



SRI BALAJI VIDYAPEETH (SBV)

(Deemed to be University)
U/S 3 of UGC Act 1956
Puducherry-607402

This document contains the details of the
Certificate course in Bioethics on Human Research
conducted by Mahatma Gandhi Medical College & Research Institute,
Sri Balaji Vidyapeeth, Deemed to be University.

REGISTRAR
SRI BALAJI VIDYAPEETH
(Deemed University u/s 3 of UGC ACT, 1956)
Accredited by NAAC with 'A' Grade
Pillaiyarkuppam, Pondicherry - 607 402.

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Criteria 1

Metrix 1.3 : Curriculum Enrichment

1.3.2

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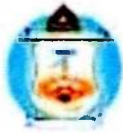
Details of Certificate course in Bioethics on Human Research

Links to documents (Click on the links to navigate to the page)

1. [Link to Prospectus](#)
2. [Brochure](#)
3. [Course Content](#)
4. [Event Report](#)
5. [Sample Certificate](#)
6. [Enrolled List of students](#)



NAAC 2020



SRI BALAJI VIDYAPEETH
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MAHATMA GANDHI MEDICAL COLLEGE & RESEARCH INSTITUTE
NH-45A, Pillayaruppam, Pondicherry - 607 403

Organized by

INSTITUTIONAL HUMAN ETHICS COMMITTEE

Chief Patrons:

Shri M K Rajagopalan

Hon'ble Chancellor, SBV

Dr. Prashanth Rajagopalan

Vice- Chairman, SBV

Patron:

Prof. Subhash Chandra Parija

Hon'ble Vice Chancellor, SBV

Advisory Board:

Prof. N Ananthakrishnan

Dean Faculty, SBV

Prof. C. Adlithan

Dean Research, SBV

Prof. M. Ravishankar

Dean, MGMCRI, SBV

Organizing Chairman:

Prof. S. Lokesh

Prof. & Head, General Medicine

Organizing Secretary

Dr. Siva Ranganathan Green

Joint Organizing Secretary & Treasurer

Dr. Uma Narayanamurthy

CERTIFICATE COURSE IN BIOETHICS ON HUMAN RESEARCH

Course Contents :

- 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
- 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

Recent Advances in Bioethics

- Human Genetics Testing and Research
- Clinical Trial with Stem cells
- Research during Humanitarian Emergencies and Disaster
- Biological material and Bio - banking
- Publication Ethics

Inauguration of the function

Chief Guest

Prof. Subhash Chandra Parija

Hon'ble Vice Chancellor, SBV

Guest of Honor

Dr. Vasantha MuthuSwamy

President, FERCI, Colmbatore

TIME :

9.00 AM

TO

4.30 PM

**MARCH
6-8
2020**

NEFT Details for online transaction:

Bank	Indian Bank
Branch	PILLAYARKUPPAM, Pondicherry
IFSC Code	IDIB000P042 (0- zero)
Account Name	MGMCRI- IHEC
Account Number	6838807509

Venue : BAPUJI - CENTRAL LIBRARY, MAULANA ABUL KALAM AZAD HALL, SBV Campus

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CERTIFICATE COURSE IN BIOETHICS ON HUMAN RESEARCH

COURSE OVERVIEW

Clinicians, non-clinicians, Faculty in the medical and Para Medical field, nurses and researchers in medicine, philosophy and law are increasingly encountering ethical issues in their daily practice. Decision making on complex ethical and moral dilemmas related to advances in medicine, law, science and technology can be challenging even for the experienced. Specialized and cross-disciplinary knowledge and dialogue is essential to enhance awareness and training in ethics to ensure preparedness of the various stakeholders to handle real-life situations. The Certificate Course in Bioethics on Human Research prepares all the above to address these challenges through an innovative learning experience featuring lectures, interactive and collaborative course activities. The course is conducted by the Institutional Human Ethics Committee of MGMCRI, SBV (Deemed to be) University.

Learning Objective

- To understand current ethical and regulatory prerequisites for directing clinical research in Medical Institutes in India.
- 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 GCP 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 credible and accurate.
- To understand the principles of GCP, roles and responsibilities of various stakeholders involved in a clinical research.

Who should attend?

- Members of the ethics committee,
- Faculty who want to become members of the ethics committee
- Faculty Members, Clinicians, Biomedical Scientists who are interested in Clinical Research
- Hospital / Health care administrators
- Clinical research and allied Professionals working at clinical trial sites, pharmaceutical companies.





