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

FERCICON 2022 (ONLINE)

10 to 12 November, 2022

Organized by
Unit of International Chair in Bioethics [WMA Cooperation Centre]
Bhaikaka University
Karamsad, Anand, Gujarat INDIA 388325

विद्या विमुक्तिदायिनी
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.

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

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 ONLINE to engage a wider audience.

FERCI Executive Board Members

President : Dr. Vasantha Muthuswamy

Vice-President : Dr. Nandini Kumar

Secretary : Dr. Urmila Thatte

Treasurer : Dr. Sandhya Kamat

Organizing committees

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 & 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
Logistic Arrangements	:	Shailesh Panchal, Dr. Chirag Patel Dr. Mitul Chhatriwala, Dr. Utkarsh Shah Dr. Manisha Gohel, Dr. Alpa Gor Balkrishna Rajput

Message from the Desk

Patron

Dr. Utpala Kharod
Provost
Bhaikaka University, Karamsad, Gujarat

Message

It give me immense joy to write this message for 9th National Conference of FORUM FOR ETHICS REVEIW COMMITTEE OF INDIA, the national chapter of India under FERCAP (FORUM FOR ETHICS REVIEW COMMITTEES IN ASIA and THE PACIFIC) organized at Bhaikaka University, Gujarat.

The theme of the conference **"Quality assurance and improvement in Biomedical and health research (BHR): The way forward"** is a very pertinent topic of discussion today in the field of biomedical and health research.

I am sure that the convergence of participants and speakers from different areas health research from within the country and outside will enrich the knowledge of the participants leading to better outcomes in quality assurance and improvement in research and publications.

I wish the conference the event every success.

Dr. Utpala Kharod

Message from the Desk

Organizing Chairperson,

Dr. Himanshu Pandya,
Dean & Professor of Medicine and Medical Education
Pramukhswami Medical College, Karamsad, Gujarat, India
Past President, Academy of Health Professions Educators (India)

Message

It gives me great pleasure to write this message on the occasion of 9th Annual Conference of FERCI (FERCICON 2022). The organizers of this conference have chosen a theme focusing on Quality Assurance and Improvement in Biomedical and Health.
The conference is preceded by a pre-conference workshop designed to sensitize Institutional Ethics Committee [IEC] members, Research Scholars and Investigators on crucial areas like roles and responsibilities of different stakeholders, issues for improving the quality of research activities.

The organizers have planned interesting topics for the conference. We wish the participants will enjoy the proceedings and have useful learning experiences. Though planned in hybrid mode to begin with, the organizers had to settle for online conference just few days before the conference. We regret the inconvenience caused to the participants who wanted to enjoy the proceedings onsite.
I take this opportunity to thank the Forum for Ethics Review Committee of India (FERCI) for giving us the opportunity to host this conference. I also thank Dr Vasantha Muthuswamy and Dr Nandini Kumar for their continuing guidance.

Dr Himanshu Pandya

Message from the Desk

Organizing Secretary

Dr. Barna Ganguly
Professor, Department of Pharmacology
Assistant Dean (Professional Development)
P.S.Medical College,
Bhaikaka University, Karamsad, Gujarat

Message

"We do not need magic to change the world, we carry all the power we need inside ourselves already: we have the power to imagine better"

J.K.Rowling

There is a ripple of thought on quality of biomedical research calling for constant improvement. It is necessary to make sure that quality never deteriorates, so that we can come out with good quality research in our country.

9th Annual conference of FERCI (ONLINE) has been planned with the theme: "**Quality assurance and improvement in Biomedical and health research (BHR): The way forward"** with objective of emphasizing mainly on quality issues and improvement of health research in different aspects of biomedical research and emerging ethical issues regarding using newer technologies in health research. To achieve this, it is necessary to start discussion with different stakeholders in an integrated way in a common platform including experts from AYUSH.

This conference is an effort to look into this matter for better outcome (thinking in line of J.K.Rowling)!

I take this opportunity to convey my heartfelt thanks to one and all taking part and contributing in this conference in some way or other and making this event successful.

(Dr. Barna Ganguly)
Organizing Secretary

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

FERCICON 2022 (ONLINE)

[**THEME**: Quality assurance & improvement in health research]

10th, 11th& 12th November 2022

Programme

Pre-Conference Workshop (10 November 2022)				
9.15-9.30 am	Welcome address by Dean, Dr. Himanshu Pandya			
9.30–9.45 am	Purpose of the Preconference workshop on **Quality assurance and improvement in Biomedical and health research (BHR)** for EC members, Sponsors & Investigators		Dr. Barna Ganguly Bhaikaka University, Karamsad	
Session I - Experience and Challenges of stakeholders				
Time	**Topic**	**Objective**	**Faculty**	**Coordinator**
9.45-10.30 am	Experience and Challenges of stakeholders	To identify and share the challenges of EC members, sponsors, and investigators in BHR	Dr. Umapati Hegde Muljibhai Patel Urological Hospital, Nadiad	Mr. Shailesh Panchal & Dr. Ashish Gupta
Session II - Roles and responsibilities of EC members				
10.40-11.25 am	Roles and responsibilities of EC members	To discuss the recent guidelines on the roles and responsibilities of EC members	Dr. S.S. Agarwal Bhaikaka University, Karamsad	Dr. Alpa Gor, Dr. Chirag Patel & Ms. Shany Thomas
11.25 am-12.10 pm	Roles and responsibilities of Sponsors	To discuss the recent guidelines on the roles and responsibilities of Sponsors	Dr. Charu Gautam IQVIA, Ahmedabad	
12.15–1 pm	Role of other stakeholders in academic trials and BHR	To discuss the recent guidelines on the roles and responsibilities of other stakeholders	Dr. Santanu Tripathi Calcutta School of Tropical Medicine, Kolkata	
Break [1 – 2 pm]				

Session III - Quality improvement				
2.00–2.45 pm	Need for quality improvement - I	To identify the issues that require quality improvement in health research	Dr. Sudha Ramalingam PSGIMER, Coimbatore	Dr. Mitul Chhatriwala & Mrs. Sonal Chitroda
2.50–3.35 pm	Need for quality improvement - II	To address the scope of quality improvement and assurance	Dr. Sucheta Banerjee Kurundkar CDSA, THSTI	
3.45–4.30 pm	Open Session (Question Answer and Sharing Experience of Participants)			Dr. Anusha Prabhakaran
Feedback and Valedictory Session [4.30 pm onwards]				

FERCICON 2022 ONLINE

CONFERENCE, DAY I [11th November 2022]				
9-9.30 am	Inauguration and Introduction to the conference			
Time	**Topic**	**Objective**	**Invited Speaker**	**Chair**
9.30–10 am	Keynote address	Global Quality Assurance and Improvement	Dr. Juntra Karbwang Mahidol University, Thailand	Dr. Vasantha Muthuswamy & Dr. Himanshu Pandya
10.10–10:25 am	Present status of research on a medical device in India - I	To discuss the emerging ethical issues related to device trials in India	Dr. Bikash Medhi PGIMER, Chandigarh	Dr. Santanu Tripathi & Dr. Swapnil Agarwal
10.25–10:40 am	Present status of research on a medical device in India - II	To discuss the ethical issues related to Materiovigilance: Indian Perspective	Dr. V. Kalaiselvan Indian Pharmacopeia Commission, Ghaziabad	
10:45–11.15 am	Stem Cell Research	To discuss the challenges and ethical issues in Stem Cell Research	Dr. Neeraj Sidharthan Amrita Institute of Medical Sciences, Kochi	Dr. Roli Mathur & Dr. Umapati Hegde
11.15-11:45 am	Research using Artificial Intelligence	To discuss ethical issues in research on the use of Artificial Intelligence	Dr. Vidur Mahajan CARPL, N. Delhi	

Break [11.45 am – 12.00 noon]				
12.00–12.30 pm	Research on vulnerable population	To discuss the ethical implications of research on vulnerable population	Dr. Urmila Thatte Seth GS Medical College & KEM Hospital, Mumbai	Dr. Sandhya Kamat & Dr. Dinesh Kumar
12.30–01 pm	Monitoring of health research	To discuss quality improvement during the monitoring of health research	Dr. Yashashri Shetty Seth GS Medical College & KEM Hospital, Mumbai	
Break [1.00 – 1.45 pm]				
01.45–2.15 pm	Responsible conduct of research: Authorship conscience	To discuss the challenges and ethical issues in publishing research work	Dr. Nithya Gogtay Seth GS Medical College & KEM Hospital, Mumbai	Dr. Nandini Kumar & Dr. Barna Ganguly
2.15–2.45 pm	Global Clinical Trials involving Healthy Volunteers	To discuss the role of and challenges faced by the ethics committee	Dr. François Bompart DNDi, Switzerland	
3 pm onwards	Free Paper Presentations			
6:15 pm onwards	General Body Meeting [FERCI Members only]			

Paper/ Poster presentations [3 – 5 pm]

Time	Topic	Presenter	Chair
3 – 3:10 pm	Evaluation of knowledge and awareness of clinical trials among undergraduate, interns, and post-graduate medical students	Firoz Tadvi	Dr. Sandhya Kamat & Dr. Deepak Sharma
3:15 – 3:25 pm	Adherence to CHEERS guidelines for published Pharmacoeconomic studies in PubMed-indexed Medical Journals over one year (2021-2022)	Mitesh Maurya	
3:30 – 3:40 pm	Impact Of Accreditation On Registered Ethics Committee in terms of Quality And Governance In India: A Cross-Sectional Study	Mrunalini Kalikar	
3:45 – 3:55 pm	Evaluation of factors that act as barriers to conducting academic clinical trials	Snehlata Gajbhiye	

