



SRI BALAJI VIDYAPEETH

(ACCREDITED WITH 'A' GRADE IN THE FIRST CYCLE BY NAAC)

Pillaiyarkuppam, Pondicherry - 607 402

PROSPECTU

CERTIFICATE COURSE in BIOETHICS on HUMAN RESEARCH



Central Inter-Disciplinary Research Facility
Sri Balaji Vidyapeeth



VISION & MISSION

VISION

- Sri Balaji Vidyapeeth will strive to be a premier global health sciences university leading in the frontiers of education, research and patient care.

MISSION

- To create an innovative ecosystem that facilitates the development of health care professionals.
- To contribute to the health care workforce with competent and committed professionals.
- To provide preventive, curative and palliative high quality evidence – based care that is affordable and accessible.
- To foster a culture of scientific inquiry, research and innovation in contemporary and emerging health and related sciences.
- To be inclusive and committed in promoting wellness and empowerment of the society.

VALUES

- Inclusiveness, Integration, Innovation
- Engagement, Empowerment, Excellence

A portrait of Shri. M. K. Rajagopalan, the Founder and Hon'ble Chancellor of SBV. He is a middle-aged man with dark hair, wearing glasses, a dark suit, a light blue shirt, and a dark patterned tie. The background of the portrait is white. The overall page background features a dynamic pattern of diagonal lines in shades of green and yellow.

CHANCELLOR'S MESSAGE

Dear Students,

You are our National Treasure, and our Country's Future is in your safe Hands. Our Nation looks forward to utilizing your talents in service to the Society. We firmly believe that the moulding of the student into a well-rounded professional largely depends on the broad vision of an educational Institute.

Sri Balaji Vidyapeeth is an embodiment of a broader vision and planned development of a sound education system... where the environment is conducive and pleasant to study, live and work, where education and research hand in hand flourish... where the hidden and inherent skills and talents of the students are nurtured and developed for the benefit of the society, for generations to come.

Come, join our world. Let us create a better, viable, integrated global community of shared benefits, responsibilities and values for the benefit of all things living. Our origins and lives may be different, but we do share the same planet and belong to the same Mother Earth. And remember... you are the nation's greatest gift and we are duty bound to do our best to our Nation.

Shri. M. K. Rajagopalan

Founder and Hon'ble Chancellor, SBV

VICE-CHANCELLOR'S MESSAGE

Welcome to SBV & your future

The millennium has ushered in challenges which will have a profound impact on the role of private universities. Professional competence will be highly sought after in India and around the globe. The challenge - shared by all Universities - is to bestow the requisite knowledge and skills, and cultivate proper etiquette and attitude to produce top-notch professionals who will be valued both for their professional competence and their inherent ability to solve problems.

Sri Balaji Vidyapeeth, Deemed to be University and accredited by NAAC with 'A' Grade is dedicated to its mission in order to nurture healthcare professionals in Medicine, Dentistry, Nursing and Allied Health Sciences, who would contribute and strive ceaselessly towards caring for the comfort of the sick. The constituent colleges of SBV are already noted for the excellence in various avenues including teaching, research, and service to the community, especially those who are marginalised and underserved. SBV is endowed with committed, dedicated and outstanding faculty- a healthy mix of the young & veterans and excellent infrastructure. Our challenge for the future is to capitalize on this good start and establish ourselves firmly among the comity of leading Universities.

The reputation of any institution is essentially based on the quality of its output; the management and the academic staff do realise this and I promise that they will do their best to train and educate you well. You, the research scholars who have gained entry into the portals of SBV this year realise your ambition and must perform well with dedication and diligence and emerge as competent research professionals and make your parents and educators proud. We wish you all the very best and hope

WITH LOADS OF GOOD WISHES,

PROF. SUBHASH CHANDRA PARIJA, MBBS , MD , PhD ,DSc, FRCPath, FAMS, FICPath , FABMS , FICAI, FISCD, FIAVP, FIATP and FIMS
Hon'ble Vice Chancellor, Sri Balaji Vidyapeeth



