UHS Course on Ethics including bioethics

The approved curriculum for UHS Course in Ethics including bioethics for Post graduate students of UHS Rohtak.

Module	Competency	Topics	Learning Objectives	T-L Method	Session Duration
Foundations of Ethics including Bioethics	Understand the historical and philosophical foundations of ethics including bioethics and apply core ethical principles in medical practice.	History and Philosophical Underpinnings of Ethics as well as Bioethics' Principles	• Brief introduction of major philosophical theories that underpin ethics, including utilitarianism, deontology, virtue ethics, and principlism. • Describe the significant historical events that have shaped the field of bioethics, such as the Nuremberg Trials, Tuskegee studies, the Declaration of Helsinki, the Belmont Report, and ethics controversies in India, etc • Explain the impact of these historical events on the development of ethical guidelines in medical practice.	Interactive Lecture Case studies/Scenarios https://medcoeckapwstorprd01.blob.core.usgovcloudapi.net/pfw-images/borden/ethicsvol1/Ethics-ch-02.pdf	20 min
		General Ethics Principles	• Define Core Ethical Principles • Identify situations in clinical practice where the principles of autonomy, beneficence, non-maleficence, and justice might conflict. • Principles that have emerged during the pandemic, such as the need for Veracity, Solidarity, Mechanisms for Priority- setting	Interactive Lecture Case studies/Scenarios	25 min
Clinical Ethics	Demonstrate the ability to address and resolve ethical issues in clinical settings by upholding professionalism, building and maintaining trust, ensuring effective communication,	Doctor-Patient Relationship: Professionalism, trust, and communication. Medical Errors Truth Telling	• Define professionalism in the context of the doctor-patient relationship and describe its key components, including competence, integrity, accountability, and respect. • Identify factors that contribute to trust in the doctor-patient relationship. • Discuss strategies for addressing situations that undermine trust. • Demonstrate effective communication techniques. • How to Conduct difficult conversations with patients. • Explain the principles of patient-centered care.	Workshop Method based on Clinical Vignettes and Plenary Role Plays	45min

	obtaining informed consent, maintaining Privacy and Confidentiality, and managing the Beginning of life and end-of-life care issues. This includes navigating the complexities of medical errors and truth-telling with integrity and sensitivity		• Communicate diagnoses and errors truthfully and sensitively.		
		Informed Consent: Importance, Process, Documentation and Addressing Challenges	• Articulate the ethical and legal significance of informed consent in medical practice • Identify the key components of informed consent, including disclosure, comprehension, voluntariness, competence, and consent. • Informed Consent in research Vs clinical scenarios • Effectively conduct the informed consent process, ensuring patient comprehension and voluntary decision-making. • Accurately document the informed consent process in patient records. • Identify common challenges and barriers to obtaining informed consent, such as language barriers, cultural differences, and patient comprehension issues. • Implement strategies to overcome challenges in obtaining informed consent	Case-Based Discussion Role Plays Check-list for PIS-ICF	45 min
		Privacy and Confidentiality: Legal and Ethical Considerations	• Explain the legal requirements and ethical principles underpinning Privacy & patient confidentiality in healthcare, focusing on research participants. • Describe the potential consequences of breaches of confidentiality • Identify situations where maintaining confidentiality might be challenging or where exceptions might apply (e.g. dual roles, third-party risks). • Discuss the role of privacy laws such as DISHA of 2018) in protecting patient information.	Group Discussion	30 min