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Topics for discussion:

- GENERAL PRINCIPLE OF ETHICS IN HUMAN RESEARCH & CODES OF ETHICS
- ICH GUIDELINE OVERVIEWS
- ICMR 2017 GUIDELINE OVERVIEW
- COMPOSITION, ROLES AND RESPONSIBILITIES OF ETHICS COMMITTEE
- REVIEWING OF RESEARCH PROPOSAL BY ETHICS COMMITTEE
- RISK CATEGORISING IN ETHICS PROPOSAL
- RISK BENEFIT ASSESSMENT
- PRIVACY AND CONFIDENTIALITY
- VULNERABLE POPULATION IN BIOMEDICAL RESEARCH
- INFORMED CONSENT
- ASSENT FROM CHILDREN AND ADOLESCENTS
- NEW DRUGS AND CLINICAL TRIAL RULES: AN OVERVIEW
- REGULATORY FRAMEWORK FOR CONDUCT OF CLINICAL TRIAL
- ETHICAL ISSUES IN CLINICAL TRIAL
- SERIOUS ADVERSE DRUG REACTION REPORTING AND MONITORING
- CLINICAL TRIAL WITH STEM CELLS
- REGISTRATION AND ACCREDITATION OF ETHICS COMMITTEE
- RESEARCH DURING HUMANITARIAN EMERGENCIES AND DISASTER
- BIOLOGICAL MATERIAL AND BIOBANKING
- PUBLICATION ETHICS
- HUMAN GENETICS TESTING AND RESEARCH

Hands on training and group exercises:

- PROVISION OF COMPENSATION FOR PARTICIPATION AND RESEARCH RELATED INJURY

Organizing Secretary:

- Dr. Siva Ranganathan Green, Professor , General medicine, SBV

Joint Organizing Secretary and Treasurer:

- Dr. Uma Narayanamurthy, Associate Professor , Pharmacology, SBV





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Speakers:

- Dr. Lokesh. S, Head and Professor of General Medicine, MGMCRI.
- Dr. Ananthkrishnan. N, Professor of Surgery, MGMCRI.
- Dr. Sivagnanam. G, Professor of Pharmacology, IGMCRI.
- Dr. Chandrasegaran. K, Retd. Associate Professor, Dr. Ambedkar Govt. Law College.
- Dr. Medha. R, Additional Professor of Biochemistry, JIMPER.
- Dr. Nandhini Kumar, Former Deputy Director General Sr. Grade (ICMR), Adjunct Visiting Prof., Kasturba Medical College, Manipal.
- Dr. Jayanthi. M, Additional Professor of Pharmacology, JIPMER.
- Dr. Sandhya. S, Assistant Professor of Clinical Pharmacology, IEC, JIPMER.
- Dr. Melvin George, Department of Clinical Pharmacology, SRM Medical College & Hospital.
- Dr. Vasantha Muthuswamy, Former Senior Deputy DG, ICMR, and President, FERCI (Forum for Ethics Review Committees in India), Coimbatore.
- Mr. Arthur "Atoy" M. Navarro, Member in FERCAP, Thailand
- Dr. Adithan. C, Clinical Pharmacologist, MGMCRI
- Dr. Gunasekaran, Professor of Paediatrics, JIPMER.
- Dr. Jambulingam P, Chair (Vector Biology), Former Director, ICMR-Vector Control Research Centre.
- Dr. Reena Gulati, Additional Professor of Paediatrics, JIPMER.
- Dr. Paul Kumaran, Deputy Director-Medical, ICMR National Institute for Research in Tuberculosis, Madurai Unit.
- Dr. Vimal, Associate Professor of Pathology, SMVMCH
- Dr. Manavalan, CDSCO, Chennai.

Prepared by,
Dr. Uma Narayanamurthy,
Joint Organising Secretary,
Additional Member Secretary, IHEC.

Approved by,
Dr. Siva Ranganathan Green,
Organising Secretary,
Member Secretary, IHEC, MGMCRI.





