SGT UNIVERSITY
SHREE GURU GOBIND SINGH TRICENTENARY UNIVERSITY
(UGC Approved) Gurugram, Delhi-NCR
Budhera, Gurugram-Badli Road, Gurugram (Haryana) – 122505 Ph. : 0124-2278183, 2278184, 2278185

Sample course content of research ethics and details of members of the ethical committee

Note: Since all supporting documents for this metric exceed the upload limit of 5 MB, we are providing samples as shown below. If required, we will provide all/any supporting documents on request.

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Faculty of Allied Health Sciences

B.Sc. (Microbiology)

RESEARCH METHODOLOGY AND BIOSTATISTICS

Semester	**: V**
L T P – CREDITS	**: 3 1 – 4**
EXAMINATION	**: 60 MARKS**
INT ASSESSMENT	**: 40 MARKS**
TOTAL MARKS	**: 100 MARKS**
DURATION OF EXAM	**: 3 HOURS**

UNIT I

1. Introduction of research, Research ethics, Clinical issue in research, pilot survey, inclusion, and exclusion criteria.
2. Research problems (questionnaire and schedule), hypotheses and type of errors, review of literature, measurement of scaling, the principle of measurements of reliability and validity,
3. Sampling design, Criteria for good samples, data types, Descriptive and analytical research.

UNIT II

1. Introduction of Biostatistics
2. Meaning, definition, and characteristics of statistics
3. Parameters and Statistics, Sources of data
4. Descriptive and inferential statistics
5. Variables and their types

Unit III

Raw & array data, frequency distribution, Basic principles of graphical representation
Types of diagrams - histograms, frequency polygons, frequency polygon, cumulative frequency curve, Normal probability curve.
Measurement of Central Tendency: Definition and calculation of mean - ungrouped and grouped data, Meaning & calculation of median for ungrouped and grouped data, Meaning and calculation of mode, Comparison of the Mean, Median and mode, Measurement of Dispersion: Range, Quartile deviation, Mean Deviation & Standard Deviation. Concept of Correlation & Regression

Unit IV

Test of significance: t-test, F-test, Z-test, chi-square test & test of homogeneity (Normal distribution) Sampling methods, sampling and non-sampling errors.

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Faculty of Agricultural Sciences
M.Sc. (Agronomy)

AGRICULTURAL RESEARCH, RESEARCH ETHICS & RURAL DEVELOPMENT PROGRAMMES

Course Details: 11060306: AGRICULTURAL RESEARCH, RESEARCH ETHICS & RURAL DEVELOPMENT PROGRAMMES (e-Course) 1(1+0)

Objective

To enlighten the students about the organization and functioning of agricultural research systems at national and international levels, research ethics, and rural development programmes and policies of Government.

Theory

UNIT-I

History of agriculture in brief; Global agricultural research system: need, scope, opportunities; Role in promoting food security, reducing poverty and protecting the environment; National Agricultural Research Systems (NARS) and Regional Agricultural Research Institutions; Consultative Group on International Agricultural Research (CGIAR): International Agricultural Research Centres (IARC), partnership with NARS, role as a partner in the global agricultural research system, strengthening capacities at national and regional levels; International fellowships for scientific mobility.

UNIT-II

Research ethics: research integrity, research safety in laboratories, the welfare of animals used in research, computer ethics, standards and problems in research ethics.

UNIT-III

Concept and connotations of rural development, rural development policies and strategies. Rural development programmes: Community Development Programme, Intensive Agricultural District Programme, Special group – Area Specific Programme, Integrated Rural Development Programme (IRDP), Panchayati Raj Institutions, Co-operatives, Voluntary Agencies/Non-Governmental Organisations. Critical evaluation of rural development policies and programmes. Constraints in implementation of rural policies and programmes.

Suggested Readings:

- Bhalla GS & Singh G. 2001. Indian Agriculture - Four Decades of Development. Sage Publ. Punia MS. Manual on International Research and Research Ethics. CCS, Haryana Agricultural University, Hisar.
- Rao BSV. 2007. Rural Development Strategies and Role of Institutions -Issues, Innovations and Initiatives. Mittal Publ.
- Singh K. 1998. Rural Development - Principles, Policies and Management. Sage Publ.

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Faculty of Nursing

ETHICS IN RESEARCH

Course Code : MGECO1024
Duration : 60 Hours (Theory+Practical)
Total Marks : 100 Marks
Duration of Exam : 2 Hours
Placement : Open to final year students of all disciplines in SGT University
Venue : Faculty of Nursing, D Block
Method of Teaching: Blended mode (Online/Offline)

Course Description

This course is designed to enable students to develop an understanding of concepts of ethics in research to participate in need-based research studies in various settings keeping in mind all the ethical principles related to research.