4 – 4:10 pm	To assess knowledge and awareness about academic clinical trials among investigators	Shruti Bhide	
4:15 – 4:25 pm	Difficulties in bringing ethics into Homoeopathic practice and research- some critical considerations	Subhadra KT	
4:30 – 4:40 pm	Readability of Informed Consent Documents and its impact on Consent Refusal Rate	Yash Kamat	
4:45 – 4:55 pm	Ethical issues in secondary research: Opinions of EC members vis-à-vis researchers	Ravi Vaswani	
5 – 5:10 pm	Ethics in research involving older people	Subhadra KT	
5:15 – 5:25 pm	Medical ethics in Ayurveda	Anjali Goyal	
5:30 – 5:40 pm	Status of registration and re-registration and accreditation of Ethics Committees in CDSCO, DHR, and NABH – evaluation of the extent of ethics oversight in the country	Ananya Rakshit	
5:45 – 5:55 pm	Ethics in Health Policy and Systems Research (HPSR)	L Surbala	
6 – 6:10 pm	Ethical Guidelines in Research, Registration and Accreditation of EC or IRB in India	Siddaram Sarate	

FERCICON 2022 (ONLINE)

CONFERENCE, DAY 2 [12th November 2022]				
Newer trends in clinical trials				
Time	**Topic**	**Objective**	**Invited Speaker**	**Chair**
9.15 – 9.45 am	Introduction to Decentralized Clinical Trials (DCT) - Lay of the land	• To identify the need & scope • To address nuances/ status of decentralized clinical trials • Direct-to-patient shipment of the medicinal product	Dr. Seema Pai Pfizer, India	Dr. Urmila Thatte & Dr. Swati A Roy
9:45 – 11 am	Deep diving into DCT capabilities and their ethical issues	• Ethical Challenges and reviewing DTP-MP in a clinical trial	Mrs. Chandana Pal Apollo Research and Innovations, Chennai	Dr. Nandini Kumar & Dr. Amol Dongre

		• Home Health Nursing in Clinical Trials • Ethical Challenges and Pragmatic review of HHN	Dr. Pooja Sharma Medanta Institute of Education & Research, Gurgaon	
		• Telemedicine in Clinical Trials • Ethical Challenges and Pragmatic review of Telemedicine	Dr. Ramesh Jagannathan Bharat Serum and Vaccines Ltd., Bangalore	
		• Pragmatic review of eCONSENT	Dr. Chirag Trivedi Sanofi, India	
Break [11 – 11:15 am]				
Ethical issues related to research in AYUSH				
11.15-11.30 am	Quality design in the proposal on AYUSH		Dr. Pradeep Dua Bureau of India Standard, New Delhi	Dr. R. N. Acharya & Dr. Bharat M Gajjar
11.30-11.45 am	Standardization of formulations		Dr. D. C. Katoch Advisor, Ministry of AYUSH, New Delhi	
11.45 am–12 noon	Experience from industry		Dr. Mukesh Chawda Solumiks Herbaceuticals Limited, Mumbai	
12.00-12.15 pm	Quality of conduct of the clinical trial in AYUSH		Dr. Supriya Bhalerao Bharati Vidyapeeth Deemed University, Pune	
12.15–12.30 pm	Valedictory speech - How to manage the Emotional Stress of Research Governance		Dr. Soumitra Datta Tata Medical Centre, Kolkata	Dr. Swati A Roy & Dr. Barna Ganguly
12.30 pm	Prize announcement, Summary, and **End of Conference**			

Speakers Notes:

Experience and challenges of Stakeholders

Dr Umapati Hegde,

MD, DNB (Nephr). Vice chairman, Dept of Nephrology, M P U Hospital, Nadiad.

Research is needed to improve healthcare and it can find answers to things that are unknown, filling gaps in knowledge and changing the way that healthcare professionals work. Stakeholders in medical research are sponsors, iinvestigators and his team, government agencies, Regulatory authorities, monitor, Institutional review board.

Investigator challenges – (1) Inadequate infrastructure / resources needed including management of Serious adverse event. (2) High turnover of junior doctors/ sub-investigators and poor patient doctor ratio leading to inadequate patient care and poor patient follow-up. (3) Patient logistic/ travel related challenges with frequent visits. (4) Lack/ inadequate patient disease data base with follow-up of the disease under investigation (5) Lack of knowledge/ awareness of GCP, NDCT (New drug CT) rules and its training. (6) Inadequate institutional support for promoting/ conducting research. It needs collaboration with other departments for the smooth running of trial. With more and more experience of the investigator and his team, research can be smooth lined to reduce protocol deviations and for the success of the trial

Ethical challenges are (1) To recruit and maintain ethical members who can give adequate time (2) Inadequate quorum for the meeting (3) Inadequate infrastructure for record keeping. (4) Improper review of protocols and reported SAEs. (5) Lack of monitoring of ongoing protocols (6) Infrequent meeting and lack of time for discussion on each protocol.

Sponsor challenges; Develop of a new drug and evaluation is complex and costly process. (1) Sponsor may not have Clinical trial experience, and may face difficulty in getting investigator and study staff with experience with adequate patient population. (2) Adequate site resources and facilities including specified equipment and storage and dispensing the IMP. Sponsor can hire Contract Research Organization (CRO) to regulatory affairs, site selection and activation, recruitment support, clinical monitoring, data management, trial logistics, pharmacovigilance, biostatistics, medical writing, and project management, among others.

Success of the trial and Performance depends on the enrolment of the subjects, data quality, retention, and appropriate follow up till the completion with appropriate reporting of adverse events.

Roles & responsibilities of ethics committee members

Agarwal, Swapnil S
Professor & Head, Forensic Medicine & Toxicology, PS Medical College & SK Hospital, Bhaikaka University, Karamsad

The responsibility to safeguard the dignity, rights, safety, and well-being of research participants rests with Institutional Ethics Committees/ Institutional Review Boards/ Independent Ethics Committees. To ensure the same, there needs to be a framework within which either of them should function. To maintain a uniformity of this framework, various guidelines and regulations are in place. Members of these committees usually consist of faculties who are qualified by education, training, and experience in their respective fields. Hence, to have efficient functioning of these ethics' committees/ review boards, their members need to be aware of their roles and responsibilities within the existing guidelines and regulations.

The current presentation revisits the historical perspectives about advent of ethics committees/ review boards and educates the reader/ participant about the existing guidelines, regulations governing them with their expected roles and responsibilities in safeguarding the dignity, rights, safety, and well-being of research participants.

Key words
Ethics committee, review board, composition, responsibility, regulations, guidelines

Roles and Responsibilities of a sponsor

Dr Charu Gautam
MD, DNB. Head -clinical development– Asia Pacific IQVIA

A sponsor is an individual, company, institution, or organization which takes responsibility for the initiation, management, and/or financing of a clinical trial.

The roles and responsibilities of a sponsor are very critical to the success of a clinical trial. The sponsor is overall responsible for the design , conduct , analyses and reporting of clinical trials. The sponsor may delegate part or whole of its responsibilities to various stakeholders, however the overall responsibility always lies with the sponsor.

This session aims to describe the various roles and responsibilities of a sponsor during the conduct of a trial including trial design and management, data handling and record keeping, management of Investigational product , Monitoring a clinical trial , handling multicentric studies , Quality control and quality assurance during the conduct of clinical trial. The sponsor is also responsible for selecting the appropriate investigators who will recruit the patients according to the protocol. Overarching all these responsibilities is to ensure that the data generated in the study is reliable and accurate and have direct access to it for regulatory inspections and to ensure that the rights safety and wellbeing of trial participants is protected.

Ethical concerns in clinical trials of medical devices in India

Prof. Bikash Medhi

Institute: Department of Pharmacology, Postgraduate Institute of Medical Education and Research, Chandigarh 160012,India

It is true that ethical issues arise when working with systems related to medical devices or apparatuses or tools during the clinical development process. Such devices' primary feature is that they are used to diagnose, treat, and rehabilitate human participant. As a result, they provide discoveries in a crucial area of applied research with immediate ramifications for culture, the economy, and the society. In order to preserve the accurate and proper usage of these technologies and prevent the development of dangers and hazards for patients' health, the function of safety and performance standards is vital. Clinical trials are currently massive, highly regulated organizations that must balance adhering to ethical norms with upholding high epistemic standards as the complexity of the research issues develops.

The Ethics Committee (EC) makes sure that the standards, regulations, and laws are followed. The regulations permit the Ethics Committee to accelerate proposals' reviews if the study entails no more than minimal risk. EC's primary concern is whether and under what circumstances it may be justified to subject some people to risks and obligations in order to benefit others. The most frequent issues with clinical trials are on inadequate informed consent and a lack of voluntarily informed participation. Finally, although being widely underappreciated, ethical dilemmas encompass a wide range of cultural, therapeutic, and managerial considerations that are not always restricted to the ideas of contemporary biomedical technology. Therefore, it is just as crucial to assess the ethical justification that are being followed in any device studies as it is in medication trials.

