



9th National Conference of Forum for Ethics Review Committees in India (FERCI)

FERCICON 2022



10 to 12 November, 2022

Venue: Bikhhabhai Patel Auditorium, Academic Centre

Organized by

Unit of International Chair in Bioethics [WMA Cooperation Centre]

Bhaikaka University

Karamsad, Anand, Gujarat INDIA 388325



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**Bhaikaka
University**

Instilling Purpose in Healthcare

Charutar Arogya Mandal, Karamsad

About Bhaikaka University

Nearly five decades ago, Charutar Arogya Mandal was established as a 'venture of faith,' founded by the late Dr. H. M. Patel, former Union Home, and Finance Minister, whose dream was to offer comprehensive, compassionate health care to everyone and anyone who needed it.

Dr. Patel's legacy, Solace for the Suffering, drives all our efforts in health care and education activities. The Trust's primary objective, as enshrined in its Constitution, is to make health care facilities accessible and affordable to the people of Gujarat. Spread over a sprawling green campus of 100 acres, the Trust's activities focus on the following four areas and are guided by their respective Boards of Management in Education, Patient care, Research, and Public health. "BHAIKAKA UNIVERSITY" was established in October 2019 under the State Private University Act 2009.

About Pramukhswami Medical College

Pramukhswami Medical College (PSMC), a Constituent Institute of Bhaikaka University, was established in 1987. It has been an MCI/NMC-designated Regional Centre for National Faculty Development Program since 2010. The college has an annual intake of 150 MBBS and 106 MD/ MS students.

About Forum for Ethics Review Committees in India [FERCI]

FERCI was established in 2002 with Dr. Vasantha Muthuswamy, who retired as Senior Dy Director General of the ICMR, as the founder President. FERCI is a forum that fosters the improved implementation of ethics review, facilitates opportunities, and acts as a coordinator between various stakeholders towards imparting appropriate protections in Research. FERCI invites ethics committees in India to join hands and work towards improving their structure, functions, and capacity for ethical review. FERCI operates in close collaboration with important institutions like the World Health Organization (WHO), the Indian Council of Medical Research (ICMR), the Central Drugs Standard Control Organization (CDSCO), FERCAP, SIDCER (Strategic Initiative for Development.

About International Chair in Bioethics [WMA Cooperation Centre]

International Chair in Bioethics, Haifa, chaired by Professor Amnon Carmi, aims to ensure the global spread of bioethics education. This may be achieved by continuous support and facilitation of the various bioethics units through the Department of Education to pursue enhanced and effective local and international collaboration with intensified professional relations with academic institutions and other partners. One of the objectives is to promote high-quality research in the field of bioethics.

About the Conference

This conference, with a pre-conference workshop, is designed to sensitize Institutional Ethics Committee [IEC] members, Research Scholars & Investigators on crucial areas like roles and responsibilities of different stakeholders, issues for improving the quality of research activities with emerging issues in biomedical and health research in India. This conference is being organized offline and online [hybrid] to engage a wider audience.

Schedule

| | |
|------------------------|---------------------------------|
| Preconference Workshop | : 10th November 2022 |
| Conference | : 11th November 2022 |
| | : 12th November 2022 [half day] |

Focus areas

Pre-conference workshop

- ◆ Challenges experienced by biomedical and health research stakeholders
- ◆ Roles and responsibilities of stakeholders given current guidelines
- ◆ Quality improvement in biomedical and health research

Conference

- ◆ Emerging ethical issues with the use of newer technologies in health research
- ◆ Newer trends in clinical trials and adherence to quality research

Objectives

Pre-conference workshop

Upon completion of the pre-conference workshop, participants can assess and reflect on individual roles and responsibilities and the scope of improvement in biomedical research.

Conference

Upon completion of the conference, the participants will be well versed in emerging ethical issues regarding using newer technologies in health research and quality improvement

FERCI Executive Board Members

| | |
|-------------------------|------------------|
| Dr. Vasantha Muthuswamy | : President |
| Dr. Nandini Kumar | : Vice-President |
| Dr. Urmila Thatte | : Secretary |
| Dr. Sandhya Kamat | : Treasurer |

