

SANTOSH

Deemed to be University



3.4.1 The Institution has a stated Code of Ethics for research, the implementation of which is ensured by the following:

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Course content of research ethics and details of Members of ethical committee

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OFFICE OF DEAN RESEARCH

Core Paper-I : Research Methodology, Biostatistics and Computer Basics

Unit-I Research problem design

Research problem and design: Meaning and objective of research, motivation in research, types of research, significance of research, research and scientific methodology, importance and criteria of good research, Formation of research problem, sources of research problem, meaning of research design, features of good design, important concepts of relating research design, different basic designs.

Unit-II Literature Searching and Report Writing

a) Literature Searching: On-line searching, different Database, Searching research articles, Citation Index, Impact Factor, H-index,

b) Writing scientific report: Structure and components of research report, revision and refining writing project proposal, Paper writing for International Journals, paper submission procedure, Conference oral and poster presentation, preparation of slides, pictures, graphs and citation styles. c) Thesis writing: parts of thesis, the preliminary pages and the introduction, the literature review, Methodology, data analysis, and conclusions.

**Unit III: Statistical analysis, Computer Basics and Computational Tool- SPSS
Theory and Practical**

Introduction of Statistics, Data, Data Collection, Sampling techniques

Measures of Central Tendency: Mean Median and Mode (Merits and Demerits).

Measures of Dispersion: Range, Inter-quartile, Quartile Deviation, Mean Deviation, Standard Deviation, Skewness & Kurtosis,

Graphical Presentation

Statistical Hypothesis and Test of significance, Procedure for testing of hypothesis, determining levels of significance & P-value, Type I and II errors

Test for relationship: Chi square test and its application, Correlation, Regression

Test for Comparison: Z-test, t-test, ANOVA (one-way, two-way, repeated measure)

Non-parametric statistical techniques: Mann Whitney test, Wilcoxon test, Kruskal Wallis & Friedman test

Introduction to Computer and its generations, hardware, software-system software and application software, computer networks and internet, Computer hardware, motherboard, power supply and drive bays, CPU, Memory Cooling components, Operating systems, application software-word processing concept, spread sheet concept, database concept, presentation graphic concepts, graphics and multimedia concepts

Computational Tool- SPSS

Data files: Basic descriptive statistics: descriptive, frequencies, explore, crosstabs; Graphs: histogram, error bar, box-plot, bar chart, scatter etc; Reading data into SPSS data files from outer sources: excel files & text files; Advanced statistical procedures such as: t-test, Chi-square, regression, correlation etc.

MS-Excel: Data entry, prepare master chart, formula use in data,

MS-PowerPoint: Creating slides, applying transitions and sound effects, setting up slide shows, Animation.

Unit IV: Introduction to Intellectual Property Right, Ethics in medical research & Plagiarism (IPR)

Research Ecosystem, Incubation centre and start-ups, Origin and Genesis of IPR, The Ways and Means of Creation of IPR, Sources of IPR-Custom, Treaties, General Principles of Law, Patents - Basic aspects, Trade Marks - Basic principles, Copy Right - Basic Issues and Industrial Designs and Geographical Indications- Basic aspects

Introduction to Bioethics & History of Principles of Ethics, Equality, Equity and Justice, Human dignity & Human rights, Autonomy and Individual Responsibility, Informed consent, Privacy and confidentiality, Research ethics and Scientific Misconduct, Public Health Bioethics, ethical review procedures, Institutional ethical committee, its organization and functions, General principles on ethical considerations involving human subjects as per ICMR Guidelines, Specific principles for clinical evaluation of drugs/devices/diagnosis/vaccines/herbal remedies as per CDSCO Guidelines, specific principles in human genetic research, Ethical guidelines for experimental animals for specific research.

Plagiarism: definitions and types of Plagiarism, causes of Plagiarism, importance of Plagiarism, ways to avoid Plagiarism, common knowledge, paraphrasing and citations and references, consequences of Plagiarism, Role of educator, Plagiarism checker software, cases of plagiary

CORE Paper II :Advanced Specialization in the subject area (8 credits), 60 hours where every research scholar is required to do a course in Recent Advances in his/her research area under the concerned supervisor, the syllabus for the same is provided by concerned department after due approval by RAC

Paper III:

Introduction to Intellectual Property Right, Ethics in medical research & Plagiarism (IPR)

Unit I: Introduction to Intellectual Property Right

Research Ecosystem, Incubation center and start-ups, Origin and Genesis of IPR, The Ways and Means of Creation of IPR, Sources of IPR-Custom, Treaties, General Principles of Law, Patents - Basic aspects, Trade Marks - Basic principles, Copy Right - Basic Issues and Industrial Designs and Geographical Indications- Basic aspects

Unit II: Ethics in medical research & Plagiarism


Introduction to Bioethics & History of Principles of Ethics ,Equality, Equity and Justice, Human dignity & Human rights, Autonomy and Individual Responsibility, Informed consent, Privacy and confidentiality, Research ethics and Scientific Misconduct, Public Health Bioethics, ethical review procedures, Institutional ethical committee, its organization and functions, General principles on ethical considerations involving human subjects as per ICMR Guidelines, Specific principles for clinical evaluation of drugs/devices/diagnosis/vaccines/herbal remedies as per CDSCO Guidelines, specific principles in human genetic research, Ethical guidelines for experimental animals for specific research.