INTRODUCING SRI BALAJI VIDYAPEETH

Young, Modern & Marching Ahead

- Sri Balaji Vidyapeeth (SBV) is a young deemed University, proud of its modernity, yet firmly grounded in rich educational heritage.
- SBV aims to excel in academic and clinical medicine; research and training; nurturing passion and enthusiasm into achievement and converting theoretical knowledge into evidence based practice and research.
- SBV was granted 'Deemed University' status by the University Grants Commission (UGC) under section 3 of the UGC Act of 1956 in 2008, in recognition of its outstanding quality of providing education, potential for excellence and obtained NAAC "A" Grade in 2015, with CGPA of 3.11 on 4 point scale.
- SBV has been placed in the top 100 for three consecutive years 2016, 2017 & 2018 at the National Institutional Ranking Framework (NIRF) and is in the top 25 among the Medical colleges through its flagship institute, namely Mahatma Gandhi Medical College & Research Institute.
- SBV(DU) thus enjoys complete autonomy to develop and implement innovative curriculum and academic programs and to design its own education process that is responsive and tailored to the evolving needs and changes of health sciences.
- The Deemed University's constituent colleges and courses are all duly accredited and recognised by the respective statutory bodies such as the Medical Council of India, Dental Council of India and the Indian Nursing Council. Graduates of SBV(DU) are eligible to register with any state council or pursue further education in any part of India.
- SBV(DU) ensures that its programs and courses are recognised internationally, by registering under appropriate provisions of various statutory and registration authorities around the world to enable its graduates the right to qualify for practice in any nation, including appearing for USMLE, (USA) PLAB, MRCP/MRCS/etc (UK), MCCQE (Canada), AMC (Australia), CGFNS/NCLEX (Nursing, USA) etc.
- SBV(DU) is a research oriented university and the establishment of state-of-the-art Central Interdisciplinary Research Facility pledges considerable resources and investment for Biomedical Research.
- SBV's research output has been consistently high in quality and impact, as evident from its rapidly growing research publication record that inspires our students, a fact attested by the region-wise lead position in number of ICMR sponsored STS research projects (Short Term Studentship) undertaken and ably accomplished by our undergraduate medical and dental students.
- SBV caters to the needs of the patients in the form of alternate medicine. The presence of Yoga and Music Therapy is an innovative move to step forward from Illness to Wellness and treating the patients through complementary medicine. MoU signed by SBV for a collaborative doctoral program in music therapy with the IMC University of Applied Sciences, Krems, Austria and with Kaivalyadhama Yoga Institute for Yoga research are noteworthy milestones and bear ample testimony.
- The Centre of Health Professions Education brings together all health professionals to achieve academic excellence through training and research in pedagogical sciences, which saw SBV signing a long term partnership with Partners Medical International, USA.
- Every year is a year of challenges, accomplishments as we attain our targets, setting newer goals and constantly striving to renew our commitment for better medical training, scientific research and clinical practice.
- SBV is governed by an enlightened collegium of eminent scholars, clinicians and scientists, headed ably by our visionary Chairman and Chancellor, Shri. M. K. Rajagopalan; Vice Chancellor Prof. SC. Parija, a well recognised medical educationist; Renowned teacher, Prof. N. Ananthakrishnan, Dean of Faculty & Allied Health Sciences; Prof. M. Ravishankar, Dean, Faculty of Medicine, providing leadership and stewardship towards excellence.

Introduction of the course

Name of the course	Certificate Course in Bio-Ethics On Human Research
Duration and Frequency	3 days (8.30am-5.00pm) 2 Sessions per year
Intended Audience	Members of the ethics committee, Faculty who want to become members of the ethics committee, Hospital /health care administrators, Clinician, Faculty members, Biomedical Scientists who are interested in Clinical Research.
Intended Learning Outcomes	<ul style="list-style-type: none">• To understand current ethical and regulatory prerequisites for directing clinical research in Medical Institutes In India and other countries.• To be aware of the latest national ethical guidelines for biomedical and health research involving participants by ICMR.• To enable the delegates to understand that by seeking compliance to Ethics they can give the public an assurance that the rights, safety and well-being of human participants are well protected and the data from the study results are incredible and accurate.• To understand the principles of Bioethics, roles and responsibilities of various stake holders involved in a clinical and biomedical research involving human participants.
Course Fee	Rs. 2000/-

Assessment & Assignment

Details of the course

Theory

Syllabus	TL strategy
<p><u>DAY 1</u></p> <ul style="list-style-type: none">• General Principles of Ethics in Human research and Codes of ethics.• ICH and ICMR 2017 Guidelines-Overview• Composition, Roles ,Responsibilities and Functioning of EC• Reviewing of Research Proposal by EC• Risk, Categorization, Risk and Benefit Assessment of EC• Privacy and Confidentiality.	Lecture
<p><u>DAY 2</u></p> <ul style="list-style-type: none">• Vulnerable population in Biomedical Research.• Informed Consent Documents.• New Drugs, Rules and Ethical Issues in Clinical Trial• Regulatory framework for conduct of Clinical trial.• SAE Reporting and Monitoring• Compensation for participants and Research related Injury	Lecture
<p><u>DAY 3</u></p> <ul style="list-style-type: none">• Human Genetics Testing and Research.• Clinical Trial with Stem Cells• Research during Humanitarian Emergencies and Disaster• Biological material and Bio-banking• Publication Ethics.	
<p>ASSESSMENT Pre & Post Test</p> <p>FEEDBACK Through feedback process</p> <p>Certification Certificate will be issued to those with >80% attendance</p>	