**Total**
	BT 105 T	Molecular Biology & Genomics	4	4	20	80	100
	BT 106 T	Recombinant DNA Technology	4	4	20	80	100
	BT 107 T	Bioinformatics	4	4	20	80	100
	CC 001 T	Research Methodology & Biostatistics (Core Course)	4	4	20	80	100
	Practical						
	BT 105 P	Molecular Biology & Genomics	2	4	10	40	50
	BT 106 P	Recombinant DNA Technology	2	4	10	40	50
	BT 107 P	Bioinformatics	2	4	10	40	50
	CC 001 P	Research Methodology & Biostatistics (Core Course)	2	4	10	40	50
		Total	24	32	120	480	600

For non CBCS Post graduation Program (same for all courses)

MODULE 4: BIOSTATISTICS & COMPUTER APPLICATIONS (THEORY)

UNIT	TOPIC
1	*Definitions and scope of Biostatistics* : Variable in biology, collection, classification and tabulation of data. Graphical and diagrammatic representation, histogram, frequency polygon, frequency curve.
2	*Descriptive statistics :* Measures of central tendency – Mean (arithmetic, harmonic and Geometric), Median and Mode. Measures of dispersion – Standard deviation and Standard errors
3.	*Basic idea of significance test.* Statistical hypotheses, types of errors, level of Significance, Student's t, chi-square, goodness of fit and F tests. Correlation and Regression Analysis- concepts and applications. Probability : Basic concepts, Basic theorems of probability- addition and multiplication theorems Conditional probability, Probability distribution-definition & applications
4.	Computational Techniques for understating above three units like Met Lab, SPSS and SAS
5	Research Methodology & Scientific Writing: Building the foundation of research, Choosing appropriate subject, Narrowing subject into topic, Writing thesis statements Managing the project; How to allow time efficiently, Creating a Schedule Researching the material (Making bibliography cards), Summarizing research material, Documentation style (DPA & MS), Preparing "Works Cited", "References" pages, Writing thesis Writing a research paper

BIOSTATISTICS PRACTICALS

1	Use of INTERNET and WWW
2	Medline, Medline Search
3	Usage of statistics for data analysis
4	To develop and design case studies according to Medical Cases with the help of statistical methods. (Minimum 10)

Reference Books:

1. D. H. Sanders Computers Today. Mc. Graw-Hill. Book Company.
2. J. Peek, G. Todino& J. Straug Learning the unix operating system. O'Reilly Associates.
3. S. C. Gupta. Fundamentals of Statistics. Himalaya Pub. House.
4. J. Medhi. Statistical Methods An introductory text. New Age International (P) Ltd. Publishers.
5. P. S. S. SudarRao& J. Richard. An introduction to biostatistics. Prentice Hall of India. N. Delhi.
6. Fundamentals of mathematical Statistics.
7. Fundamentals of Applied l Statistics.
8. Statistical Method.

Name of the Programme	**M. SC MEDICAL BIOTECHNOLOGY**
Course Code	**CC 001 T**
Name of the Course	**RESEARCH METHODOLOGY & BIOSTATISTICS (CORE COURSE)**

Teaching Objective	The course is intended to give an overview of research and statistical models commonly used in medical and bio-medical sciences. The goal is to impart an intuitive understanding and working knowledge of research designs and statistical analysis. The strategy would be to simplify, analyse the treatment of statistical inference and to focus primarily on how to specify and interpret the outcome of research.
Learning Outcomes	Student will be able to understand develop statistical models, research designs with the understating of background theory of various commonly used statistical techniques as well as analysis interpretation & reporting of results and use of statistical software.