Key words: medical Devises, ethics, clinical trials

Telemedicine in Clinical Trials: Ethical Challenges and Pragmatic review of Telemedicine

Ramesh Jagannathan,
MBBS, MD, MSc

Telemedicine involves use of technology (computers, mobile communications and image/video transfer via internet and digital means) by healthcare professionals to provide clinical services to patients without being physically present before them. The COVID-19 pandemic accelerated the adoption of this concept in clinical research in which patients or volunteers participate to enable advances with newer and existing treatments. Telemedicine can address the participants' concerns on convenience, and improve diversity, equity and access for patients in clinical trial participation. Medical obligations, the inability to protect patient privacy and confidentiality, profiles on the subject of authorization and jurisdictional issues are few potential legal and ethical implications of adopting telemedicine-based approaches. The challenges in adopting telemedicine in developing countries include inadequate healthcare professionals and medical specialists, insufficient internet access in remote locations, and many patients who are not educated. The challenges related to technology can be addressed through training, changing management strategies, combination of direct patient to health care provider contact and telemedicine. With proper implementation of regulatory and ethical considerations, leveraging partnerships with existing telemedicine providers, enhancing collaborations across stakeholders, telemedicine can benefit patients who participate in clinical trials. The uptake of telemedicine was accelerated during pandemic for patient clinical care and is expected to have a significant and positive impact on clinical research benefitting both patients and healthcare providers.

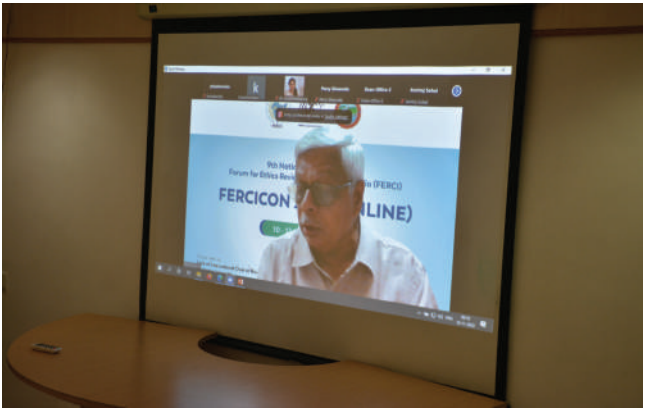
Standardization of AYUSH Formulations

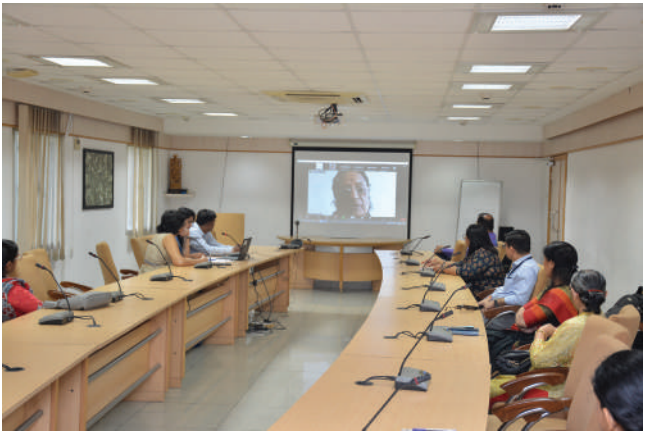
Dr. D.C. Katoch
Sr CMO (Ay.), CGHS
Former Adviser (Ay.), Ministry of AYUSH

Standards are the essential pre-requisite for regulation and quality control of Ayurvedic, Siddha, Unani and Homeopathic (ASU&H) drugs like for conventional drugs of the modern medical system. The responsibility of standards setting of these drugs is vested with the respective Pharmacopoeia Committees and Pharmacopoeia Commission of Indian Medicine & Homeopathy set up by the Government of India under the purview of Ministry of AYUSH. Specifications and Standards of single-ingredient based or multi-ingredient based classical or generic ASU drugs mentioned in 104 authoritative books enlisted in the first schedule to the Drugs & Cosmetics Act, 1940 are prescribed respectively in the respective Formulary and Pharmacopoeia . Whereas standards of Homeopathic drugs are prescribed only in officially recognized Homeopathic Pharmacopoeia of India and for any proprietary formulations or new combinations of ASU drugs need to have and follow in-house standards in the pharmacopoeial format. The work of standardization of ASU&H formulations started and is under way with the establishment of pharmacopoeia committees since 1962 . Presently, monographs of standards of 848 Ayurvedic formulations, 499 Unani formulations, 140 Siddha formulations and 1117 Homoeopathic formulations in different dosage forms are published in the respective pharmacopoeias.

Each pharmacopoeial monograph of single drug standards provides title & definition, classical names, names in regional and English language, description of macroscopic features - microscopic features - powder features - diagram with self-explanatory captions, pharmacoognosy / identification with HPTLC/HPLC/GC profile, phytochemical reference markers wherever possible, physico-chemical parameters (whichever applicable), prominent functional groups, limits for heavy metals (Mercury/Lead/Cadmium/Arsenic) - microbial contamination - pesticide residues-aflatoxins (B1, B2, G1, G2), Properties and Actions , dose, important formulations and therapeutic uses. Similarly, monographs of multi-ingredient formulations comprise of title, Definition , Formulation Composition , Method of Preparation , Description, Identification including Powder Microscopy and Chromatographic (HPTLC/HPLC/GC) Profile, Physico-chemical Parameters (whichever applicable) including moisture content , total ash , acid-insoluble ash , alcohol-soluble extractive , water-soluble extractive , pH (5% aqueous suspension), hexane soluble extractive, volatile oil content (%v/w), any other suitable parameter (based on dosage form and ingredients of the formulation) , Assay of suitable elements / functional groups / compounds , phytochemical reference markers wherever possible (Quantitative analysis preferred), Limits for Heavy metals - (Mercury/Lead/Cadmium/Arsenic) - Microbial contamination - Pesticide residues -Aflatoxins (B1, B2, G1, G2) , dose and therapeutic uses.

Glimpses of Conference





Oral presentation Abstracts:

OP 1:

EVALUATION OF KNOWLEDGE AND AWARENESS OF CLINICAL TRIALS AMONG UNDERGRADUATE, INTERNS AND POST-GRADUATE MEDICAL STUDENTS.

Dr. Firoz Tadavi*, Dr. Sudhir Pawar, Dr. Ajitkumar Gondane, Dr. Likith H.S, Dr. Pravin Dhage, Dr. Yashvira Patil [Lokmanya Tilak Municipal Medical College & General Hospital Sion, Mumbai- 400022]

Abstract:

Aim: The aim of the study was to evaluate the knowledge and awareness of clinical trials among undergraduate, interns and post-graduate medical students

Methodology: We conducted a cross-sectional questionnaire-based study in 3 months with 300 participants (150 undergraduate & interns and 150 postgraduate medical students) at a tertiary care centre in Mumbai. The questionnaire was designed & was validated by experts from various departments of our institute. Participants were contacted through WhatsApp and Google form was circulated. The data was summarized in percentages and frequencies. The Data was analyzed by using descriptive statistics. p-value <0.05 was considered significant. The analysis was performed using SPSS version 25.

Results & conclusion: 93.7% of the participants were aware of the term clinical trial and only 33.7% could completely understand and define clinical trial. 96.7% believed that there is a need for CT. 93% believed that clinical trial helps to bring out newer therapies and 74.3% believed that it improves health services. 46.7% were not sure about the clinical trial being conducted in an ethical manner. 56.3% knew the full form of the GCP guidelines whereas only 46.7% were aware of the GCP guidelines. Only 12.3% were aware of the primary purpose of the IEC. 95.3% were aware of the proceedings of the ICF & 90.7% agreed to fact that the data should be kept confidential. More number of PGs (63.3%) knew about the reporting of the adverse effects during the trial. Only 42% of the PGs and 38% of the UGs knew that the sponsors were responsible for compensation in case of clinical trial-related injury.

OP 2:

ADHERENCE TO CHEERS GUIDELINES FOR PUBLISHED PHARMACOECONOMIC STUDIES IN PUBMED-INDEXED MEDICAL JOURNALS OVER ONE YEAR (2021-2022).

Munshi R*, Maurya M * [*Department of Clinical Pharmacology, Topiwala National Medical College and BYL Nair Charitable Hospital, Mumbai 400008.]

Abstract :

Introduction: Economic evaluation of health interventions studies should follow CHEERS [Consolidated Heath Economic Evaluation Reporting Standards] guidelines for reporting and publication. The CHEERS 2022 guideline, a 28 items checklist, is an attempt to consolidate and update the previous 2013 guidelines (24-items checklist) to make it a useful reporting guidance. These reporting standards are to be followed by researchers reporting economic evaluations and also for editors and peer reviewers assessing them for publication. Very few studies have been previously published assessing the adherence of published health economic intervention studies to CHEERS. Hence, we planned our study with the objective to evaluate the adherence of PubMed indexed medical journals to CHEERS guideline for pharmacoeconomic studies.

Methods: The study has been exempted from ethics review as the data is available on public domain. PubMed database search was performed using keywords "Pharmacoeconomic study" OR "Pharmacoeconomic analysis". This study assessed the adherence to CHEERS guidelines among PubMed-indexed medical journals over year [from November 10, 2021 to October 11, 2022] and the extent of endorsement of these guidelines by journals. Full text publications of pharmacoeconomic studies with drug interventions published in PubMed indexed medical journals were evaluated for adherence to CHEERS statement 2013 and updated CHEERS 2022 statement. Each article was assessed for 1] Type of pharmacoeconomic study performed (e.g cost effectiveness/utility, cost benefit, cost minimization, budget impact analysis) 2] Type of interventions used (drug, diagnostic, behavioural, digital) 3] whether they followed any of the CHEER guidelines 4] If the CHEERS guidelines were followed then whether CHEERS 2013 or 2022 checklist items were followed with year of publication.