Organizing Committee

Patron

Dr. Utpala Kharod, *Provost, BKU*

Organizing Chairperson

Dr. Himanshu Pandya, *Dean, PSMC*

Organizing Secretary

Dr. Barna Ganguly, *Professor, Pharmacology*

Joint Organizing Secretary

Dr. Swati Arora Roy, *Member Secretary, IEC*

Scientific Committee

Dr. Swapnil S Agarwal, *HoD, Forensic Medicine*

Dr. R. Harihara Prakash, *Principal KMPIP*

Dr. Anusha Prabhakaran, *HoD Psychiatry*

Dr. Shweta Parikh, *Physiotherapist*

Ms. Shainy Thomas, *Nursing College*

Souvenir and Journal Subcommittee

Dr. Swapnil S Agarwal, *HoD, Forensic Medicine*

Dr. Bharat M. Gajjar, *HoD Pharmacology*

Dr. Nazima Mirza, *Professor Pharmacology*

Registration

Dr. Dinesh Kumar, Dr. Deepak Sharma

Dr. Aashish Gupta, Dr. Sonal Chitroda
Dharmendra Shah, Dharmendra Dave

Hospitality

Shailesh Panchal, Dr. Chirag Patel

Dr. Mitul Chhatrivala, Dr. Utkarsh Shah
Balkrishna Rajput, Vimal Patel

Venue Arrangements

Dr. Manisha Gohel, Dr. Alpa Gor

Important Dates:

| | |
|-----------------------------------|----------------------|
| Early Bird Registration | : 16th October, 2022 |
| Last date for Abstract Submission | : 16th October, 2022 |
| Last date of registration | : 1st November, 2022 |

Registration Fees

| Delegate Details | Mode | Till 16th October | From 17th October* |
|------------------|---------|-------------------|--------------------|
| FERCI Member | Online | Rs.3000 | Rs. 3000 |
| | Offline | Rs.5000 | Rs. 6000 |
| Non FERIC Member | Online | Rs.4000 | Rs. 4000 |
| | Offline | Rs.7000 | Rs. 8000 |
| International | Online | \$ 100 | \$ 100 |
| | Offline | | |
| Students | Online | Rs.750 | Rs.1000 |
| | Offline | Rs.2000 | Rs.2500 |

*Registration closes on 1st November 2022 (Midnight)

Registration form: google form link : <https://forms.gle/PyvTHRptg3sthDBP6>

Details for registration fee transfer:

Bank Name: Axis Bank
A/c Name: Bhaikaka University
A/c Number: 919020095966727
IFSC code: UTIB00000038
Branch Code: 038
Branch: Vallabh Vidyanagar
Type of account: Current A/C

For any queries, do write to

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barnag@charutarhealth.org - Mo.+91 971 290 6493

SCIENTIFIC PROGRAM

| Pre-Conference Workshop (10 November 2022) | | | |
|--|---|--|---|
| 8.30 – 9.15 am | Registration & Breakfast | | |
| 9.15 - 9.30 am | Welcome address | | |
| 9.30 – 9.45 am | Purpose of Preconference workshop on Quality assurance and improvement in Biomedical and health research (BHR) for EC members, Sponsors & Investigators | | |
| Session I Experience and Challenges of stakeholders | | | |
| Time | Topic | Objective | Methodology |
| 9.45- 10.45 am | Experience and Challenges of stakeholders | To identify and share the challenges of EC members, sponsors, and investigators in BHR | Interactive session [10 m] Presentation by the Resource Faculty [30 m] Q& A [20 m] |
| Tea Break [10.45 – 11 am] | | | |
| Session II Roles and responsibilities of EC members | | | |
| 11 am - 12 noon | Roles and responsibilities of EC members | To discuss the recent guidelines on roles and responsibilities of EC members | Interactive session [10 m] Presentation by the Resource Faculty [40 m] Q & A [10 m] |
| 12 – 1 pm | Roles and responsibilities of Sponsors | To discuss the recent guidelines on roles and responsibilities of Sponsors | Presentation by the Resource Faculty [45 m] Q & A [15 m] |
| LUNCH BREAK [1 – 2 pm] | | | |
| 2 – 2.30 pm | Role of other stakeholders in academic trials and BHR | To discuss the recent guidelines on roles and responsibilities of other stakeholders | Presentation by the Resource Faculty [20 m] Q & A [10 m] |
| Session III Quality improvement | | | |
| 2.30 – 3.30pm | Need for quality improvement - I | To identify the issues that require quality improvement in health research | Interactive session [10 m] Presentation by Resource Faculty [40 m] Q & A [10 m] |

| Tea break [3.30 – 3.45pm] | | | |
|---|-----------------------------------|---|---|
| 3:45 - 4:45pm | Need for quality improvement - II | To address the scope of quality improvement and assurance | Interactive session [10 m] Presentation by the Resource Faculty [40 m] Q & A [10 m] |
| Feedback of Delegates/ Participants and Valedictory session [4.45 – 5 pm] | | | |
| High tea [5 - 5:30 pm] | | | |