Sr. No.	**Topics**	**Hours allotted 60hrs**
A	**Research Methodology:**	
1	Scientific Methods of Research: Definition of Research, Assumptions, Operations and Aims of Scientific Research. Research Process, Significance and Criteria of Good Research , Research Methods versus Methodology, Different Steps in Writing Report, Technique of Interpretation, Precaution in interpretation, Significance of Report Writing, Layout of the Research Report	5
2	Research Designs: Observational Studies: Descriptive, explanatory, and exploratory, Experimental Studies: Pre-test design, post-test design, Follow-up or longitudinal design, Cohort Studies, Case Control Studies, Cross sectional studies, Intervention studies, Panel Studies.	5
3	Sampling Designs: Census and Sample Survey, Implications of a Sample Design, Steps in Sampling Design Criteria of Selecting a Sampling Procedure, Characteristics of a Good Sample Design, Different Types of Sample Designs (Probability sampling and non probability sampling), How to Select a Random Sample?, Systematic sampling, Stratified sampling, Cluster sampling, Area sampling, Multi-stage sampling, Sampling with probability proportional to size, Sequential sampling.	5
4	Measurement in research: Measurement Scales, Sources of Error in Measurement, Tests of Sound Measurement, Technique of Developing Measurement Tools, Scaling Meaning of Scaling, Scale Classification Bases, Important Scaling Techniques, Scale Construction Techniques, Possible sources of error in measurement, Tests of sound measurement	5

5	Methods of Data Collection: Types of data, Collection of Primary Data, Observation Method, Interview Method, Collection of Primary Data	5
6	Sampling Fundamentals : Need and importance for Sampling, Central Limit Theorem, Sampling Theory, Concept of Standard Error, Estimation, Estimating the Population Mean Estimating Population Proportion, Sample Size and its Determination, Determination of Sample Size through the Approach Based on Precision Rate and Confidence Level.	5
B	**Biostatistics**	
7	Data Presentation: Types of numerical data: Nominal, Ordinal, Ranked, Discrete and continuous. Tables: Frequency distributions, Relative frequency, Graph: Bar charts, Histograms, Frequency polygons, one way scatter plots, Box plots, two way scatter plots, line graphs	3
8	Measures of Central Tendency and Dispersion: Mean, Median, Mode Range, Inter quartile range, variance and Standard Deviation, Coefficient of variation, grouped mean and grouped standard deviation (including merits and demerits).	3
9	Testing of Hypotheses: Definition, Basic Concepts, Procedure for Hypothesis Testing, Measuring the Power of a Hypothesis Test, Normal distribution, data transformation Important Parametric Tests, Hypothesis Testing of Means, Hypothesis Testing for Differences between Means, Hypothesis Testing for Comparing Two Related Samples, Hypothesis Testing of Proportions, Hypothesis Testing for Difference between Proportions, Hypothesis Testing for Comparing a Variance to Some Hypothesized Population Variance, Testing the Equality of Variances of Two Normal Populations.	6
10	Chi-square Test: Chi-square as a Non-parametric Test, Conditions for the Application Chi-square test, Steps Involved in Applying Chi-square Test, Alternative Formula, Yates' Correction, and Coefficient by Contingency.	2
11	Measures of Relationship: Need and meaning, Correlation and Simple Regression Analysis	2
12	Analysis of Variance and Covariance: Analysis of Variance (ANOVA):Concept and technique of ANOVA, One-way ANOVA, Two-way ANOVA, ANOVA in Latin-Square Design Analysis of Co-variance (ANOCOVA), ANOCOVA Technique.	4
13	Nonparametric or Distribution-free Tests: Important Nonparametric or Distribution-free Test Sign test, Wilcoxon signed-Rank Test, Wilcoxon Rank Sum Test: Mann-Whitney U test Kruskal Walli's test, Friedman's test, and Spearman Correlation test.	3
14	Vital Health Statistics: Measurement of Population: rate, crude rate, specific rate, Measurement of fertility: specific fertility rate, Total fertility rate, Reproduction rate, Gross Reproduction Rate, Net Reproduction Rate, Measures related to mortality: Crude Death Rate (CDR), Age-specific death Rate, Infant and child mortality rate, Measures related to morbidity.	4
15	Computer Application Use of Computer in data analysis and research, Use of Software and Statistical package. Introduction to SPSS. Importing data from excel, access, tab and comma separated files. Entering data, labeling a variable, coding and recoding a categorical and continuous variable. Converting data from string to numeric variables, sorting & filtering, merging, appending data sets. Frequencies, descriptive statistics, cross tabulations. Diagrammatic presentation include histogram, bar chart, pie chart, scatter diagram, box plot, line chart. Parametric test of hypothesis-one sample, Independent and paired sample t test, one way ANOVA& post HOC test. Testing for normality, Chi-square test with measures of association. Pearson correlation. Non parametric test.	3