Plagiarism: definitions and types of Plagiarism, causes of Plagiarism, importance of Plagiarism, ways to avoid Plagiarism, common knowledge, paraphrasing and citations and references, consequences of Plagiarism, Role of educator, Plagiarism checker software, cases of plagiary



NOTIFICATION

This Ethics committee is available by letter F No: SU/N/2022/853 Dated 25/04/2022. The existing members of ethics committee are since 25th April 2022. The details are as follows:-

**SANTOSH**
Deemed to be University
(Established u/s 3 of the UGC Act, 1956)

F. No: SU/N/2022/853 Dated: 25/04/2022

NOTIFICATION


Subject: Re-constitution of the Ethics Committee – Medical & Dental Courses.

References:

1.	F. No. SU/N/2012/254	dated:	23/05/2012
2.	F. No. SU/N/2014/437	dated:	30/04/2014
3.	F. No. SU/N/2015/1150	dated:	07/10/2015
4.	F. No. SU/N/2016/378,	dated:	04/03/2016
5.	F. No. SU/N/2019/1262,	dated:	29/08/2019
6.	F. No: SU/N/2020/1229,	dated:	17/07/2020
7.	F. No: SU/N/2020/1669,	dated:	07/09/2020
8.	F. No: SU/N/2020/2375,	dated:	07/12/2020
9.	F. No: SU/N/2021/656,	dated:	10/03/2021
10.	F. No: SU/N/2021/1213,	dated:	24/05/2021

As per the Rule 46 of the **Santosh Deemed to be University** Rules and Bylaws – 2010, **the Ethics Committee of Medical and Dental Courses** of the Santosh Medical College & Hospital and Santosh Dental College & Hospital, Ghaziabad has been re-constituted as under: -

1. Dr. Bal Krishana, Professor of Physiology Maulana Azad Medical College Bahadur Shah Zafar Marg New Delhi	-	Chairperson
Social Scientist:		
2. Dr. Jyoti Batra, Prof of Biochemistry Santosh Medical College & Hospital Ghaziabad	-	Member
3. Dr. Rani Srivastava, Ph.D. Professor of Psychology Santosh Medical College & Hospital Ghaziabad	-	Member
4. Ms. Anita Tyagi Psychologist Santosh Medical College Hospital Ghaziabad	-	Member


REGISTRAR

Basic Medical Scientist

5. Dr. Saktibala Dutta,
Professor & HOD of Pharmacology
Santosh Medical College & Hospital
Ghaziabad - Member
6. Dr. Preeti Sharma,
Professor of Biochemistry
Santosh Medical College & Hospital
Ghaziabad - Member

Clinicians:

7. Dr. Kailash Chander Aggarwal
Professor of Paediatrics
Santosh Medical College & Hospital
Ghaziabad - Member
8. Dr. Shalabh Gupta,
Professor & HOD of Surgery
Santosh Medical College & Hospital
Ghaziabad - Member
9. Dr. Shivani Bansal,
Professor of Medicine
Santosh Medical College & Hospital
Ghaziabad - Member

Scientific Member

10. Dr. Dakshina Bisht,
Prof of Microbiology
Santosh Medical College & Hospital - Member
11. Dr. Sivanesan Dhandaythapani
Deputy Dean Research
Santosh Deemed to be University
Ghaziabad
NCR Delhi - Member

Legal Expert

12. Shri Satyaketu Singh,
No.21, Gandhi Nagar
Ghaziabad - Member
13. Shri. Raja Rajan
H-16, Pratap Vihar
Ghaziabad - 201 009



Other External Members

14. Mrs. Sangita Kumar
Philosopher - Member
Tapapsya Corpheights
Tower A, Ko create, 3rd Floor
Sector -126, Nodia - 201 301
15. Dr. Manoj Kumar Gupta - Member
Veterinary Doctor
J- Block, Santosh Nagar, Pratap Vihar,
Ghaziabad - 201 009.

