SOUVENIR

FERCI

FORUM FOR ETHICS REVIEW COMMITTEES IN INDIA

FERCICON 2024

11th National Conference

Conference Theme:
Assuring Quality of Review and Oversight by the Ethics Committees

7-9TH NOVEMBER 2024

Jagannath Gupta Institute of Medical Sciences and Hospital (JIMSH)
Budge Budge, Buita, Kolkata, West Bengal 700137

https://ferci.org/

FERCICON 2024

Organizing Committee

Advisors

Prof Dr. Debasish Basu
Pro Vice Chancellor,
WBUHS, Kolkata

Dr. Nandini Kumar
President, FERCI

Dr. Lalita Savardekar
Secretary, FERCI

Patrons

Mr K K Gupta
Chairperson

Dr. Balram Gupta
Vice Chairman

Dr. Shubhangi Gupta
Executive Director

Prof. Debasish Bhattacharya
Director General
JIMSH, Budge Budge

Organizing Chairperson

Prof Santanu K Tripathi
Principal
JIMSH, Budge Budge

Organizing Secretary

Dr. Shambo S Samajdar
Consultant Clinical Pharmacologist & Physician

Joint Convener

Prof Paramita Pal
Dr. Payodhi Dhar
Dept of Pharmacology
JIMSH, Budge Budge

Organizing Joint Secretary

Prof. Aditi Aikat
Dean, Students' Affairs

Prof. Rajasri Chunder
Dean, Academics
JIMSH, Budge Budge

Treasurer

Dr. Pradipta Das
Dept of Pharmacology
JIMSH, Budge Budge

Sub-Committees

Registration

Dr. Sayantani Majumdar

Resource & Logistics

Prof. Ashis Kumar Saha
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Scientific

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Reception & Hospitality

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Dr. Tanusree Nath

Cultural

Ms. Runu Ghosh

The 11th National Conference of

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About JIMSH

About the Venue: JIMSH

Jagannath Gupta Institute of Medical Sciences and Hospital (JIMSH) is a renowned and leading multi-specialty hospital located at Budge Budge, Buita, Kolkata-700137. Since its establishment in the year 2016, it has been successfully serving people from West Bengal as well as from other states. JIMSH has been committedly working in the medical field to foster patient care with advanced medical approach. Apart from providing quality health care services, it has also focused to create excellence in education where through establishing technologically advanced learning system and implementing innovative learning approaches, JIMSH is creating a new dimension in the medical studies.

How to Reach:

Via Flight: Kolkata is well connected to other major cities of the country via regular flights. **Airports**: Netaji Subhash Chandra Bose International Airport JIMSH, Budge budge is at a distance of 45 kms from the Airport.

Via Train: Nearest Rail stations are Sealdah (29.8 kms via sampriti bridge), and Howrah station(29.1 km via BT Road) for long distance trains*. Nearest Local railway station: Budge budge station(6 kms)**

*We will be providing bus pick up and drop two nearby Medical colleges, NRS Medical College and IPGMER for facilitating the transport of Delegates.

**Pick up and Drop facilities will be there for the delegates.

Gram Bangla Retreat	Arshinagar Shilpagram	Bawali Farmhouse	The Rajbari Bawali	JIMSH Guest House
				
983-631-0106 801-711-6648	824-010-4102	810-018-1600	033-4180-0305	

Message from the desk of Chairman, JIMSH

It is my distinct honor to welcome you to the 11th Annual National Conference of the Forum for Ethics Review Committees in India (FERCICON 2024), hosted by Jagannath Gupta Institute of Medical Sciences & Hospital (JIMSH), from November 7-9, 2024. This year's conference theme, "Assuring Quality of Review and Oversight by Ethics Committees," is particularly timely and relevant, addressing pressing contemporary issues.

We take immense pride in organizing this prestigious event, and I extend my sincerest appreciation to the Organizing Committee members for their tireless efforts in ensuring its success. The conference promises an engaging and comprehensive program, featuring esteemed experts delivering invited lectures, symposia, panel discussions, and mini-lectures over three days.

I believe this conference will strengthen unity among Association members and serve as a source of inspiration and motivation for the younger generation, fostering greater enthusiasm for medical education and scientific research,.