CC 001 P – Research Methodology & Biostatistics

Sr. No.	Topics	Hours allotted 60hrs
A	**Research Methodology**	
1	Sampling Designs	**4 hrs**
2	Measurement in research	**5 hrs**
3	Methods of Data Collection	**3 hrs**
4	Sampling Fundamentals	**3 hrs**
B	**Biostatistics**	
5	Data Presentation	**4 hrs**
6	Measures of Central Tendency and Dispersion	**4 hrs**
7	Testing of Hypotheses	**12 hrs**
8	Chi-square Test	**2 hrs**
9	Measures of Relationship	**3 hrs**
10	Analysis of Variance and Covariance	**4 hrs**
11	Nonparametric or Distribution-free Tests	**4 hrs**
12	Vital Health Statistics: Measurement of Population	**6 hrs**
13	Computer Application Using Statistical Software	**6 hrs**

File No. EC/19/000122

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Ethics Committee Registration Division)

सत्यमेव जयते

FDA Bhawan, Kotla Road,
New Delhi - 110002, India
Dated: 08-Aug-2019

To

The Chairman
Institutional Ethics Committee
MGMs Dental College and Hospital
Junction of NH-4 and Sion Panvel Highway Sector - 1,
Kamothe Navi Mumbai Raigad Maharashtra - 410209
India

Subject: Ethics Committee Re-Registration No. ECR/786/Inst/MH/2015/RR-18 issued under New Drugs and Clinical Trials Rules, 2019.

Sir/Madam,

Please refer to your application no. EC/RENEW/INST/2019/2956 dated 09-Apr-2019 submitted to this Directorate for the Re-Registration of Ethics Committee.

Please find enclosed registration of the Ethics Committee in Form CT-02 vide Registration No. ECR/786/Inst/MH/2015/RR-18. The said registration is subject to the conditions as mentioned below:-

Yours faithfully

S ESWARA REDDY

Digitally signed by S ESWARA REDDY
Date: 2019.08.09 13:39:41 +05'30'

(Dr. S. Eswara Reddy)
Drugs Controller General (I) &
Central Licensing Authority

Conditions of Registration

1. The registration is valid from 09-Apr-2019 to 08-Apr-2024, unless suspended or cancelled by the Central Licencing Authority.

2. This certificate is issued to you on the basis of declaration/submission made by you.

3. Composition of the said Ethics Committee is as per the Annexure.

4. No clinical trial or bioavailability or bioequivalence protocol and related documents shall be reviewed by an Ethics Committee in meeting unless at least five of its members as detailed below are present in the meeting, namely:-

(i) medical scientist (preferably a pharmacologist);
(ii) clinician;
(iii) legal expert;
(iv) social scientist or representative of non-governmental voluntary agency or philosopher or ethicist or theologian or a similar person;
(v) lay person.

5. The Ethics Committee shall have a minimum of seven and maximum of fifteen members from medical, non-medical, scientific and non-scientific areas with at least,

(i) one lay person;

(ii) one woman member;

(iii) one legal expert;

(iv) one independent member from any other related field such as social scientist or representative of non-governmental voluntary agency or philosopher or ethicist or theologian.

6. One member of the Ethics Committee who is not affiliated with the institute or organization shall be the Chairperson, and shall be appointed by such institute or organization and one member who is affiliated with the institute or organization shall be appointed as Member Secretary of the Ethics Committee by such Institute or organization.