Results: PubMed database search with appropriate keywords yielded 1226 studies over a year. However, of 1226 studies, 744 studies were found to be non-relevant [not a health-related economic study]. Thus, 152 studies were shortlisted as

health economic research studies that included different types of intervention - behavioural [4/152, 2.63%], diagnostics [13/152, 8.55%], surgical or medical devices [10/152 19.23%], drugs [64/152, 42.11%], non-interventional reviews [61/152, 40.13%]. As part of our final pharmacoeconomic study analysis, we focused on N=64 drug intervention studies only [drug, vaccines and blood products] and evaluated these for adherence to CHEERS 2013 and updated CHEERS 2022 statement. Of these 64 pharmacoeconomic studies, only 11/64 (17.18%) studies adhered to the CHEERS statement. All these eleven studies were published in year 2022 [5 studies submitted in year 2022 and 6 studies were submitted in year 2021]. However, only 4/11 [36.36%] studies followed the updated CHEERS 2022 statement and 7/11 [63.63%] studies still followed the previous version of CHEERS 2013 statement.

Conclusion: As part of research publication ethics, it is strongly recommended for authors, reviewers and journal editors to adhere to CHEERS guidelines for publication of health economic intervention studies. In our study, we have observed very few published pharmacoeconomic studies [17%] adhering to CHEERS guidelines 2013 or 2022. Also, authors, reviewers and journal editors need to be aware of the updated CHEERS 2022 guidelines.

OP 3:

IMPACT OF ACCREDITATION ON REGISTERED ETHICS COMMITTEE IN TERMS OF QUALITY AND GOVERNANCE IN INDIA: A CROSS SECTIONAL STUDY

Dr .Ganesh Dakhle, Dr. Mrunalini Kalikar* [Department of Pharmacology, AIIMS Nagpur]

Abstract:

Introduction: Ethics Committee accreditation is a process to assess the performance against a set of standards. Very few studies have shown that process of accreditation results in the improvement of the overall functioning of ECs in terms of quality and governance. Hence, the present study was planned to evaluate the impact of accreditation on registered EC in terms of quality and governance and to compare functioning of accredited versus non accredited EC in terms of quality and governance.

Materials and Methods: Study design: This was a cross sectional, observational, questionnaire-based survey conducted on 28 registered Ethics Committee in India after approval from the Institutional Ethics Committee. .Accredited(n=12) and non-accredited EC 's (n=16) reviewing clinical trials were included in the study.

Results: Accredited EC's (n=12) were compared for NABH standard for accreditation before and after accreditation in terms of percentage. It was found that majority of the standards related to structure and composition , adherence to specific policies , completeness of review and after approval process were met by majority of EC's after accreditation .Only a few EC 's fulfilled some of the criteria before accreditation. There was a statistically significant difference with reference to adherence to specific policies by accredited and non-accredited EC's like updating SOP according to changing requirements ($p<0.0237$), process for preparing SOP ($p<0.0237$),categorization of review process mentioned in SOP ($p<0.0237$) procedure to be followed for vulnerable population ($p<0.0103$) , process of handling issues related to complaints by participants and other stakeholders violation ($p<0.0103$) etc. Comparison of completeness of review process and after approval process between accredited and non accredited ECs showed statistically significant difference for the criteria of EC ensuring whether reimbursement and compensation paid to the subject is appropriate as per the contract($p <0.0103$)

Conclusion: Accreditation results in improving of EC functioning in terms of quality and governance.

OP 4:

EVALUATION OF FACTORS THAT ACT AS BARRIERS TO CONDUCTING ACADEMIC CLINICAL TRIALS

Gajbhiye SV*, Dakhale GN, Chindhalore CA, Gupta A, Tamil Selvi [All India Institute Of Medical Sciences, Nagpur]

Abstract:

Aim: The aim of the study is to evaluate the investigator's perception of obstacles to carrying out academic trials and to identify factors that will motivate investigators in conducting academic trials.

Methodology: We conducted a prospective observational study in a tertiary care hospital for 2 months. Faculty members working in academic institutes were selected. A structured questionnaire was designed for the study and administered using google forms. Validity and reliability assessments were carried out. Responses were taken on a Likert scale. The data was summarized in percentages and frequencies. Mann-Whitney test was applied to assess differences between demographic groups; $p < 0.05$ was considered significant.

Results: 78 faculty members participated in the study. Content validation ratio was calculated as 0.854 and test-retest reliability was found to be 0.56. Obtaining funds (40%) and payment towards compensation of adverse events (43%) were identified as major challenges. Inadequate time (35%) and training of staff (38%) were identified as moderate challenges. There were significantly higher challenges perceived by faculty members working for a duration of less than 10 years and had not undertaken any trials in the past as compared to those working for more than 10 years and had undertaken any trial in the past respectively.

Conclusion and recommendations: The institutes or national bodies must make provisions to financially support the academic clinical trials and also provide compensation for trial-related adverse events. Early exposure of researchers to academic clinical trials will reduce the perception of hurdles.

OP 5:

TO ASSESS KNOWLEDGE AND AWARENESS ABOUT ACADEMIC CLINICAL TRIALS AMONG INVESTIGATORS.

Bhide Shruti*, Snehal Ambre, Saurabh Patil, Renuka Munshi, Neha Kadhe, Chetan Phirke, Amitoj Sohal, Sudhir Pawar, Ruchita Patil [[1,3,6,7]Department of Pharmacology & Therapeutics, GSMC & KEM Hospital, Mumbai; [2]Department of Biotechnology, The Institute of Science, Mumbai, [4,9]Department of Clinical Pharmacology, TNMC & BYL Ch. Nair Hospital, Mumbai, [5,8]Department of Pharmacology, LTGMC Sion Hospital, Mumbai]

Abstract:

Introduction: In 2019, CDSCO issued guidelines for 'Clinical Trials' and 'Biomedical and Health Research' in the gazette G.S.R.227(E) / New Drugs and Clinical Trials Rules 2019 (NDCTR). These rules clearly defined the difference between a clinical trial and an academic clinical trial (ACT), with well-defined guidelines for the regulatory clinical trials. However, ACTs are expected to follow Indian Council of Medical Research (ICMR) 2017 guidelines. An Academic clinical trial is conceived, planned, and managed by individual physician/researchers or an institution or a collaboration of clinical researchers or institutions. These pose a lot of challenges in conduct of ACTs and investigators must know guidelines thoroughly, hence we planned this study to assess knowledge and awareness of ACT among investigators.

Methodology: The study was commenced after obtaining approval from the Institutional Ethics Committee from the 3 tertiary care hospitals of Mumbai. Study was conducted in 2 phases. In Phase 1 we assessed the number of ACTs registered at CTRI (Apr 2019- Oct 2022) and number of ethics committees registered at DCGI and DHR as on October 2022. In Phase 2 we assessed knowledge and awareness about ACTs among academicians by using a pre-validated questionnaire.

Findings: A total of 10207 studies that may fall under ACT were registered at CTRI and ethics committees registered were1410, re-registered were 1748. Ethics committees registered at DHR were 658 (provisional) and 168 (final). 100 participants consented were aware that there are guidelines to be followed for the conduct of clinical trial. 67% participants were aware that the guidelines for ACT differ from that of sponsored clinical trial. However, only 58% participants were aware of exact definition Academic clinical trial as per NDCTR, 2019. General knowledge assessed regarding initiation -85%, intervention-30% and regulatory applicability of results -27%. Guideline specific -17 % knew guidelines to be followed for ACTs and 73 % knew what type of studies fall under ACT.71% knew that SAEs occurring in ACT need to be reported but knowledge about compensation was poor. Few investigators cited perceived challenges and practical experience with conduct of ACTs.

Conclusion: Although some awareness about ACT is there, knowledge needs improvement for better conduct of ACTs.

OP 6:

DIFFICULTIES IN BRINGING ETHICS INTO HOMOEOPATHIC PRACTICE AND RESEARCH- SOME CRITICAL CONSIDERATIONS

Dr Subhadra KT* [School of Family health Studies (on deputation), Kerala University of Health Sciences]

Abstract:

Background: Homoeopaths always argue that the research methodology and ethics is not completely inclusive and friendly towards the Homoeopathic approach of therapy. The wholistic and individualistic approach of homoeopathic management makes it difficult to conduct randomized clinical trials which is the golden standard in any research. Most of the active researches which are conducted by Homoeopaths become graded as low quality due to variability in the intervention given to the participants. This again becomes a matter of concern from the ethical point of view. But this is countered by the homoeopathic practitioners by the fact that they are able to address the concerns of patients individually and wholistically. What are the major ethical as well as "good research" concerns in Homoeopathic racticee as well as homoeopathic research and what are the practical solutions for such concerns- a review was conducted based on the above concerns to address the issues of ethics in research in homoeopathy.

Objective: To review the ethical concerns and research concerns in publications from the years of 2011-2021 related to Homoeopathy.

