

3.4.1.: Institute have and run Research Methodology with course on research ethics

Course on Ethics, GCP and GLP
SGPGIMS, Lucknow
30th Jan to 4th Feb. 2023
Venue: Telemedicine Auditorium

Date and Time	Topic	Speaker
30th Jan. 2023, Monday		
3-4pm	Why do we need Ethics guidelines in Medical Research?	Rakesh Aggarwal, JIPMER
4-5pm	Principles of Ethics	Vinita Agrawal
5-6pm	Group assignment on Case studies: Identify ethical issues	Facilitators: Vinita, Amita
31st Jan. 2023, Tuesday		
3-4pm	Risk-benefit assessment	Shagun Mishra
4-5pm	Informed Consent Documents	Amita Aggarwal
5-6pm	What to do about consent in these situations: child, illiterate, unconscious, epidemic?	Preeti Dabodghao Shagun Mishra
Home assignment (2hrs)	Group assignment: Prepare hand-written patient information document (English and Hindi)	
1st Feb. 2023, Wednesday		
3-4pm	What are the GCP and Ethics Guidelines used around the world?	Nandini Kumar, ICMR
4-5pm	Ethics committee: constitution and responsibilities	Vinita Agrawal
5-6pm	Mock EC proceedings and discussion	Vinita, Amita, Durga, Shagun
2nd Feb. 2023, Thursday		
3-4pm	Publication Ethics	Peush Sahni, AIIMS
4-5pm	Conflicts of Interests and how to address them?	Aditya Kapoor
5-6pm	Group assignment and discussion: Publication ethics	Amita, Amit Goel
3rd Feb. 2023, Friday		
3-4pm	Research misconduct	Amita Aggarwal
4-5pm	Plagiarism	DP Misra
Home assignment (2hrs)	Group assignment: Case studies on research misconduct	
4th Feb. 2023, Saturday		
12-1pm	Issues related to Interventional studies: adverse events reporting, compensation, regulatory requirements	Amit Goel
1-1.30pm	Monitoring in clinical studies and Introduction to Data Safety Monitoring Boards (DSMBs)	Mohan Gurjar
1.30-2.30pm	Introduction to Good Clinical Laboratory Practice	Raghavendra L
2.30pm	Course evaluation	



Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS, Lucknow

MBT-206: Research Methodology, Biosafety, Ethics, Intellectual Property Rights

1. **Research Methodology:** Meaning, objective & types of research, how to select a research topic? Motivation in research, Research Methodologies Survey, Philosophical, Descriptive and Experimental Methods, Importance of knowing how research is done, , Criteria of good research.
2. **Defining Research Problem and Hypothesis:** Identification of Research Problem and Selection design, Formulation of Research Problem, Necessities & techniques in defining the problem, designing the research plan, concepts, types and basic principles of experimental design, Selection of appropriate methodology.
3. **Data collection & Sampling:** Methods of data collection: Observation method, Interview method, Questionnaire method for the collection of primary data, Collection of secondary data, selection of appropriate method for data collection, Case study method. Guidelines for developing questionnaire
4. **Importance of literature review, Writing research papers and grants, Paper presentation in scientific conference.**
5. **Biosafety and risk assessment issues; Regulatory framework; National biosafety policies and law, The Cartagena protocol on biosafety, WTO and other international agreements related to biosafety, Cross border movement of germplasm; Risk management issues - containment.**
6. **General principles for the laboratory and environmental biosafety; Health aspects; toxicology, allergenicity, antibiotic resistance, etc; Impact on environment: gene flow in natural and artificial ecologies; Sources of gene escape, tolerance of target organisms, creation of superweeds/superviruses, etc.**
7. **Ecological aspects of GMOs and impact on biodiversity; Monitoring strategies and methods for detecting transgenics; Radiation safety and nonradio isotopic procedure; Benefits of transgenics to human health, society and the environment.**
8. **Bioethics: Concepts; Philosophical considerations; Epistemology of Science; Ethical Terms; Principles & Theories; Relevance to Biotechnology; Ethics and the Law Issues: Genetic Engineering, Stem Cells, Cloning, Medical techniques, Transhumanism, Bioweapons; Research concerns - Animal Rights, Ethics of Human Cloning, Reproduction and Stem Cell Research; Emerging issues: Biotechnology's Impact on Society; DNA on the Witness Stand - Use of genetic evidence in civil and criminal court cases; Challenges to Public Policy – To Regulate or Not to Regulate; Improving public understanding of biotechnology products to correct misconceptions**
9. **Intellectual property rights (IPR): Intellectual properties, copyrights, trademarks, trade secrets, patents, geographical indications, etc; Requirement of a patentable novelty; Issues related to IPR protection of software and database; IPR protection of life forms. Obtaining patent; Invention step and prior art and state of art procedure; Detailed information on patenting biological products and biodiversity. trade related aspects of Intellectual Property Rights and Budapest treaty; Indian patent act and amendments, patent filing; Implications of intellectual property rights on the commercialization of biotechnology products.**



Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS, Lucknow

10. Recommended Links

- <http://www.w3.org/IPR/>
- <http://www.wipo.int/portal/index.html.en>
- http://www.ipr.co.uk/IP_conventions/patent_cooperation_treaty.html
- www.patentoffice.nic.in
- www.iprindia.org
- <http://www.cbd.int/biosafety/background>



Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS, Lucknow