Lay Person:

16. Sister Gracelin - Member
NGO:
"Jeevan Dhara"
Mariam Nagar,, Ghaziabad

Other Supporting Staff

17. Shri D.Kannan - Member
H-18, Santosh Nagar, Ghaziabad - 201 009.

Special Invitees:

18. Dr. Alka Agrawal - Member
Dean
Santosh Medical College & Hospital, Ghaziabad
19. Dr. Akshay Bhargava - Member
Dean
Santosh Dental College & Hospital, Ghaziabad
20. Dr. Rajiv Ahluwalia - Member
Vice Dean
Santosh Dental College & Hospital, Ghaziabad
21. Dr. Alpana Agrawal
Registrar - Member Secretary



1. TENURE OF THE MEMBERSHIP:

- [i] The tenure of all the Members, shall be for two years from the date of issue of this Notification or till such time they hold the position through which they represent whichever is earlier. The Members shall not be eligible further unless everyone has completed one full term or if he / she accepts any appointment in other College / University or if he / she does not attend three consecutive meetings of the Ethics Committee without proper leave of absence in writing to the Chairperson, he / she ceases to be a Member of the Ethics Committee.
- [ii] Notwithstanding the above said term of office, the Vice Chancellor with the approval of the Board of Management and Chancellor shall have the power to terminate any Member[s], at any time before the expiry of his/ her term, without any notice, in case if found that he/ she is acting prejudicial to the interest of the University.

2. POWERS AND FUNCTIONS:

The Powers and functions of the Ethics Committee shall be issued separately.

3. This notification shall take effect from the date of issue.

Distribution: As above.

Copy to:

1. The Secretariat
2. Vice-Chancellor
3. Guard file

[DR. ALPANA AGRAWAL]



Profiling of Ethics Committee Members				
S.No.	Name of member	Qualification	Designation in Ethics Committee	Role in Ethics Committee
1	Dr. Bal Krishana, Professor of Physiology, Maulana Azad Medical College Bahadur Shah Zafar Marg New Delhi	M D Physiology	Chairperson	1)Conduct EC meetings and be accountable for independent and efficient functioning of the committee 2) Ensure active participation of all members(particularly nonaffiliated, nonmedical/non technical) in all discussion and deliberations 3) Ratify minutes of previous meetings. 4)Handle complaints against researchers, EC members, conflict of interest issues.
2	Dr. Rani Srivastav, Ph.D Professor of Psychology, Santosh Medical College & Hospital	PhD -Cl.Psycology	Social Scientist member	1. Ethical review of the proposal, ICD along with the translations. 2. Assess impact on community involvement, socio-cultural context, religious or philosophical context, if any 3. Serve as as patient/participant/societal/community representative and bring in ethical and societal concerns.
3	Ms. Anita Tyagi Psychologist Santosh Medical College & Hospital Ghaziabad	M.Phil PhD	Social Scientist member	1. Ethical review of the proposal, ICD along with the translations. 2. Assess impact on community involvement, socio-cultural context, religious or philosophical context, if any 3. Serve as as patient/participant/societal/community representative and bring in ethical and societal concerns.
4	Dr. Shaktibala Dutta, Professor & HOD of Pharmacology Santosh Medical College & Hospital Ghaziabad	MD -Pharmacology	Basic Medical Scientist Member	1. Scientific and ethical review with special emphasis on the intervention, benefit-risk analysis, research design, methodology and statistics, containing review process, SAE, protocol deviation, progress and completion report. 2. For Clinical trials, Pharmacologist to review the drug safety and Pharmacodynamics.
5	Dr. M. Meghachandra Singh, Director Professor of Community Medicine Maulana Azad Medical College New Delhi	MD -Community- medicine	Basic Medical Scientist Member	1. Scientific and ethical review with special emphasis on the intervention, benefit-risk analysis, research design, methodology and statistics, containing review process, SAE, protocol deviation, progress and completion report. 2. For Clinical trials, Pharmacologist to review the drug safety and Pharmacodynamics.
6	Dr. Sunita Kalra, Director Professor of Anatomy UCMS, New Delhi	MS -Anatomy	Basic Medical Scientist Member	1. Scientific and ethical review with special emphasis on the intervention, benefit-risk analysis, research design, methodology and statistics, containing review process, SAE, protocol deviation, progress and completion report. 2. For Clinical trials, Pharmacologist to review the drug safety and Pharmacodynamics.
7	Dr. Manoj Kumar Gupta, Veterinary Doctor J-Block, Santosh Nagar, Pratap Vihar, Ghaziabad - 201 009	BVMS	Basic Medical Scientist Member	1. Scientific and ethical review with special emphasis on the intervention, benefit-risk analysis, research design, methodology and statistics, containing review process, SAE, protocol deviation, progress and completion report. 2. For Clinical trials, Pharmacologist to review the drug safety and Pharmacodynamics.
8	Dr. Alka Agrawal, Dean - Medical and Professor of Paediatrics Santosh Medical College & Hospital Ghaziabad	MD Pediatrics	Clinicians Member	1. Scientific review of protocols including review of the intervention, benefit-risk analysis, research design, methodology, sample size, site of study and statistics. 2. Ongoing review of the protocol (SAE, protocol deviation or violation, progress and completion report). 3. Review medical care, facility and appropriateness of the principal investigator, provision for medical care management and compensation. 4. Thorough review of protocol, investigators brochure (if applicable) and all other protocol details and submitted documents.
9	Dr. Shalabh Gupta, Dean Academics and Professor of General Surgery Santosh Medical College & Hospital Ghaziabad	MS-Surgery	Clinicians Member	1. Scientific review of protocols including review of the intervention, benefit-risk analysis, research design, methodology, sample size, site of study and statistics. 2. Ongoing review of the protocol (SAE, protocol deviation or violation, progress and completion report). 3. Review medical care, facility and appropriateness of the principal investigator, provision for medical care management and compensation. 4. Thorough review of protocol, investigators brochure (if applicable) and all other protocol details and submitted documents.
10	Dr. Akshaya Bhargava, Dean Dental, Santosh Dental College and Hospital Ghaziabad	MDS- Prosthodontics	Clinicians Member	1. Scientific review of protocols including review of the intervention, benefit-risk analysis, research design, methodology, sample size, site of study and statistics. 2. Ongoing review of the protocol (SAE, protocol deviation or violation, progress and completion report). 3. Review medical care, facility and appropriateness of the principal investigator, provision for medical care management and compensation. 4. Thorough review of protocol, investigators brochure (if applicable) and all other protocol details and submitted documents.
11	Dr. Atul Gupta, Professor of Surgery GIMS, Greater Noida	MS-Surgery	Clinicians Member	1. Scientific review of protocols including review of the intervention, benefit-risk analysis, research design, methodology, sample size, site of study and statistics. 2. Ongoing review of the protocol (SAE, protocol deviation or violation, progress and completion report). 3. Review medical care, facility and appropriateness of the principal investigator, provision for medical care management and compensation. 4. Thorough review of protocol, investigators brochure (if applicable) and all other protocol details and submitted documents.