Methodology: Literature reviews carried out in the PubMed using the following describers -barriers with research in homoeopathy, ethical constraints in research in homoeopathy, constraints with research in Homoeopathy, difficulties with research in homoeopathy, ethics and homoeopathic research, difficulties in ethical approaches in homoeopathic research.

Results and conclusions: Though no articles were available on difficulties in ethical approaches in homoeopathic research, many articles had been published on the ethical concerns with mainstreaming of Homoeopathy and other AYUSH systems in the society. It is high time to discuss on the factors related to difficulties in following ethics in Homoeopathic research and practice and make necessary corrections to make the alternative and complementary practices a necessary adjuvant to the strained health care system.

OP 7:

ETHICAL ISSUES IN SECONDARY RESEARCH: OPINIONS OF EC MEMBERS VIS-À-VIS RESEARCHERS

Dr. Ravi Vaswani*, Dr. Uma Kulkarni [Yenepoya Medical College Hospital and Yenepoya Ethics Committee – 1, Mangalore]

Abstract:

Background: Data is the new age currency that encashes power. Increasing technological advances have also meant that scientists can now store biological tissues and samples for much longer times than ever before, with better retrieval. It seems natural and practical to not throw away samples, as there is still unextracted data in them. The increasing use of artificial intelligence to perform "omics" based research has meant that researchers are more likely than ever to retrieve "conveniently" stored biological samples to carry out new research. New research done on stored samples that were collected for some other purpose or some other research is known as secondary research. This will give rise to a demand on creating and providing for more and more biobanks across the country. As on date no one has carried out a survey or assessment on the number and status of biobanks. On paper there are a handful, but in reality, experts agree that there must be many more unregulated biobanks in the country. The explosion of biobanks, the quantum leap in computer technology and the sudden interest in retrieving stored samples is definitely leading to increase in secondary research. The ethical issues surrounding secondary research on the other hand are not very well explored, especially within the sociocultural context of India. Since ethical approval is a must for any biomedical research involving human participants, it made sense to find out and compare the perceptions of EC members and basic science researchers towards use of stored samples in secondary research.

Methodology: After institutional ethics committee approval and due permissions from Chairperson of the ethics committees, 50 bonafide members and 50 researchers were asked (after consent) to respond to a questionnaire to assess their perceptions about ethical issues in secondary research on stored samples. The questionnaire was anonymous, self-administered and used the modified Likert scale. The data gathered was analysed using descriptive statistics.

Results: In this study, the following domains were explored in the questionnaire (using a case scenario): type of consent, return of research results, ownership, benefit sharing, privacy and confidentiality of the data/samples; MTA; and data/sample disposal. Agreement scores between the two groups have been compared.

Conclusion: This study provides more clarity on the extent of awareness of the ethical issues in the use of stored samples in secondary research.

OP 8:

ETHICS IN COMMUNITY RESEARCHES INVOLVING OLDER PEOPLE

Dr Subhadra KT* [School of Family health Studies (on deputation), Kerala University of Health Sciences]

Abstract:

It's known that the world demography is shifting towards older people. The researches with geriatric care and gerontology as the central subject is receiving more importance than ever before. But ethically seen, this is a more vulnerable group considering the economic, social, emotional as well as physical dependency. Hence such researches are to be more sensitive. Taking into these considerations fundamental principles in researches involved with older people will have to be considered based on the soundness of the project, informed consent, justice, beneficence/ non- maleficence and confidentiality. Inclusion of the older people should be considered based on distributive justice based on the benefit – burden ratio, gender disparity issues as well as protection of privacy. The article tries to review the special concerns in researches related to the geriatric population based on the lessons learnt from community based research on older people.

OP 9:

MEDICAL ETHICS IN AYURVEDA

Dr. Anjali Goyal*, Dr. Mahesh Vyas [Dept. of Samhita & Siddhanta at All India Institute of Ayurveda, New Delhi]

Abstract:

Introduction: Medical Ethics in normal sense refers to guideline generally written by physician about ideal relationship of physician to his peers and patients. **Ayurveda** focuses more on principles of beneficence and non-malfeasance for therapy in terms of **Vaidyanimitta Vyapada** (complications due to doctor's ignorance), **Yogya-Ayogya** patient (eligible /non eligible patient for treatment), **Vaidyavritti** (code of conduct for doctor), **Chatuspada** (Four Quadruple of treatment), **Sadvritta** (right conducts), **Yogyavidhi** (Practical training), **Rajagya** (Permission of the king before treatment), **Pathyapathya kalpana** (wholesome and unwholesome diet) and **Sadachara** (simple living style for doctor).

Purpose: To prove the status of medical ethics in ancient period of Ayurveda and its current status in present scenario.

Methodology: On the basis of all available fundamentals of Ayurveda in classical literature, a conceptual study to explicate the importance and status of medical ethics in ancient Ayurveda period and present era will be drawn into light.

Result: Our literary research on Ayurveda gives us vital clues and excellent results to prove that ancient Ayurved Acharya gave much concern on medical ethics. Medical ethics protect not only patients but also provide care by setting standards of conduct.

Discussion: Ayurveda literature has description about medical ethics. Physician should have friendliness and compassion towards the diseased. Vaidya should not use the unknown drugs that may become fatal. Vaidya should obtain Permission/ license from the king/ government before start practice. Vaidya should keep himself all confidential information received from patient. In surgical cases, only the experienced surgeons are authorized to perform. The benefit to the patient is of fore most importance.

Conclusion: It is clear that medical ethics was well known and appreciated by Ayurveda Acharya in ancient period. It is very useful to provide guidance in making decisions because healthcare deals with moral dilemmas regarding life and death.

OP 10:

STATUS OF REGISTRATION AND RE-REGISTRATION AND ACCREDITATION OF ETHICS COMMITTEES IN CDSCO, DHR AND NABH – EVALUATION OF THE EXTENT OF ETHICS OVERSIGHT IN THE COUNTRY.

Rakshit A*, Thatte UM, Gogtay NJ, Muzumdar K, Desai Y [Department of Clinical Pharmacology, Seth GS Medical College & KEM Hospital, Mumbai]

Abstract:

Rationale: The 'New Drugs and Clinical Trials Rules 2019' rule mandates registration of an Ethics Committee (EC) with CDSCO with a 5 year validity. ECs in medical colleges that oversee Postgraduate thesis and academic studies need to be registered with the DHR. The present study was carried out with the objective of evaluation of the current status of EC registration and re-registration as a metric of ethical oversight in the country.

Methodology: The data from the websites of CDSCO, DHR, CTRI, NMC and population demographics of states in India was collated. (last accessed - 30th September 2022). Information on registration, re registration of both institutional and independent ECs from CDSCO and DHR were collated as also NABH accreditation. Volume of studies [culled from CTRI] was matched vis a vis the number of ECs in a state [and its population]. Both descriptive and inferential statistics [chi square at 5% significance and a crude odds ratio] were applied.

Results: A total of 1722 ECs, were registered with CDSCO. Of these 1498/1722(87%) were Institutional and 224/1722(13%) were Independent. A total of 921/1722(53.48%) ECs were re-registered with CDSCO. Institutional ECs [821/921(89.15%)] had twice the odds of being re-registered with CDSCO relative to Independent ECs 100/921(10.85%), $p < 0.05$). Only 186/1722(10%) ECs were accredited with NABH. A total of 977 ECs were registered with the DHR of which only 17% were re-registered. A total of 370 medical colleges were recognized by the NMC for post-graduate courses of which only 184/370 (49.72%) had DHR registered ECs.

Conclusion: The registration and re-registration status of ECs as also the accreditation status is not commensurate with the quantum of studies in the country.

OP 11:

ETHICS IN HEALTH POLICY AND SYSTEMS RESEARCH (HPSR)

Mr. Siddaram Sarate, L Surbala Devi* [Charotar University of science & Technology, Changa, Ta. Petlad, Dist. Anand]

Abstract:

Background: Health policy and systems research focuses on generating, disseminating, and using health-related knowledge. Major objectives include understanding the functioning of existing health systems, how health policy is developed and implemented, and how health systems can be improved. There is an increasing recognition in low- and- middle income countries (LMICs) of the importance of health systems in achieving health- related development goals, and of the constraints related to the limitations of health systems. Health policy and systems research often involves circumstances that are beyond the researchers' control, raising questions about their accountability. As opposed to directly affecting an individual's health, health policy and systems research impacts communities, institutions, and systems functioning. Contrary to clinical research, health policy and systems research is mainly used by policy makers and managers focused on system-wide health issues.

Key learnings: This paper will list out the relevance of ethical considerations in health policy and systems research. It will further discuss on the considerations about the ethics of HPSR listed out by the Alliance for Health Policy and Systems Research (WHO) with the Global Health Ethics Unit (WHO). A few examples of HPSR studies approved by IEC-CHARUSAT will also be discussed in relevant sections of the presentation.

Conclusion: Health policy and systems research is a rapidly evolving and broad research field and there is a growing need for researchers and research ethics committees to understand the ethical implications.