INSTITUTIONAL HUMAN ETHICS COMMITTEE

Reg No. ECR/451/Inst/PO/2013/RR-16

**CERTIFICATE COURSE IN BIOETHICS ON
HUMAN RESEARCH**

VENUE: AGASTHIYAR HALL (LECTURE HALL 2), FIRST FLOOR,
COLLEGE BLOCK

DATE: 06/03/2020 - 08/03/2020

EVENT REPORT

DAY 1 - 06/03/2020

The first day began with the registration of the entire faculty who participated in the 3 day course. After a warm welcome to all, a brief overview and insight into the 3 day program was presented by the organizing secretary, Dr. Siva Ranganathan Green.

The first session was chaired by Prof. Ananthkrishnan introduced the guest speaker, Dr. Vasantha Muthuswamy and set the stage for the day's first talk on "General Principle of Ethics in Human Research and Codes of Ethics". After the enlightening talk, Prof. C. Adithan presented Dr. Vasantha Muthuswamy with certificates.

This was followed by the inaugural ceremony. The organising chairman Dr. Lokesh, Honourable Vice chancellor Dr. Subash Chandra Parija, Esteemed Dean of Research Prof. C. Adithan along with the Guest of honour Dr. Vasantha Muthuswamy were welcomed onto the Diaz. The ceremony was initiated with the SBV anthem followed by the welcome address by the organizing chairman, Dr. Lokesh. The Vice Chancellor welcomed the guest of honor with a bouquet and the organising chairman Dr. Lokesh welcomed our Vice Chancellor with a bouquet. The organising secretary Dr. Siva Green honored the dean of Research with a bouquet. This was followed by an eye opening talk on this course and its need by the guest of honour Dr. Vasantha Muthuswamy. The Inaugural speech was given by the honourable Vice Chancellor Dr. Subash Chandra Parija followed by a few words of

Digitally signed by Dr. A. R. Srinivasan

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encouragement by the esteemed Dean of research Prof. C. Adithan. The ceremony closed with the vote of thanks presented by the joint organising secretary and Treasurer Dr. Uma Narayanamurthy.

The congregation broke for high tea and reassembled shortly after.

The second session for the day was chaired by Dr. Vasantha Muthuswamy. After a brief introduction of the speaker, Dr. Paul Kumaran took over for his talk on “ICH Guideline overviews”. The third speaker for the day, Prof. C. Adithan was introduced briefly and presented his talk on “ICMR 2017 guideline overview”

The third session for the day was chaired by Dr. Paul Kumaran. After a brief introduction of the speaker, Dr. Vimal M. presented his talk on “Composition, Roles and responsibilities of Ethics committee”. The next speaker for the day, Dr. C. Lokesh S. was introduced briefly and took over for his talk on “Reviewing of research proposal by Ethics committee”

The congregation broke for lunch and reassembled shortly after.

The post-lunch session for the day was chaired by Dr. Manimegalai. After a brief introduction of the speaker, Dr. Jambulingam took over for his talk on “Risk categorising in Ethics proposal”. The last session for the day was chaired by Dr. Jambulingam. The next speaker for the day, Dr. Sivagnanam was introduced briefly and presented his talk on “Risk Benefit Assessment”. The last talk for the day was presented by Dr. Chandrasekaran on “Privacy and Confidentiality”.

All the key speakers of the day were presented with certificates by their respective chairpersons. The panel discussion was headed by Prof. C. Adithan, Dr. Paul Kumaran, Dr. Vimal and Dr. Chandrasekaran. A wide array of queries were raised and discussed efficiently.

This marked the end of the first day of the 3 day session.

DAY 2 - 07/03/2020

The second day began with a warm welcome to all.

The first session was chaired by Prof. C. Adithan who introduced the first speaker, Dr. Uma Narayanamurthy for the day’s first talk on “Vulnerable population in biomedical research”. After a brief introduction of the speaker, Prof. Ananthakrishnan took over for his talk on “Informed Consent”.

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The congregation broke for high tea and reassembled shortly after.

The second session for the day was chaired by Dr. Paul Kumaran. After a brief introduction of the speaker, Dr. Reena Gulati elaborated on “Assent from children and adolescents”. The next speaker for the day, Prof. C. Adithan presented his talk on “New drugs and clinical trial rules: An overview”

The third session for the day was chaired by Prof. Ananthkrishnan. After a brief introduction of the speaker, Dr. Paul Kumaran presented his talk on “Regulatory framework for conduct of clinical trial”.

The congregation broke for lunch and reassembled shortly after.

The post-lunch session for the day was chaired by Dr. Paul Kumaran. Dr. Lokesh presented his talk on “Ethical issues in clinical trial”.