7. The Ethics Committee shall consist of at least fifty percent of its members who are not affiliated with the institute or organization in which such committee is constituted.

8. The committee shall include at least one member whose primary area of interest or specialisation is non-scientific and at least one member who is independent of the institution.

9. The Ethics committee can have as its members, individuals from other Institutions or Communities, if required.

10. Members should be conversant with the provisions of New Drug and Clinical Trials Rules, 2019, Good Clinical Practice Guidelines for clinical trials in India and other regulatory requirements to safeguard the rights, safety and well-being of the trial subjects.

11. The members representing medical scientists and clinicians shall possess at least post graduate qualification in their respective area of specialization, adequate experience in the respective fields and requisite knowledge and clarity about their role and responsibility as committee members.

12. As far as possible, based on the requirement of research area such as HIV, Genetic disorder, etc., specific patient group may also be represented in the Ethics Committee.

13. The Ethics Committee may associate such experts who are not its members, in its deliberations but such experts shall not have voting rights, if any

14. No member of an Ethics Committee, having a conflict of interest, shall be involved in the oversight of the Clinical trial or bioavailability or bioequivalence study protocol being reviewed by it and all members shall sign a declaration to the effect that there is no conflict of interest.

15. While considering an application which involves a conflict of interest of any member of the Ethics Committee, such member may voluntarily withdraw from the Ethics Committee review meeting, by expressing the same in writing, to the Chairperson. The details in respect of the conflict of interest of the member shall be duly recorded in the minutes of the meetings of the Ethics Committee.

16. Any change in the membership or the constitution of the registered Ethics Committee shall be intimated in writing to the Central Licencing Authority within thirty working days.

17. The Ethics Committee shall review and accord approval to a Clinical trial, Bioavailability and Bioequivalence study protocol and other related documents, as the case may be, in the format specified in clause (B) of Table 1 of the Third Schedule of New Drugs and Clinical Trials Rules, 2019 and oversee the conduct of clinical trial to safeguard the rights, safety and wellbeing of trial subjects in accordance with these rules, Good Clinical Practices Guidelines and other applicable regulations.

18. Where a clinical trial site does not have its own Ethics Committee, clinical trial at that site may be initiated after obtaining approval of the protocol from the Ethics Committee of another trial site; or an independent Ethics Committee for clinical trial constituted in accordance with the provisions of rule 7: provided that the approving Ethics Committee for clinical trial shall in such case be responsible for the study at the trial site or the centre, as the case may be: provided further that the approving Ethics Committee and the clinical trial site or the bioavailability and bioequivalence centre, as the case may be, shall be located within the same city or within a radius of 50 kms of the clinical trial site.

19. Where a Bioavailability or Bioequivalence study centre does not have its own Ethics Committee, bioavailability or bioequivalence study at that site may be initiated after obtaining approval of the

from the Ethics Committee registered under rule 8:Provided that the approving Ethics Committee shall in such case be responsible for the study at the centre:Provided further that both the approving Ethics Committee and the centre, shall be located within the same city or within a radius of 50 kms of the bioavailability or bioequivalence study centre.

20. Ethics committee shall indicate the reasons that weighed with it while rejecting or asking for a change or notification in the protocol in writing and a copy of such reasons shall also be made available to the Central Licencing Authority.

21. Ethics committee shall make, at appropriate intervals, an on-going review of the trials for which they have reviewed the protocol. Such a review may be based on the periodic study progress reports furnished by the investigators or monitoring and internal audit reports furnished by the sponsor or by visiting the study sites.

22. Where any serious adverse event occurs to a trial subject or to study subject during clinical trial or bioavailability or bioequivalence study, the Ethics Committee shall analyse the relevant documents pertaining to such event and forward its report to the Central Licencing Authority and comply with the provisions of Chapter VI, New Drugs and Clinical Trials Rules, 2019.

23. The Ethics committee shall undertake proper causality assessment of SAE's with the help of subject experts wherever required, for deciding relatedness and quantum of compensation, as per condition no (22) mentioned above.