Objective of the Course:

The aim of the course is to train students so as to equip them with Competencies to:
1. Describe various ethical aspects in research
2. Explain frameworks to propose solutions to ethical dilemmas.
3. Analyze the ethical issues around public health policies

Syllabus

Unit	Hours	Content	Teaching learning activities	Assessment method
1	3	Introduction to ethics and bioethics	Lecture & Discussion	MCQs and SAQs
2	2	The historical development of clinical and research ethics	Lecture & Discussion	MCQs and SAQs
3	15	The guidelines, codes and ethical principles in research	Lecture & Discussion	MCQs and SAQs
4	15	Ethical dilemmas and use of frameworks to propose solutions to ethical dilemmas	Lecture & Discussion	MCQs and SAQs
5	10	Ethical issues in the planning, conducting, analysing and reporting of research, and suggest methods to endure ethical conduct of research	Lecture & Discussion	MCQs and SAQs VIVA-VOCE

- The examination will be conducted by SGT university, Haryana.
- At the end of the course a test will be conducted to assess the performance of acquired knowledge and skills.
- In order to pass a candidate should obtain at least 50% marks respectively to test of this course. Certification:
- The certification will be awarded by the Faculty of Nursing, SGT university, Haryana at the end of the course.

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Faculty of Law

BA LL..B (Hons)

LEGAL METHODS AND RESEARCH METHODOLOGY

Trimester : XII
Course Code : 08011204

Course Objective:

This course will introduce the student to the academic study of various aspects of Legal methods and Legal Research. The students will learn about the various objectives and methods of Legal Education and will also learn about the various forms of Clinical Legal Education. The students will learn about the importance of Legal Research and will also be able to understand the forms of legal writing and their usage in the field of Law.

Detailed Curriculum

Unit – I

Introduction: Objectives of Legal Education, Method of Teaching: Lecture Method; Problem Method; Discussion method and Seminar Method.
Examination System and Problems in Evaluation: External and Internal assessment.

UNIT II

a. Student Participation in Law School Programmes: Organization of Seminars, Publication of journal and assessment of teachers Clinical Legal Education: Legal aid, Legal literacy, Legal survey and Law reform.
Research Methods: Socio-Legal Research, Doctrinal and Non-doctrinal, Relevance of empirical research, Induction and Deduction.

Unit – III

Legal Writing and Research

a. Legal materials – Case law
b. Statutes, Reports, Journals, Manuals, Digests, etc.
c. Importance of legal research
d. Techniques of Legal Research
e. Legal writings and citations

Course Outcomes:

After the completion of the course, the students will be able to:
1. Understand the various aspects of Legal Education and the various forms of imparting it.
2. Determine the importance of research in law and the importance of active participation in legal education.
3. Understand the various aspects related to legal writing and the various techniques of the same.

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Budhera, Gurugram

File No. EC/20/000268

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: 20-Aug-2020

To

The Chairman
Institutional Ethics Committee
SGT Medical College Hospital
Chandu, Budhera, Gurugram-Badli Road Gurugram
Gurugram Gurugram Haryana - 122505 India

Subject: Ethics Committee Registration No. ECR/1443/Inst/HR/2020 issued under New Drugs and Clinical Trials Rules, 2019.

Sir/Madam,

Please refer to your application no. EC/NEW/INST/2020/9188 dated 23-Jul-2020 submitted to this Directorate for the Registration of Ethics Committee.

Please find enclosed registration of the Ethics Committee in Form CT-02 vide Registration No. ECR/1443/Inst/HR/2020. The said registration is subject to the conditions as mentioned below:

Yours faithfully

VENUGOPAL GIRDHARILAL SOMANI

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Date: 2020.08.21 12:50:34 +05'30'

(Dr. V.G. Somani)
Drugs Controller General (I) &
Central Licensing Authority

Conditions of Registration

1. The registration is valid for a period of five years from the date of its issue, unless suspended or cancelled by the Central Licencing Authority. Provided that if the application for renewal of registration is received by the Central Licencing Authority ninety days prior to the date of expiry, the registration shall continue to be in force until an order is passed by the said authority on such application.

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;

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(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 inwriting 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.

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Budhera, Gurugram

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 protocol 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 50kms 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.