OP 12:

Ethical Guidelines in Research, Registration and Accreditation of EC or IRB in India

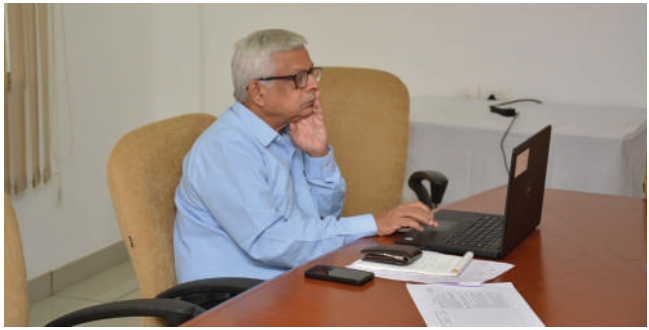
Mr. Siddaram Sarate* [Charotar University of science & Technology, Changa, Ta. Petlad, Dist. Anand]

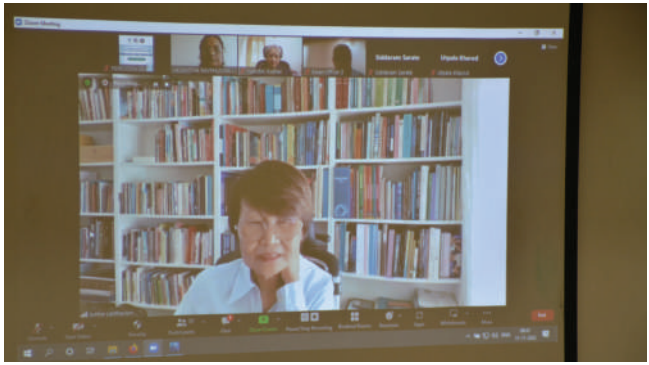
Abstract:

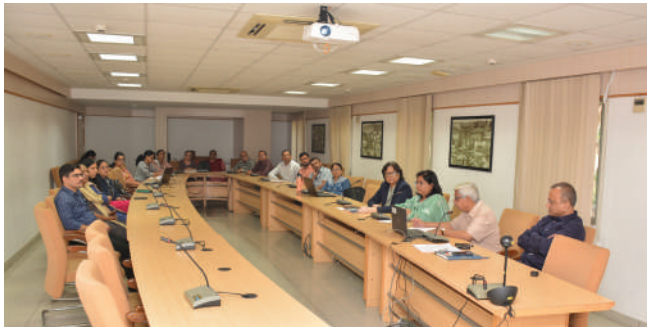
Context: Research Ethics provides footprints to carry out the research in any discipline, it seems to be moral responsibility of researcher to conduct a research fairly by safeguarding the participants, honesty in collecting, managing the data and disseminating the results. To mention few principles of research ethics are honesty, objectivity, Integrity, carefulness, openness, respect for intellectual property, confidentiality, responsible publication, responsible mentoring, respect for colleagues, social responsibility, non-discrimination, competence, legality, animal care and human subject protections.

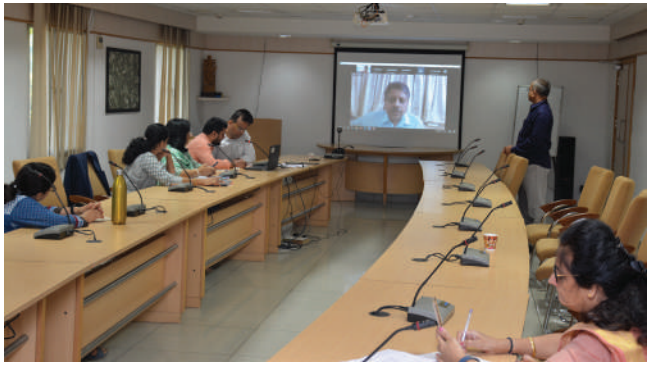
Important Guidelines for ethics in Research visited: Five Principles of research ethic by American Psychological Association, Ethical guidelines for good research practice by Association of Social Anthologists, UK), Australian Code for the responsible conduct of research, Economic and Social Research Council, UK and Registration of Institutional Ethics Committee or Institutional Review Board and Accreditation of Institutional Ethics Committee or Institutional Review Board.

Conclusion: The Ethics Committee must look into various updated guidelines, need more focus in Health policy and system Research and available accreditation for ensuring ethically and scientifically sound research.









List of Participants FERCICON 2022

List of Participants FERCICON 2022:

Sr. No.	Name Designation	Address	Mobile No. & Email
1	Dr. Khushboo Juneja Associate Professor	Department Of Community Medicine, Manipal Tata Medical College, Jamshedpur	7060600602 khushboojuneja 22@gmail.com
2	Dr. R Anusha Rebecca Assistant Professor	Forensic Medicine & Toxicology, Saveetha Medical College & Hospital, Chennai	9486733058 anusha181193 rebecca@ gmail.com
3	Mr. Siddaram Sarate Assistant Professor	Nursing/Manikaka Topawala Institute Of Nursing, A Constituent Of CHARUSAT, Nadiad-Petlad Off Highway, Changa-388421, Ta. Petlad, Anand, Gujarat.	7567561243 siddaramsarate.nur@ charusat.ac.in
4	Dr. Ananya Rakshit DM Resident	Clinical Pharmacology Department, Seth GS Medical College And KEM Hospital Mumbai	9774314774 drananyarakshit@gmail.com
5	Dr. Jeyalalitha Rathinam Professor	Government Medical College The Nilgiris	9443159765 jeya0909@gmail.com
6	Dr. Mrunalini Kalikar Associate Professor	Department Of acology,GMC, Nagpur	9850045375 mrunalinikalikar@yahoo.com
7	Dr. Ganesh Dakhale Professor	Pharmacology Plot No 2 Sector 20 Mihan Aiims Nagpur 441108	9850539353 gndakhle@aiimsnagpur. edu.in
8	Dr. Shruti Bhide Associate Professor	Department Of Pharmacology & Therapeutics, Seth GS Medical College & KEM Hospital, Acharya Donde Marg, Parel, Mumbai-400012	92244154446 shrutibhide72@gmail.com

9	Dr. Sandhiya Selvarajan Additional Professor	Department Of Clinical Pharmacology, Institute Block, Jipmer, Gorimedu, Puducherry-605006	9443492922 sandhiyaselvarajan@gmail.com
10	Dr. Suchet Trigotra Professor & Head	Department Of Physiology, Dr.B.R.Ambedkar State Institute Of Medical Sciences, Mohali, Punjab.	9855600633 suchet.dr@gmail.com
11	Mr. Yash Kamath MBBS Student	Seth GS Medical College And KEM Hospital, Acharya Donde Marg, Parel, Mumbai	9930127275 yvk914@gmail.com
12	Dr .V. Rajalakshmi Professor	Pathology Panimalar Medical College Hospital And Research Institute	9841077698 raji_path@rediffmail.com
13	Ms Rana Hemangini Bharatbhai Msc Nursing Student	GH College Of Nursing, Bhaikaka University, Karamsad.	9725039969 ranahemangini66@gmail.com
14	Dr. Miteshkumar Maurya Assistant Professor	Department Of Clinical Pharmacology	9.19168e+11 mitesh.maurya4@gmail.com
15	Ms. Monika Makwana PG Nursing Student	Institute Of Nursing Sciences, Bhaikaka University, Karamsad.	6261162672 anahimakwana96@gmail.com
16	Ms. Patel Shivani Bhaveshkumar PG Nursing Student	Institute Of Nursing Sciences, Bhaikaka University, Karamsad.	8160492721 patelshivani1912@gmail.com
17	Ms. Disha Kantilal Vaja PG Nursing Student	Institute Of Nursing Sciences, Bhaikaka University, Karamsad.	9624181704 dishavaja040597@gmail.com

18	Ms. Ansu Varghese PG Nursing Student	Institute Of Nursing Sciences Shri GH Patel School Of Nursing, Bhaikaka University, Karamsad.	7990608294 ansushaan24@gmail.com
19	Dr. Snehalata Gajbhiye Assistant Professor	Pharmacology AIIMS Nagpur	9769153876 dr.ssborkar@gmail.com
20	Dr. Firoz Mubarak Tadavi Associate Professor	Department Of Pharmacology, Lokmanya Tilak Municipal Medical College & General Hospital SION, Mumbai 400022	9920549222 drfiroztadavi@gmail.com
21	Dr.Priya Kannian Member Secretary	Institutional Ethics Committee, The Voluntary Health Services, Rajiv Gandhi Salai, Taramani, Chennai - 600113, Tamil Nadu.	8056293602 vhsclinresearch@gmail.com
22	Dr. Saradha Suresh Chairperson	The Voluntary Health Services, Rajiv Gandhi Salai, Taramani, Chennai-600113	9444021231 drsaradhasuresh@gmail.com
23	Lourembam Surbala Devi Assistant Professor	Department Of Paediatric Physiotherapy, ARIP, Charusat	9429540559 lsurbala.phy@charusat.ac.in
24	Dr. Ajay Prakash Associate Professor	Pharmacology, PGIMER, Chandigarh	9781119969 india.drajay@gmail.com
25	Dr. Meera Govindarajan Consultant Pathologist	R&D Histopath Lab	9444905055 meera.govindarajan@gmail.com
26	Dr. Ravi Vaswani Professor/Joint Secretary	Internal Medicine/ Yenepoya Ethics Committee - 1	9448858983 ravi.vaswani@yenepoya.edu.in