24. Where at any stage of a clinical trial, it comes to a conclusion that the trial is likely to compromise the right, safety or wellbeing of the trial subject, the Ethics committee may order discontinuation or suspension of the clinical trial and the same shall be intimated to the head of the institution conducting clinical trial and the Central Licencing Authority.

25. Ethics committee shall comply with the requirements or conditions in addition to the requirements specified under the Drugs & Cosmetics Act, 1940 and New Drugs and Clinical Trials Rues, 2019, as may be specified by the Central Licencing Authority with the approval of the Central Government, to safeguard the rights of clinical trial subject or bioavailability or bioequivalence study subject.

26. Ethics Committee shall review and approve the suitability of the investigator and trial site for the proposed trial.

27. The Ethics Committee shall maintain data, record, registers and other documents related to the functioning and review of clinical trial or bioavailability study or bioequivalence study, as the case may be, for a period of five years after completion of such clinical trial.

28. Funding mechanism for the Ethics Committee to support their operations should be designed and approved to ensure that the committee and their members have no financial incentive to approve or reject particular study.

29. SOP's for funding of the Ethics committee in order to support their operations must be maintained. The records of income & expenditure of Ethics Committee shall be maintained for review and inspection.

30. The Chairman of Ethics Committee shall enter into MOU with head of institution, that necessary support and facilities and independence will be provided to Ethics Committee and their records will be maintained.

31. The Ethics Committee shall allow any officer authorized by the Central Licencing Authority to enter, with or without prior notice, to inspect the premises, any record, or any documents related to clinical trial, furnish information to any query raised by such authorized person, in relation to the conduct of clinical trial and to verify compliance with the requirements of these rules, Good Clinical Practices Guidelines and other applicable regulations for safeguarding the rights, safety and well-being of trial subjects.

32. Where Central Licencing Authority is of the opinion that Ethics Committee fails to comply with any provision of the Drugs and Cosmetics Act, 1940and New Drugs & Clinical Trials Rules, 2019, it may issue show cause notice to such Ethics Committee specifying therein such non-compliances and the period within which reply shall be furnished by such Ethics Committee. After consideration of the facts and reply given by the Ethics Committee, the Central Licencing Authority may take one or more actions specified under provision of Rule 14, Chapter III of New Drugs and Clinical Trials Rules, 2019.

File No. EC/19/000122

सत्यमेव जयते

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Ethics Committee Registration Division)

FDA Bhawan, Kotla Road,
New Delhi - 110002, India
Dated: 08-Aug-2019

Composition of the Ethics Committee:-

Sr. No.	Name of Member	Qualification	Role/Designation in Ethics Committee
1	Mr. Rita Abbi	BSc (MSc)	Member
2	Dr. Nithya Eldho Varghese	B. COM (M.Com)	Lay Person
3	Dr. Srivalli Natarajan	BDS (Oral and Maxillofacial Surgery)	Member Secretary
4	Dr. Shilpa Patel	BDS (Oral Pathology)	Basic Medical Scientist
5	Dr. Ashvini Padhye	BDS (Periodontics)	Clinician
6	Dr. Ravindranath V K	BDS (Orthodontics)	Clinician
7	Mr. Rajesh Goel	MBBS (MD in Preventive and Social Medicine)	Clinician
8	Mr. Karuna Akshay Malviya	LLB (Ph.D. in Law)	Legal Expert
9	Mr. Rupali Gujar	BA (MS in Psychotherapy and Counselling)	Social Scientist
10	Dr. Deepak-Kumar Govindrao Langade	MBBS (MD in Pharmacology)	Chair Person
11	Mr. Jyoti Nadgere	BDS (Prosthodontics)	Clinician
12	Dr. Sumanthini M V	BDS (MDS)	Clinician

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Date: 2019.08.09 13:39:59 +05'30'

(Dr. S. Eswara Reddy)
Drugs Controller General (I) &
Central Licensing Authority