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File No. EC/20/000268

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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: 20-Aug-2020

Composition of the Ethics Committee:-

Sr. No.	Name of Member	Qualification	Role/Designation in Ethics Committee
1	Dr. Nudrat Jahan	BA (MA - Psychology)	Social Scientist
2	Ms. Shraddha Oberoi	LLB (Master of Laws (LL.M.))	Legal Expert
3	Ms. Yogita Jain	LLB (Master of Laws (LL.M.))	Legal Expert
4	Dr. Mohindar Pal Sawhney	MBBS (MD - Dermatology , Venereology & Leprosy)	Clinician
5	Dr. Kapil Hazarika	MBBS (MD - Pharmacology and Therapeutics)	Basic Medical Scientist
6	Dr. Nimarpreet Kaur	MBBS (MD/MS – Physiology)	Basic Medical Scientist
7	Dr. Sanjiv Kumar Bansal	MBBS (MD/MS- Biochemistry)	Basic Medical Scientist
8	Dr. Akanksha Yadav	BSc (MSc)	Scientific Member
9	Ms. Savitri Yadav	BA (Not Applicable)	Lay Person
10	Dr. Pradeep Garg	MBBS (Surgeon)	Chair Person
11	Dr. Bindoo Yadav	MBBS (Women Representative)	Clinician
12	Dr. Debasish Chattopadhya	MBBS (MIcrobiologist)	Member Secretary

VENUGOPAL GIRDHARILAL SOMANI

(Dr. V.G. Somani)
Drugs Controller General (I) &
Central Licensing Authority

Registrar
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Budhera, Gurugram

FORM CT-02

(See rules 8, 9, 10 and 14)

GRANT OF REGISTRATION OF ETHICS COMMITTEE RELATING TO CLINICAL TRIAL OR BIOAVAILABILITY AND BIOEQUIVALNENCE STUDY

Registration No. ECR/1443/Inst/HR/2020

The Central Licencing Authority hereby registers and permits Institutional Ethics Committee , SGT Medical College Hospital Chandu, Budhera, Gurugram-Badli Road Gurugram Gurugram Gurugram Haryana - 122505 Contact No.: 01242278183,84 Fax No.: 01242278151 to perform duties of ethics committee as specified in the New Drugs and Clinical Trials Rules, 2019.

2. The ethics committee shall observe the conditions of registration specified in Chapter III of the New Drugs and Clinical Trials Rules, 2019 and the Drugs and Cosmetics Act, 1940.

VENUGOPAL GIRDHARILA L SOMANI

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Date: 2020.08.21 12:51:03 +05'30'

Place : New Delhi

Date : 20-AUG-2020

Central Licencing Authority
Stamp

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

Registrar
SGT University
Budhera, Gurugram

File No. - EC/NEW/INST/2020/976

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Government of India
Ministry of Health & Family Welfare
Department of Health Research

2nd Floor, IRCS Building,
New Delhi - 110001
Dated : 06-Oct-2020

Provisional Certificate

Subject: Provisional registration of the Ethics Committee relating to Biomedical and Health Research with the National Ethics Committee Registry for Biomedical and Health Research (NECRBHR), Department of Health Research (DHR).

In exercise of the powers conferred by sub-rule (3) of rule 17 of the New Drugs and Clinical Trials Rules, 2019, the designated authority in the Department of Health Research, Ministry of Health & Family Welfare, hereby provisionally registers and permits the following Ethics Committee to perform the duties of ethics committee as specified in Chapter–IV of the New Drugs and Clinical Trials Rules, 2019.

Name :	**Institutional Ethics Committee**
Address :	**SGT Medical College Hospital, Chandu, Budhera, Gurugram-Badli road, Gurugram, Gurugram, Gurgaon, Haryana - 122505**
Contact No:	**01242278183,84**
Fax :	**01242278151**

2. The Ethics Committee shall observe all the conditions as stipulated in Chapter-IV of the aforesaid Rules, i.e., New Drugs and Clinical Trials Rules, 2019 and the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, specified by the Indian Council of Medical Research (ICMR).

3. The designated authority shall scrutinize the documents and information furnished with the application by the Ethics Committee for the issue of final registration certificate.

4. The above provisional registration shall be valid for a maximum period of two years from the date of its issue or till grant of final registration or rejection of provisional registration, whichever is earlier.

ANU NAGAR
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Date: 2020.10.06 17:04:21 +05'30'

(Anu Nagar)
Joint Secretary
Department of Health Research
Designated Authority

Registrar
SGT University
Budhera, Gurugram