I extend my heartfelt best wishes to all participants and wish for the grand success of this esteemed conference.Best

Regards,

Krishna Kumar Gupta
Chairman, JIMSH

Message from the desk of Vice Chairman, JIMSH

It gives great pleasure to welcome you to the 11th Annual National Conference of the Forum for Ethics Review Committees in India (FERCICON 2024), hosted by Jagannath Gupta Institute of Medical Sciences & Hospital (JIMSH), from November 7-9, 2024. The theme of the conference, "Assuring Quality of Review and Oversight by Ethics Committees," is apt and opens up scopes of the way Ethics Committee functions.

We are happy to have the opportunity to host this National Conference and sincerely appreciate the Organizing Committee members of FERCICON 2024 for their immense efforts in ensuring its success. We hope the conference unfolds an enlightening program, featuring esteemed experts delivering invited lectures, symposia, panel discussions, and mini-lectures over three days.

I believe this conference will strengthen unity among Association members and serve as a source of inspiration and motivation for the younger generation, fostering greater enthusiasm for medical education and scientific research. I extend my heartfelt best wishes to all participants and wish for the grand success of this esteemed conference.

Best Regards,

Dr. Balram Gupta
Vice Chairman, JIMSH

Message from the desk of Executive Director, JIMSH

It is my proud privilege to welcome you to the 11th Annual National Conference of the Forum for Ethics Review Committees in India (FERCICON 2024), hosted by Jagannath Gupta Institute of Medical Sciences & Hospital (JIMSH), from November 7-9, 2024. This year's conference theme, "Assuring Quality of Review and Oversight by Ethics Committees," is particularly timely and relevant, addressing pressing contemporary issues.

We take immense pride to host this prestigious event, and I deeply appreciate the relentless efforts of the Organizing Committee members to culminate this into a grand success. The engaging and comprehensive program, and its esteemed experts from all parts of the globe delivering invited lectures, symposia, panel discussions, and mini-lectures over three days promises interesting insights.

I believe this conference will serve as a source of inspiration and motivation for the younger generation, taking research ethics to greater heights.

I wish all participants insightful learning over the 3 day . May the Conference be a grand success.

Best Regards,

Dr. Shubhangi Gupta
Executive Director

The 11th National Conference of

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FERCI

Message from the President of Forum for Ethics Review Committees in India

It gives me great pleasure to write this message for the 11th National Conference of Forum for Ethics Review Committees in India (FERCI), the national chapter of WHO initiated Forum for Ethics Review Committees in Asia Pacific region (FERCAP) which is being held at the Jagannath Gupta Institute of Medical Sciences, Kolkata this year. We are grateful to the institution for holding the Conference this year and extending its hospitality and support for this event. The two most important factors which will help good research are a review of the science and ethics content of research proposals and informed consent documents. The ethics committee (EC) members should gear themselves to meet the demand by being updated on research ethics and related regulations. FERCI conference chose 'Assuring Quality of Review and Oversight by the Ethics Committees' as this year's theme for making EC members aware that they must take their role and responsibilities more seriously to protect the rights, safety and well-being of research participants. I am sure that the convergence of participants and national and international speakers from different areas of health research will enrich the participants' knowledge, leading to better outcomes in quality assurance and improvement in research and publications. I wish the program all success and hope that it will lead to fruitful learning at the conference.

Dr. Nandini Kumar
President, FERCI

The 11th National Conference of

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FERCI

Message from the desk of Secretary FERCI

The Forum for Ethics Review Committees in India(FERCI) welcomes all the delegates to the annual academic meet focusing on Quality of Review and Oversight by the Ethics Committee. Over the years, FERCI is striving towards capacity building of the ethics committee members and researchers all over India. The ulterior gain is to facilitate effective functioning of the Ethics Committees all over India, leading effectively towards safeguards of the dignity, rights and well being of research participants.

FERCI is organizing this conference jointly with Jagannath Gupta institute of Medical Sciences & Hospital(JIMS), Kolkata. We express our deep gratitude to Mr. KK Gupta, Chairman, and Dr Balram Gupta Vice Chairman, JIMS hospital for hosting the conference. We sincerely appreciate the efforts of Dr Shantanu Tripathi, Organising Chairman, FERCON 2024, Principal JIMS hospital for painstakingly working towards making this academic meet possible. Our gratitude to the entire organising team for their hard work and assiduous efforts over the last few months to make this day possible.

This hybrid meet will ensure that the learnings from this 3 day meet will empower you to face challenges along your path in research ethics with ease and confidence. The varied topics in the 3 day meet from multicenter trials, WHO benchmarking tool, ethical review challenges for EC functioning to integrative research will give new learnings in conduct and review of Ethics research. Ethics committees have the most important role to ensure quality research by having an oversight (comprehensive review and monitoring mechanisms) with simultaneous quality check through self assessments. We look forward to your active participation and brainstorming to leash out new challenges in Biomedical research. Once again, a warm welcome to all. Wishing a grand success to the organizing team.