The last session for the day was chaired by Dr. Lokesh S. The next speaker for the day, Dr. Melvin George was introduced briefly and presented his talk on “Serious adverse drug reaction, reporting and monitoring”. The last talk for the day was presented by Dr. Sandhiya on “Compensation for participants and research related injury”.

All the key speakers of the day were presented with certificates by their respective chairpersons after each of their enlightening talks. The group exercise was headed by Dr. Sandhiya and was an informative discussion.

This marked the end of the second day of the 3 day session.

DAY 3 - 08/03/2020

The third day began with a warm welcome to all.

The first session was chaired by Prof. C. Adithan who introduced the first speaker, Dr. Jayanthi for the day’s first talk on “Clinical trial with stem cells”. After a brief introduction of the speaker, Dr. Manavalan took over for his talk on “Registration and accreditation of ethics committee”. The next talk on “Research during humanitarian emergencies and disaster’ by Dr. Medha was chaired by Prof. Ananthkrishnan

The congregation broke for high tea and reassembled shortly after.

The second session for the day was chaired by Prof. Adithan. After a brief introduction of the speaker, Dr. Nandhini Kumar elaborated on “Biological material and biobanking”.

The third session for the day was chaired by Dr. Nandhini Kumar. The next speaker for the day, Prof. Ananthkrishnan presented his talk on “Publication ethics”

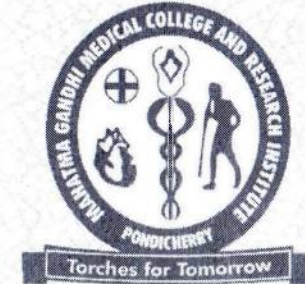
The congregation broke for lunch and reassembled shortly after.

The post-lunch session for the day was chaired by Dr. Nandhini Kumar. Dr. Reena Gulati presented his talk on “Human genetics testing and research”.

All the key speakers of the day were presented with certificates by their respective chairpersons after each of their enlightening talks. A few questions and doubts were raised after each talk which was efficiently discussed. All the chairpersons were honored with certificates. All faculties who attended the 3 day program were handed over their certificates after submission of the feedback forms.

The congregation broke for high tea after reaching the end of a brain-storming course on bioethics in human research.


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Certificate of Completion

This is to Certify that Mr/Ms..... with UIN of

..... has successfully completed a

Certificate course in Bioethics on Human Research

conducted by Mahatma Gandhi Medical College at Sri Balaji Vidyapeeth deemed-to-be university

on.....

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Course Coordinator

Principal

Vice-Chancellor



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Certificate course in Bioethics in Human Research

1. Dr.S.Joseph philipraj
2. Dr. Jean Fredrick M A
3. Dr. Sabari Anandh J V
4. Dr. Karthick S
5. Dr. Manimekalai K
6. Dr. Karthikeyan V P
7. Dr. Johan Pandian
8. Dr. Saravana Kumar
9. Dr. Pratheesh Ravindran
10. Dr. Swathi N
11. Dr. Vikneshan
12. Dr. Pratebha B
13. Dr. Aruna
14. Dr. Vijayasundaram
15. Dr. Prabavathy
16. Dr. Anandraj Vaithy K
17. Dr. Bhavani K
18. Dr. Venkat Raghavan A T M
19. Dr. Pallavee P
20. Dr. Seetesh Ghose
21. Dr. Rani P
22. Dr. Senthil Coumare
23. Dr. Soma Venkatesh
24. Dr. Kartik J Salwe
25. Dr. Anitha t s
26. Dr. Sadeesh T
27. Dr. Suguna
28. Dr. Santhoshakumari T M J
29. Dr. Revathy G
30. Dr. Karthikeyan K
31. Dr. Rajesh Kumar
32. Dr. Valentina Y
33. Dr. Rupal Samal
34. Dr. Sudarcodi R
35. Mrs. Kanimozhi d
36. Mr. Baidyanath Mishra
37. Dr. Rani P
38. Mr. Angamou ttou R
39. Dr. Vijaya Rani
40. Dr. Maheswary K
41. Dr. Arthy S
42. Dr. Sakthi Balan M
43. Dr. Senthil G
44. Dr. Sivaraj R
45. Dr. Vijaya Koothan
46. Dr. A. Janani
47. Dr. V. Nagavalli

Manoj
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