S.No.	Name of member	Qualification	Designation in Ethics Committee	Role in Ethics Committee
12	Mr. H.K. Tyagi, Advocate Room No. 663, Civil Court, Ghaziabad	LLB	Legal-Expert Member	<ol style="list-style-type: none"> 1. Ethical review of the proposal, ICD along with translations, MoU, Clinical Trial Agreement (CTA), regulatory approval, insurance document, other sire approvals, researcher's undertaking, protocol specific other permissions, such as, stem cell committee for stem cell research, HMSC for international collaboration, compliance with guidelines etc. 2. Interpret and inform EC members about new regulations if any.
13	Mr. Udit Tyagi, Assistant, Legal Cell Ghaziabad	LLB	Legal-Expert Member	<ol style="list-style-type: none"> 1. Ethical review of the proposal, ICD along with translations, MoU, Clinical Trial Agreement (CTA), regulatory approval, insurance document, other sire approvals, researcher's undertaking, protocol specific other permissions, such as, stem cell committee for stem cell research, HMSC for international collaboration, compliance with guidelines etc. 2. Interpret and inform EC members about new regulations if any.
14	Sister Gracelin NGO: "Jeevan Dhara" Mariam Nagar,, Ghaziabad	Graduate	Lay-Person member	<ol style="list-style-type: none"> 1. Ethical review of the proposal, ICD along with translation(s). 2. Evaluate benefits and risks from the participant's perspective and opine whether benefits justify the risks. 3. Serve as a patient/participant/community representative and bring in ethical and societal concerns. 4. Assess on societal aspects if any.
15	Dr. Jyoti Batra, Dean Research and Professor of Biochemistry Santosh Medical College & Hospital Ghaziabad	Ph D Biochemsitry	Member Secretary	<ol style="list-style-type: none"> 1. Organize an effective and efficient prodecure for receiving, preparing, circulating and maintaining each proposal for review. 2. Schedule EC meetings, prepare the agenda and minutes. 3. Organize EC documentation, communication and archiving 4. Ensure training of EC secretariat and EC members. 5. Enusre SOPs are updated as and when required 6. Ensure adherence of EC functinoning to the SOPs 7. Prepare for and respond to audits and inspections 8. Ensure completeness of documentation at the time of receipt and timely inclusion in agenda for EC review. 9. Assess the need for expedited review/exemption from review or full review. 10. Assess the need to obtain prior scientific review, invite independent consultant, patient or community representatives. 11. Ensure quorum during the meeting and record discussions and decisions



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