With regards,

Dr. Lalita Savardekar
Secretly FERCIScientist F,
Reproductive and Bone Health Unit &In-Charge,
Woman's Health Clinic & Bone Health Clinic,
NaigaonICMR- National Institute for Research in Reproductive and Child HealthJ
.M.Street, Parel,
Mumbai 400012

JIMS Hospital | Jagannath Gupta Institute of Medical Sciences & Hospital
(A Unit of Urmila Devi Jagannath Gupta Charitable Trust)

From the Desk of Organizing Chairperson, FERCICON 2024

Dear Delegates, Respected Dignitaries, Honoured Guests,

I have the pleasure in welcoming you ALL to the 11th Annual National Conference of Forum for Ethics Review Committees in India – FERCICON 2024 to be held at our institution, Jagannath Gupta Institute of Medical Sciences & Hospital, Budge Budge (JIMSH), during 7-9 November, 2024. The Conference Theme is interesting – "**Assuring Quality of Review and Oversight by the Ethics Committees**" that is indeed very pertinent carrying huge contemporary relevance.

We are proud that our Department of Pharmacology took this challenge to organise this Conference at our institute. I most cordially congratulate the members of the Organising Committee who put their best to make this great event a grand success.

An engaging learning programme awaits us over the three whole days – 7th, 8th and 9th November, 2024 with invited lectures, symposia, panel discussions and mini lectures, covering diverse state-of-the-art and contemporary topics to be deliberated by renowned experts, along with an optimum number of oral presentations by youngsters.

I express my sincere thanks to all the dignitaries and delegates who would grace this event taking a break from their busy schedule sparing their valuable time. My institute offers the perfect ambience for learning as well as social communication and networking. I take this opportunity to extend our thanks and gratitude to all the delegates who have come from far and distance to attend this important Conference. On behalf of JIMSH, Budge Budge, I assure you all the best of our support and cooperation as necessary to achieve the objectives of the Conference.

Wish FERCICON 2024 a grand success!

Prof Santanu K Tripathi
Principal
JIMSH, Budge Budge
&
Organizing Chairman,
FERCICON 2024

Dated 5th November, 2024
Kolkata

Hospital : K. P. Mondal Road, Buita, Budge Budge, Kolkata - 700137
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JIMS Hospital | Jagannath Gupta Institute of Medical Sciences & Hospital
(A Unit of Urmila Devi Jagannath Gupta Charitable Trust)

Prof Debasis Bhattacharyya
Director General – Academics
JIMSH, Kolkata

Date: 05.11.2024

Message

It is a great pleasure to know that JIMSH is conducting FERCICON 2024 during 7th-9th November, 2024. The theme of the Conference "Assuring Quality of Review and Oversight by the Ethics Committees" is very much timely and appropriate.

I wish the conference grand success and I believe the deliberations in the conference shall bring newer insights and recommendations that we can follow towards better and more ethical conduct of clinical research in the country.

Prof Debasis Bhattacharyya

To
Prof Santanu K Tripathi
Principal, JIMSH &
Organizing Chairman – FERCICON 2024

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MESSAGE FROM THE DESK OF
Organizing Secretary, FERCICON 2024

It is with immense pride and honor that I extend a warm welcome to all esteemed participants of FERCICON 2024. This year, the conference theme, *"Assuring Quality of Review and Oversight by the Ethics Committees,"* resonates with the crucial role that ethics committees play in safeguarding the integrity and ethical rigor of clinical research. In an era where research methodologies are evolving rapidly, and trials are becoming increasingly complex, the need for robust ethical review and oversight mechanisms has never been more pressing. Our theme reflects the commitment to uphold these standards, ensuring that ethics committees remain vigilant and adaptive to contemporary ethical challenges.

On behalf of the organizing committee, I would like to extend heartfelt gratitude to the **Jagannath Gupta Institute of Medical Sciences and Hospital (JIMSH)** for graciously hosting FERCICON 2024. JIMSH has been instrumental in facilitating an environment conducive to meaningful dialogue and learning, further enriching the conference experience for all delegates.

It has been a true honor to work under the guidance of **Prof. Santanu K. Tripathi**, whose contributions to clinical research ethics in India are both profound and inspiring. Prof.