		Beginning of life issues to End-of-Life Care: Advance Directives, Palliative Care, and Euthanasia	• What are possible Beginning-of-life issues and ethical dilemmas related to prenatal care, genetic testing, reproductive technologies, and neonatal intensive care • **Importance and Need of End-of-Life Care and Palliative Care** • Advance Directives and their Role in Respecting Patient Autonomy at the End of Life • Explain the Principles and Goals of Palliative Care • Identify Strategies for Effective Communication • Explain the current legal status of euthanasia and physician-assisted suicide in India, including recent court rulings and legislative developments • **Address Challenges in End-of-Life Care:** Identify and Manage Common Challenges and develop Skills in Ethical Decision-Making and Conflict Resolution	Case-Based Discussion	45 min
Research Ethics	Conduct research ethically, adhere to human research standards, and recognize and manage conflicts of interest.	ICMR National Ethical Guidelines for Biomedical & Health Research Involving Human Participants Submission of Protocol to Ethics Committee	• **Understand the ICMR Guidelines and Their Importance** • **Comprehend Ethical Principles in the ICMR Guidelines:** i. Identify the core ethical principles outlined in the ICMR Guidelines, such as respect for persons, beneficence, non-maleficence, and justice. ii. Explain how these principles are applied in the design, conduct, and review of biomedical research involving human participants. • **Implement ICMR Guidelines in Research Practice** • **Navigate Ethical Review Processes** • **Address Specific Issues in Biomedical Research:** i. Potential conflicts of interest in biomedical research	ICMR guidelines will be given as Mandatory Pre-reading material. Conduct session based on case discussions https://www.youtube.com/watch?v=VZTPYstlCJI Demonstrate with submitted Protocols having flaws.	45 min

			ii. Vulnerable populations and how to address these in research studies		
		NDCT Rules, GCP & GLP Guidelines	Describe key provisions and objectives of NDCT rules Define GCP and its principles and explain regulatory requirements Define GLP and its purpose and identify key elements and implementation Primarily cover Academic Clinical Trial vs. regulatory Clinical Trials Compensation Requirements **Maintaining Compliance with Regulatory Standards**	Salient points in lecture along with Case Scenarios	30 min
Publication Ethics/ Responsible Conduct of Research (RCR)	Uphold ethical standards in academic publishing, including appropriate authorship, avoiding plagiarism, and ensuring data integrity.	**Why RCR** **Data Fabrication and Falsification:** Ethical issues and consequences. **Plagiarism:** Identifying and preventing plagiarism in research and publications. **Authorship Criteria:** Defining and recognizing contributions appropriately. **Copyrights & IPR and COPE guidelines** **Emerging RCR issues.**	**What is the need of RCR?** **Data Fabrication and Falsification:** • Define data fabrication and falsification. • Explain how these practices compromise scientific integrity. **Plagiarism:** • Define plagiarism and its forms (e.g., direct, self-plagiarism). • Explain the ethical, legal, and academic consequences of plagiarism. • Use plagiarism detection tools to ensure manuscript originality. **Authorship Criteria:** • Define authorship and outline criteria according to international standards like ICMJE guidelines. • Identify contributors' roles in research projects to determine appropriate authorship **Copyrights & IPR:** • Define copyrights and intellectual property rights (IPR). • Explain their importance in protecting authors' and creators' rights.	Short movie clip Workshop Method based on Clinical Vignettes and Plenary Discussion	40 min

			• Describe the copyright acquisition process and legal implications of infringement. **COPE Guidelines:** • Explain COPE guidelines and their role in promoting integrity in scholarly publishing **Emerging RCR issues**		
Legal and Regulatory Issues	Navigate the legal landscape of medical practice, including understanding malpractice	Medical Malpractice: Legal Implications and Ethical Responsibilities	• Define medical malpractice and explain its key components: duty, breach, causation, and damage. • Describe the difference between negligence and malpractice in the context of medical practice. • Recognize the Legal Implications of Medical Malpractice • Understand Ethical Responsibilities in Preventing Malpractice. • Violence on Health Providers • Institutional Ethics	Videos Case Scenarios & Discussion	40min

Assessment Method:

- Post-Test MCQ 20 in number with a minimum 80% score as Pass criteria
- Case scenario Analysis or Analysis of Relevant Videos at the end of the workshop
- Engagement in discussions during the workshop.
- Ability to draft a PIS-ICF based on a protocol