27	Ms. Sruthi Mol. V Dietitian	Institute Of Applied Dermatology, Uliyathadka, Madhur Road, Kasaragod, Kerala	9497606391, 8921597265 sruthimolv9@gmail.com
28	Dr. Ratinder Jhaj Additional Professor	Aiims, Sket Nagar, Bhopal, MP	9.17773e+11 ratibala@yahoo.com
29	Dr. Sandeep Murali Director	Seethapathy Clinic And Hospital Private Limited	9840061740 surgeonsan@gmail.com
30	Subhadra K T Associate Professor	Kerala University Of Health Sciences	9447356378 drsubhadrapai@gmail.com
31	Dr V. Prasanna Professor	Pharmacology , RVM Institute Of Medical Sciences & Research Center, Laxmakkapally, Siddipet Dist, Telangana	9848028351 vprasanna@yahoo.com
32	Dr. Chandrashekar J Professor and Head	Public Health Dentistry	9481789572 sekarcandra@gmail.com
33	Dr. Sohom Mondal Post-Graduate Trainee	KPC Medical College & Hospital 1f, Raja Subodh Chandra Mallick Road, Jadavpur, West Bengal, 700032	8860843699 sohom.mondal.sm@gmail.com
34	Dr. Nilay N Suthar Professor of Medicine	Smt NHL Municipal Medical College, Ellisebridge, Ahmedabad	9825295840 nilaysuthar@gmail.com
35	Dr. Jyotsna Agarwal Associate Professor Anaesthesia	N-9, Green Park (Main)	9650252828 jyotsna_mamc@yahoo.com
36	Dr. Avantika Gupta PG Student Senior Professor & Head	Community Medicine, Regional Institute Of Medical Sciences, Imphal, Manipur 795004	9123876066 avantikajinny4594@gmail.com

37	Dr. Simmi Kharb	Biochemistry/ PT BDS PGIMS, Rohtak	9812016036 simmikh@gmail.com
38	Dr. Renuka Munshi Professor & Head	Department Of Clinical Pharmacology, Tn Medical College & Byl Nair Ch Hospital, Mumbai Central, Mumbai 400 008	9820377409 renuka.munshi@gmail.com
39	Francois Bompart	France Inserm Ethics Committee	33608256167 fbompart@dndi.org
40	Vasantha Muthuswamy President, FERCI	FERCI, Dept. Of Clinical Pharmacology, GSMC & KEMH, Parel, Mumbai,400012	9600042029 drvasanthamuthuswamy@gmail.com
41	Dr. Urmila Thatte Secretary, FERCI	Emeritus Professor, Dept. Of Clinical Pharmacology, GSMC & KEMH, Parel, Mumbai 400 012	9820198462 urmilathatte2gmail.com
42	Dr. Sandhya K Kamat Treasurer, FERCI	Professor & Head, Dept. Of Pharmacology & Therapeutics, GSMC & KEMH, Parel, Mumbai 400 012	9820165681 drsandhyakamat@gmail.com
43	Dr. Nandini K Kumar Vice President, FERCI	Former Deputy Director General Sr. Grade (Icmr) Res : Tc 16/1051-10 Ceemex Centre, CS Road, Jagathy, Trivandrum 695014	9810438157 nandkku@gmail.com
44	Dr. Anjali Goyal Ph. D. Scholar	Samhita & Siddhanta Department, All India Institute Of Ayurveda, New Delhi, 110044	9413201899
45	Dr. Chaitali Chindhalore Assistant Professor	Department Of Pharmacology, AIIMS Nagpur	8999905594 drchaitali@aiimsnagpur.edu.in
46	Dr. Ankur Kumar Tanwar Ph.D.Scholar	Kriya Sharir , All India Institute Of Ayurveda, Guatam Puri, Sarita Vihar, New Delhi	9250868756 ankurkumartanwar1@gmail.com

47	Dr. Sujeet Krishna Bhilwade Junior Resident Doctor	Seth GSMC & KEMH, Parel, Mumbai. 400012	7276613562 sujeetbhilwade@gmail.com
48	Dr. Ajinkya Parhe Junior Resident	Department Of Pharmacology & Therapeutics , GSMC & KEMH, Parel, Mumbai 400012	9518901855 ajup009@gmail.com
49	Dr. Pooja Redkar Junior Resident	Department Of Pharmacology And Therapeutics, GSMC & KEMH, Parel, Mumbai-400012	7506897015 predkar00@gmail.com
50	Dr. Amitoj Sohal Junior Resident	Department Of Pharmacology And Therapeutics, GSMC & KEMH, Parel, Mumbai-400012	9779428499 amysohal@gmail.com
51	Dr. Uma Anand Bhosale Professor & Head	Smt. Kashibai Navale Medical College And General Hospital, Narhe(Ambegaon) Pune 411041	9226767554 umabhosale2000@gmail.com
52	Dr. Ankita Kulkarni Junior Resident	Pharmcology &Therapeutics, Seth GSMC & KEMH Mumbai	8411000086 ankita.00194@gmail.com
53	Dr. Pranali Vasant Puradkar Junior Resident-3	Dept Of Pharmacology And Therapeutics, Seth Gs Medical College, Parel	9833296746 pranalipuradkar26@gmail.com
54	Dr. Komal Gorakshanath Kurhade Junior Resident	Pharmacology And Therapeutics, Seth GS Medical College And KEM Hospital, Mumbai.	9167621056 komalkurhade25@gmail.com
55	Mr. Varghese P.A. Student Of Master In Bio Ethics (MBE)	Cochin University Of Science And Technology,(CUSAT), Kochi, Kerala.	9447115037 varghesepa61@gmail.com

56	Dr. Soham Sinha Post Graduate Student	Department Of Pharmacology And Therapeutics, Seth GS Medical College And KEM Hospital, Parel , Mumbai 400012	8910971639 sohamsinha1217@gmail.com
57	Gaurav Shashikant Kansara Associate Professor	Dr. Kiran C. Patel Medical College & Research Institute, New Civil Hospital Campus, Bharuch, Gujarat - 392001	9604977167 gskansara@gmail.com
58	Dr. Zahida Inkisar Khan Asst Professor	Pediatrics Dr KMCRI Medical College And Research Centre, Bharuch	9426142609 khan.zahidadr@gmail.com
59	Mr. Brogen Singh Akoijam Professor & Head	Department Of Community Medicine, Regional Institute Of Medical Sciences, Lamphel, Imphal West, Manipur-795004	9436037373 brogrn@rediffmail.com
60	Ms. Meetu Maradi Tutor	Biochemistry/ S.Nijalingappa Meidcal College HSK Hospital And Research Centre, Bagalkot, Karnataka	7996228305 meetumaradi@gmail.com
61	Dr. Deepali S. M. Lecturer	Department Of Biochemistry. S Nijalingappa Medical College Navanagar Bagalkot.	9743760123 malgavkardeepali@yahoo.in
62	Dr. Divakar Junior Resident	Department Of Pharmacology And Therapeutics, Seth GSMC And KEMH, Parel, Mumbai-400012	7829635349 divakaralmad@gmail.com
63	Dr. Yangshen Lhamo Assistant Professor	AIIMS, Bilaspur Himachal Pradesh	9.19655e+11 yangshenlhamo@yahoo.com

64	Dr. Meenakshi Meenu Assistant Professor	Department Of Pharmacology, Second Floor, Academic Block, AIIMS, Bilaspur, Himachal Pradesh, India 174001	9958132184 meenakshimeenu185@gmail.com
65	Dr. Serah Johny Associate Professor	Department Of Pharmacology, Mosc Medical College, Kolenchery, Ernakulam, Kerala	9961629889 serahjohny@gmail.com
66	Dr. Rashmi Bhavasar Member Secretary SVIEC	Sumandeep Vidayspeeth Vadodara, Gujarat	8980153879 rbhavasar99@gmail.com
67	Dr. Riddhi Patel Research Associate	Sumandeep Vidyapeeth, Vadodara, Gujarat	9428353116 riddhi111.patel@gmail.com
68	Mrs. Sweety Subha P Associate Professor	PSG College Of Physiotherapy Peelamedu, Coimbatore	9791334396 sweeta.gr8@gmail.com
69	Dr. Harshitha Resident	Department Of Pharmacology And Therapeutics, Seth GSMC And Kem Hospital Mumbai	9945165849 harshithahavaldar2@gmail.com
70	Dr. Vijayadhaaran Sekar Junior Resident	Department Of Pharmacology And Therapeutics, Seth GS Medical College And KEM Hospital, Mumbai-400012	9049056123 vijayadhaaranisekar@gmail.com
71	Mr. Percy Soli Ghaswala Institutional Ethics Committee Member	Sir H N Reliance Foundation Hospital, Prarthana Samaj, Raja Rammohan Roy Rd, Girgaon, Mumbai, Maharashtra 400004	9820863931 percy@ghaswalafoundation.org
72	Dr. Shetty Yasha Ravindra Student	A J Institute Of Medical Sciences And Research Centre, Mangalore	9901688429 shettyyashars@gmail.com

