

SW812 Living Dharma: Responsible Conduct in Research with Humans 4-0-0 4

Course Description

Scientific discoveries have made essential contributions to advancing numerous aspects of life, and increasing our understanding of the world around and within us. Science has given to us responsible methods by which to harness electricity, instruments by which to observe the inner workings of the brain and other biological organs, knowledge of microscopic organisms, the structure of DNA, and the technology to send humans into space to explore the cosmos. Our Amrita Chancellor tells us that Science and Spirituality are one. When science is practiced with dharma, with integrity and respect, wonders can open up before us that uplift societies and all living beings. But when scientific practices compromise moral principles either through ignorance or for some form of personal gain, then much harm can result. This harm can affect the participants, the researcher, and the sponsoring institution. This leads to the demeaning of Science as a mockery in the eyes of society, rather than as a venerated method by which to understand and serve the world. This course is to help us stay on the path of responsible science by conducting research practices guided by proper knowledge and honesty. We will learn to understand the need for Ethics in Research, and the methods and practices by which to conduct research with integrity.

Course Aims and Objectives

This course is suited to anyone conducting, or wishing to conduct, research with human participants. Researchers often lack knowledge about the multidimensional layers of ethical standards that we must implement in research. Research can involve multifaceted societal and human issues that can be complex, requiring skill and consideration to ensure the safety and wellbeing of the participants. This course will provide the knowledge, understanding, and skills necessary to mobilize Responsible Research practices. Students will learn:

- The historical research practices that led to an essential global need for ethical research practices as guided by internationally collaborative foundational guidelines.
- India's National and International Research Ethics Principles, and why these are needed in research
- The role of "deception" in research: When is it ethical and when not.

- Gaining a deeper understanding of how to protect participants, especially vulnerable groups.
- The specific role of the Institutional Ethics Committee
- The specific role and responsibilities of the Researcher
- Ethical guidelines for a successful Research Proposal, step by step, including Informed Consent
- Ethics in Publishing (including data storage, conflicts of interest, authorship)
- Understand the role of Retraction Watch and numerous examples of rescinded research

Course Outline

I. Why Research & Why Ethics?

- Understanding ancient to current dharma, morality, honor
- Historical events that shaped global ethics
 - Human Participants: Misuse, Exploitation, Abuse
- Precipitants of Fundamental Global Documents
 - o Universal call for ethical research practices
 - Deception Research
 - Tuskegee & Milgram
- Outcomes of Research Impropriety vs Integrity & Honor
 - o Dr. Kelsey & the giant

II. Principles of Research Ethics: India

- International & National standards
- Expertise/Competency
- Special Considerations
 - Vulnerable Groups

III. Oversight of Research Ethical Compliance

• Institutional Responsibility

- Institutional Review Board Institutional Ethics Committee
- o Institutional, National, International

Researcher Professional Responsibility

- Scientist: responsible member of society
 - Impacts of scientific research (environmental, societal)
- Human/Environment Research Policies

- Informed Consent
- o Research Proposal
 - Competency to conduct study: Expertise/knowledge
 - Lit Review/ Rationale/Relevance
 - Research tools
 - Data Management & Practices
- Mentor/Mentee Responsibilities

IV. The Watchdog: Ethics in Publishing & Retraction Watch

- Authenticity of data
- Research Misconduct: Plagiarism/Fabrication/Falsification
- Responsible Authorship & Publication
- Peer Review
- Scientifically Authentic vs Predatory Journals
 - Resources & databases
- Conflicts of Interest
- Problems with Science

Course Tools to deepen understanding and knowledge acquisition

- Discussion
- Brief teaching videos
- Case Studies
- Debates
- Practice (e.g., IC, research design, tools)
- Activities, e.g., Role Plays
- Quizzes

Assessment

- 1. Brief Quizzes 25%
- 2. Class participation 20%
- 3. Case analysis: identify ethical compliance and neglect 20%
- 4. Case Practice: creating an assigned aspect of the research study (e.g., Informed Consent, Research Design, etc) 20%
- 5. Debates 15%

Course Outcomes

Dharma implies righteousness reflected through duty and responsibility to oneself, others, Nature, and the world. By the end of this course the student will be able to:

- Explain and understand why Research Ethics Guidelines are essential to conducting research.
- Recognize and avoid misconduct in research
- How to conduct responsible and meaningful research with accountability
- Apply best ethical practices and knowledge a to all aspects of a study, from the literature review, study design, tools used, data storage, selection of participants, proper Informed Consent, to publishing with scientific integrity.
- Have heightened sensitivity and awareness of the dynamics in working with "vulnerable groups," and successfully work with such situations.
- Be able to select the best journal for your paper
- Have a clearer understanding of the best practices for publishing, including authorship, journal selection, and conflicts of interest.

Resources

Books:

Research Ethics Consultation: A Casebook. Danis et al., (2014) Department of Bioethics Clinical Center, National Institutes of Health. Oxford University Press.

Scientific Integrity by Francis L. Macrina, ASM Press, Washington, D.C., 4th Edition (2014).

Other Resources:

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Bebeau, M. J.& "Developing a Well-reasoned Response to a Moral Problem in Scientific Research Ethics." In *Teaching Research Ethics: A Workshop at Indiana University.* May, 1995.

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Cuerda, E., & López-Muñoz, F. (2013). Ethical considerations of the human research: Syphilis experiments and denial of drug therapy. *Clin Exp Pharmacol*, *3*(4), e124.

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Nijhawan, L. P., Janodia, M. D., Muddukrishna, B. S., Bhat, K. M., Bairy, K. L., Udupa, N., & Musmade, P. B. (2013). Informed consent: Issues and challenges. *Journal of advanced pharmaceutical technology & research*, *4*(3), 134.

Oakes, J. M. (2002). Risks and wrongs in social science research: An evaluator's guide to the IRB. *Evaluation Review*, *26*(5), 443-479.

Resnik, D.B. (2019). Stewardshop of research resources. National Institute of Health.

Rhodes, R. (2010). Rethinking research ethics. The American Journal of Bioethics, 10(10), 19-36.

Thatte, U. M., & Marathe, P. A. (2017). Ethics Committees in India: Past, present and future. *Perspectives in clinical research*, 8(1), 22.

UCLA Research Administration: Policies and Guidance https://ohrpp.research.ucla.edu/policies-and-guidance/

World Health Organization. (2009). Research ethics committees: basic concepts for capacity-building. World Health Organization