**9th National Conference
of Forum for Ethics Review Committees in India
PROGRAM SCHEDULE
Conference: Day I (11th November 2022)**

Focus areas:

1. Emerging ethical issues with the use of newer technologies in health research
2. Newer trends in clinical trials and adherence to quality research

| CONFERENCE : DAY I | | | |
|--------------------|---|--|---|
| 9.00 - 9.30 am | Inauguration and Introduction to the conference | | |
| Time | Topic | Objective | Methodology |
| 9:30 – 10 am | Keynote address | Global Quality Assurance and Improvement | Didactic |
| 10 – 10:30 am | Present status of research on a medical device in India | To discuss the emerging ethical issues related to device trials in India | Didactic Lecture [20 m] Q & A [10 m] |
| 10:30 – 11 am | Stem Cell Research | To discuss the challenges and ethical issues in Stem Cell Research | Didactic Lecture [20 m] Q & A [10 m] |

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|---|--|---|---|
| 11 am -11:30 am | Research using Artificial Intelligence | To discuss ethical issues in research on the use of Artificial Intelligence | Didactic Lecture [20 m] Q & A [10 m] |
| Tea break [11:30 - 11:45 am] | | | |
| 11:45 am-12:15 pm | Research on vulnerable population | To discuss the ethical implications of research on vulnerable population | Didactic Lecture [20 m] Q & A [10 m] |
| 12:15 - 12:45 pm | Monitoring of health research | To discuss quality improvement during monitoring of health research | Didactic Lecture [20 m] Q & A [10 m] |
| 12:45 - 1:15 pm | Responsible conduct of research: Authorship conscience | To discuss the challenges and ethical issues in publishing research work | Didactic Lecture [20 m] Q & A [10 m] |
| LUNCH BREAK [1:15 - 2 pm] | | | |
| 2 - 4 pm | Paper presentation | | |
| | E poster Presentation (ONLINE) | | |
| High tea [4 - 4:30 pm] | | | |
| General Body Meeting [4:30 pm onwards] | | | |

PROGRAM SCHEDULE
Conference : Day II (12th November, 2022)

| CONFERENCE : DAY II | | | |
|--|---|--|-------------|
| 8:30 - 9:15 am | Breakfast | | |
| Newer trends in clinical trials | | | |
| Time | Topic | Objective | Methodology |
| 9:15 - 9:45 am | Introduction to Decentralized Clinical Trials (DCT) - Lay of the land | <ul style="list-style-type: none"> To identify the need & scope To address nuances/ status of decentralized clinical trials Direct to patient shipment of the medicinal product | Didactic |

| | | | |
|---|--|--|-------------|
| 9:45 – 11 am | Deep diving into DCT capabilities and their ethical issues | <ul style="list-style-type: none"> Ethical Challenges and reviewing DTP-MP in a clinical trial | Minilecture |
| | | <ul style="list-style-type: none"> Home Health Nursing in Clinical Trials Ethical Challenges and Pragmatic review of HHN | Minilecture |
| | | <ul style="list-style-type: none"> Telemedicine in Clinical Trials Ethical Challenges and Pragmatic review of Telemedicine | Minilecture |
| | | <ul style="list-style-type: none"> Pragmatic review of eCONSENT | Minilecture |
| Tea Break [11 – 11:15 am] | | | |
| Ethical issues related to research in AYUSH | | | |
| 11,15 -11.30 | Quality of conduct of clinical trial in AYUSH | | |
| 11.30- 11.45am | Quality design in proposal on AYUSH | | |
| 11.45 – 12.00 | Standardisation of formulations | | |
| 12.00- 12.15pm | Experience from industry | | |
| 12:15 – 12:30 pm | Global Clinical Trial Scenario | | |
| 12:30 – 12:45 pm | Valedictory speech on "Spiritual Intelligence in adherence to Ethical Standards in Research" | | |
| 12:45 onwards | Prize distribution Summary and End of Conference | | |
| LUNCH [1.30 pm onwards] | | | |