73	Mr. Sundarraj Palanichamy Head- R&D	Meenakshi Mission Hospital And Research Centre	9952405440 charityrd@gmail.com
74	Dr. Ratnesh Bhai Mehta Head	ZIFO Genomics Research Institute, Chennai	6363451484 ratnesh.m@zifogenomics.com
75	Ms. Shofia.S Secretariat Member-ZGRI	ZIFO Genomics Research Institute (ZGRI), 21 A, Anna Salai, Littlemount, Saidapet, Chennai -600 015.	7708396832 sofiasofi9502@gmail.com
76	Dr. Monika Kumari PhD Scholar	Department Of Shalya Tantra, All India Institute Of Ayurveda, New Delhi	9773213856 dr.monika19@rediffmail.com
77	Ms. Sujata Dutta Gupta Member Secretary - ZGRI Ethics Committee	ZIFO Genomics Research Institute, 21a, Anna Salai, Little Mount, Saidapet, Chennai - 600015	9994187509 sujata.d@zifornd.com
78	Dr. Vikrant M Bhor Scientist E, Member Secretary, ICMR-NIRRCH IEC	ICMR-NIRRCH, Jehangir Merwanji Street, Parel, Mumbai-400012.	9987036993 bhorv@nirrch.res.in
79	Dr. Ajinkya Manish Bavlecha PG Resident	Department of Pharmacology, Seth GS Medical College And KEM Hospital, Acharya Donde Marg, Parel, Mumbai- 400 012	7045923463 ajinkya.schumi@gmail.com
80	Dr. Shetty Nikitha Ravindra Intern	AJ Institute Of Medical Sciences	7588337735 nikitharsshetty@gmail.com
81	Dr. Ruckmani A Former Professor And Head	Dept. Of Pharmacology, Chettinad Hospital & Research Institute, Kelambakkam, Chennai, 603103	9500102346 ruckmani.nirmal@gmail.com

82	Dr. Chithra K S Medical Officer	Govt. Taluk Homoeopathy Hospital, Koyilandy, Kozhikode, Pin 673305, Under Department Of Homoeopathy, Kerala	9496802486 drchithraks@gmail.com
83	Dr. Lalita Shankar Savardekar Scientist F	Bone Health Clinic, ICMR-NIRRCH	9.19893E+11 savardekarl@gmail.com
84	Dr. Swarnalakshmi	YRG CARE, Chennai	
85	Dr. Bankim P. Gandhi Program Manager	Extension Program Department, Bhaikaka University, Gokal Nagar, Karamsad, Gujarat - 388325	9426363161 drbankimgandhi@gmail.com
86	Dr. Jashbhai B. Prajapati Chairperson	Verghese Kurien Centre of Excellence, Institute of Rural Management, Anand	9879105948 jbprajapati@gmail.com
87	Dr.Suchitra	Additional Professor & Dept. of Pediatric & Preventive Dentistry, Govt. Dental College, Alappuzha, Kerala.	suchithraharikesh@yahoo.co.in
88	Dr. Devangi Soaham Desai Professor of Medicine	Department of Medicine, Pramukhswami Medical College, Bhaikaka University, Gokal Nagar, Karamsad, Gujarat - 388325	9879131650 devangisd@charutarhealth.org
89	Dr. Priyadarshini Professor and Head	Department Of Otorhinolaryngology, Pramukhswami Medical College, Bhaikaka University, Gokal Nagar, Karamsad, Gujarat - 388325	8422911222 priyadarshini@charutarhealth.org

90	Ms. Jaishree Deepak Ganjiwale ASST PROF	Department of community medicine; Pramukhswami Medical College, Bhaikaka University, Gokal Nagar, Karamsad, Gujarat - 388325	9727740247 jaishreeganjiwale@gmail.com
91	Dr. Smruti B.Vaishnav Professor	Department of OB & GY Pramukhswami Medical College, Bhaikaka University, Gokal Nagar, Karamsad, Gujarat - 388325	8980809523 smrutiv@charutarhealth.org
92	Dr. Wasim Abdulaziz Shaikh Professor	Department of Physiology, Pramukhswami Medical College, Bhaikaka University, Gokal Nagar, Karamsad, Gujarat - 388325	9376187844 drwasimsh@gmail.com
93	Dr Punam Bhende Assistant Professor	Department of Medicine, Pramukhswami Medical College, Bhaikaka University, Gokal Nagar, Karamsad, Gujarat - 388325;	9480703214 punamvb@charutarhealth.org
94	Dr. Hemlata Vithal Kamat Professor	Department of Emergency Medicine, Pramukhswami Medical College, Bhaikaka University, Gokal Nagar, Karamsad, Gujarat - 388325	9909929422 hemlatavk@charutarhealth.org
95	Dr. Riddhi Bhatt PG Resident	Department of Pharmacology, Pramukhswami Medical College, Bhaikaka University, Gokal Nagar, Karamsad, Gujarat - 388325	9429661451 bhattriddhi20.rb@gmail.com

96	Dr. Ankit Patel PG Resident	Department of Pharmacology, Pramukhswami Medical College, Bhaikaka University, Gokal Nagar, Karamsad, Gujarat - 388325	9974754237 drankitnpatel@gmail.com
97	Dr. Bhakti Bajpai Associate Professor	ARIBAS, New Vallabh Vidyanagar	9428811922 bhaktibajpai@aribas.edu.in
98	Dr. Himanshu Pandya Dean	Pramukhswami Medical College, Bhaikaka University, Gokal Nagar, Karamsad, Gujarat - 388325	9825098919 himanshu@charutarhealth.org
99	Dr. Barna Ganguly Professor	Department of Pharmacology, Pramukhswami Medical College, Bhaikaka University, Gokal Nagar, Karamsad, Gujarat - 388325	9712906493 barnag@charutarhealth.org
100	Dr. Swapnil Sudhir kumar Agarwal Professor and Head	Department of Forensic medicine and toxicology, Pramukhswami Medical College, Bhaikaka University, Gokal Nagar, Karamsad, Gujarat - 388325	9824477874 swapnilagarwal@yahoo.in
101	Dr. Swati A Roy Member Secretary, Institutional Ethics Committee	Bhaikaka University, Gokal Nagar, Karamsad, Gujarat - 388325	8208782286 swatiar@charutarhealth.org
102	Dr. Dinesh Kumar Professor	Department of Community Medicine, Pramukhswami Medical College, Bhaikaka University, Gokal Nagar, Karamsad, Gujarat - 388325	9409601530 drdineshkl@gmail.com

103	Dr. R. Harihara Prakash Professor and Principal	KM Patel institute of Physiotherapy, Bhaikaka University, Gokal Nagar, Karamsad, Gujarat - 388325	8238238685 hariharap@bhaikakauniv.edu.in
104	Dr. Sonal Chitroda Associate Professor	Smt. L.P. Patel Institute of Medical Laboratory Technology, Bhaikaka University, Karamsad.	8980221343 sonalmc@charutarhealth.org
105	Dr. Deepak Kumar B Sharma Professor	Department of Community Medicine, Pramukhswami Medical College, Bhaikaka University, Gokal Nagar, Karamsad, Gujarat - 388325	9727739711 drdeepak1105@gmail.com
106	Dr. Manisha Gohel Professor	Department of Community Medicine, Pramukhswami Medical College, Bhaikaka University, Gokal Nagar, Karamsad, Gujarat - 388325	9824610142 manishakg@charutarhealth.org
107	Dr. Shweta Maheshkumar Parikh Associate Professor	K.M.Patel Institute of Physiotherapy, Bhaikaka University, Gokal Nagar, Karamsad, Gujarat - 388325	9427083406 shwetap@charutarhealth.org
108	Dr. Bharat Gajjar Professor	Department of Pharmacology, Pramukhswami Medical College, Bhaikaka University, Gokal Nagar, Karamsad, Gujarat - 388325	9537500302 gajjarbm@gmail.com
109	Dr. Anusha Prabhakaran Professor	Department of Psychiatry, Pramukhswami Medical College, Bhaikaka University, Gokal Nagar, Karamsad, Gujarat - 388325	9825757797 Anushamcp@charutarhealth.org

110	Ms. Shany Thomas Professor	Institute of Nursing Sciences, Bhaikaka University, Gokal Nagar, Karamsad, Gujarat - 388325	9925025023 shanyt@charutarhealth.org
111	Dr Alpa Gor Professor and Head	Department of Pharmacology, Pramukhswami Medical College, Bhaikaka University, Gokal Nagar, Karamsad, Gujarat - 388325	9924115170 alpapg@charutarhealth.org alpagor15@gmail.com
112	Dr. Utkarsh M Shah Associate Professor	Department of Community Medicine, Pramukhswami Medical College, Bhaikaka University, Gokal Nagar, Karamsad, Gujarat - 388325	9879149295 drutkarsh2537@gmail.com
113	Prof. Shailesh Panchal Principal	Institute of Nursing Science, Bhaikaka University, Gokal Nagar, Karamsad, Gujarat - 388325	9879401720 shaileshgp@bhaikakauniv.edu.in
114	Dr. Nazima Mirza Professor	Department of pharmacology, Pramukhswami Medical College, Bhaikaka University, Gokal Nagar, Karamsad, Gujarat - 388325	9898041036 nymirza2016@gmail.com
115	Dr. Mitul Chhatriwala Associate professor	Department of Biochemistry, PSMC, Bhaikaka University, Gokal Nagar, Karamsad, Gujarat - 388325	9601530026 mitulnc@charutarhealth.org
116	Dr. Dharmik Savjibhai Patel Professor	Department of Biochemistry, PSMC, Bhaikaka University, Gokal Nagar, Karamsad, Gujarat - 388325	9978919892 dharmiksp@charutarhealth.org

117	Dr. Ashishkumar Vasantkumar Gupta Associate Professor	KM Patel institute of Physiotherapy, Bhaikaka University, Gokal Nagar, Karamsad, Gujarat - 388325	9925048223 ashishvg@charutarhealth.org

To make an end is to make
a beginning
the end is where we start from.

- JS Eliot