Tripathi's visionary approach and deep commitment to ethical research practices have set a benchmark in the field. His guidance has been invaluable in shaping this conference, and his unwavering dedication to ethical rigor serves as a model for us all. Serving as the Organizing Secretary under his leadership has been a rewarding experience, one that has allowed me to gain deeper insights into the principles that should guide all clinical research endeavors.

Our gratitude also extends to **Dr. Nandini Kumar** and **Dr. Lalita Savardekar**, along with all respected members of the organizing committee and steering committee, for their unwavering support and dedication. Their efforts have been central to curating an academic feast that brings together diverse perspectives and fosters rich discussions on the evolving landscape of research ethics. Each member's unique contributions have been pivotal in ensuring the success of this event, and it is through this collective effort that we are able to present a conference of this scale and substance.

Reflecting on the essence of ethics, it can be understood as the multiplied product of morality and materialism. Ethical conduct in research, therefore, is not merely a matter of following established guidelines; it is about integrating moral values with the practical considerations that arise in real-world scenarios. This balanced approach is vital in ensuring that research remains both impactful and respectful of human dignity. By viewing ethics through this lens, we can cultivate a framework that not only adheres to regulatory standards but also resonates with the deeper moral obligations inherent in research involving human participants.

In closing, let us remember the timeless wisdom of Vidura from the Mahabharata:
"Aatmana Pratikulani Pareshuna Samacharet"
(*Do unto others what you would like others to do unto you*).

This simple yet profound principle encapsulates the essence of ethical conduct, reminding us that ethics is not only about rules but about empathy and respect for all individuals involved. If we can follow this guiding principle, we will create a research environment that is just, compassionate, and truly ethical.
With sincere gratitude and best wishes for an enriching FERCICON 2024,

Shambo Samrat Samajdar
MD DM (Clinical Pharmacology)
FIPS Fellow Diabetes India Diploma in Allergy Asthma and Immunology;
Fellowship in Respiratory and Critical Care

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UNTOLD STORY OF BUDGE BUDGE

Pre-Colonial Era (320-550 AD): Budge Budge was an important center for trade and commerce during the Gupta Empire. During the Sena Empire (11th-12th century AD), it became a major center for Buddhist learning and culture.

Colonial Era (17th century): The Portuguese established a trading post, which became a significant center for exporting jute, cotton, and other commodities. The British East India Company took control in 1756, and it remained under British rule until India's independence in 1947.

Industrialization: During the British colonial era, Budge Budge underwent significant industrialization, becoming a major center for jute mills, cotton mills, and other industries. The construction of the Eastern Railway and port of Budge Budge further boosted the town's economy.

Independence and Beyond (1947-present): After India's independence, Budge Budge continued to grow, becoming a major center for small-scale industries, including manufacturing, engineering, and food processing. Recent years have seen significant investment in infrastructure development. Budge Budge and Swami Vivekananda: Swami Vivekananda landed in Budge Budge in 1897 after returning from Chicago, marking his first landing on Indian soil after his journey to the West.

Important historical places:-

- Swami Vivekananda Railway Station
- Komagata Maru
- Old Budge Budge Railway Station

Milestones:- **1756:** British General Robert Clive captured a fort in Budge Budge **1884:** West Bengal Municipal Act established Budge Budge Municipality **1890:** Komagata Maru steamship was built 1897: Swami Vivekananda returned to India **1900:** Budge Budge became a municipality **1914:** Komagata Maru incident occurred **1940s-1950s:** Budge Industries started manufacturing vinyl car covers and automotive seat covers **1941:** Municipal Town Hall was built **1965-66:** Railway electrification **1971:** Supply of raw materials decreased after India's partition **2013:** Budge Budge railway station renamed **2014:** Area industrialized with oil storage and jute mills **2015:** Bogie manufacturing factory started producing coaches for Indian Railway.

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KOMAGATA MARU

The Komagata Maru Incident: A Tragic Chapter in Canadian History In 1914, the Komagata Maru, a Japanese steamship, set sail from Hong Kong bound for Vancouver, Canada, carrying 376 passengers from India, mostly Sikhs. The journey was meant to be a new beginning for these immigrants seeking a better life in Canada. However, their dreams were shattered when they were denied entry into Canada due to discriminatory immigration laws.

Background: In the early 20th century, Canada was experiencing a surge in immigration, leading to growing concerns about job security and cultural identity among the Canadian population. In response, the Canadian government implemented the Continuous Passage Regulation, which required immigrants to travel directly from their country of origin to Canada without stopping en route. This regulation effectively banned immigration from India, as there were no direct ships from India to Canada.

The Journey: The Komagata Maru passengers, mostly Sikh farmers and laborers, had paid a significant amount of money to travel to Canada, hoping to find work and a better life. They sailed from Hong Kong on April 4, 1914, and arrived in Vancouver on May 23, 1914. However, upon arrival, they were not allowed to disembark due to the Continuous Passage Regulation.

The Standoff: The passengers, led by Gurdit Singh, a Sikh businessman who had chartered the ship, refused to leave without being allowed to disembark. They argued that they had fulfilled all the necessary requirements and should be granted entry. The Canadian government, however, remained firm in its refusal.

The Return Journey: After a two-month standoff, the Komagata Maru was forced to return to India, leaving behind 22 passengers who had been allowed to stay in Canada due to special circumstances. The ship arrived at the port town of Budge Budge, near Kolkata, on September 29, 1914.

The Budge Budge Incident: Upon arrival, the British authorities attempted to arrest and detain the passengers, fearing they would spread revolutionary ideas. However, the passengers resisted, leading to a violent confrontation. British soldiers opened fire, killing 19 passengers and injuring many more.

Legacy: The Komagata Maru incident highlighted the discriminatory nature of Canada's immigration policies and exposed the racist attitudes prevalent in Canadian society at the time. It also became a symbol of resistance against colonial rule and a catalyst for the Indian independence movement.

Apology: and Recognition In 2016, the Canadian government officially apologized for the Komagata Maru incident, acknowledging the "racism and xenophobia" that led to the tragedy. The incident is now recognized as a significant moment in Canadian history, serving as a reminder of the country's past mistakes and the importance of diversity and inclusion.

Remembering the Komagata Maru: Today, the Komagata Maru incident is commemorated through various events, exhibitions, and memorials in Canada and India. The incident serves as a powerful reminder of the struggles faced by immigrants and the importance of fighting for human rights and equality.

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Conference Theme: *Assuring Quality of Review and Oversight by the Ethics Committees*
Date: November 07, 2024 Thursday
Venue: Jagannath Gupta Institute of Medical Sciences & Hospital, Kolkata (6th floor Auditorium)

Event Objectives: Concerns, challenges and potential solutions for ethical conduct of clinical research
Learning Methods: Brief lectures, Interactions, Group activities
Audience Size & Type: 50; Ethics committee members, Investigators, Support staff in investigators team

Program Schedule

Time	Session	Resource Persons
10.00 am	Reception, Registration, Refreshments	-
10.15 am	Introduction & Welcoming All Participants	**Dr Santanu K Tripathi, Principal – JIMSH & Organizing Chairman, FERCICON 2024**
10.25 am	Pre-Conference Event	**Chair: Dr Nandini Kumar (President, FERCI)**
10.30 am	Session 1: Common Ethics Review for Multi-Centre Studies	**Dr Roli Mathur, Scientist G & Head, (Virtual Presence)** **Dr Dileep G, Scientist B** **Dr Elna Paul Chalisserry,** **Project Research Scientist II (Medical)** **ICMR Bioethics Unit, ICMR-DHR, Govt. of India**
12.00 pm	**TEA BREAK**	
12.15 pm	Session 2: WHO Tool for Benchmarking in Research Ethics Oversight (Virtual Session)	**Dr Cristina Torres, University of the PhilippinesDr Madhur Gupta, Technical Officer - Pharmaceuticals, WHO India**
01.30 pm	**LUNCH BREAK**	
02.15 pm	Session 3: Research in Fragile Settings (Virtual Session)	**Dr Doris Schroeder,** **Professor of Moral Philosophy and Director** **Kate Chatfield, Faculty** **Centre for Professional Ethics, University of Central Lancashire**
03.30 pm	**TEA BREAK**	
03.45 pm	**Meeting of FERCI Executive Committee and Steering Committee Members**	

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FERCICON 2024 :: Program Schedule

Date: November 08 & 09, 2024 Friday & Saturday

Conference Theme: *Assuring Quality of Review and Oversight by the Ethics Committees*

DAY 1: November 08, 2024 Friday		
Time	**Session**	**Resource Persons**
09.00 am	Reception, Registration, Refreshments	-
09.25 am	Welcoming All Delegates	**Dr Balram Gupta, Vice Chairman, JIMSH & Dr Santanu K Tripathi, Organizing Chairperson, FERCICON 2024 & Principal, JIMSH**
09.30 am	SYMPOSIUM – I. Contentious Issues in Ethical Conduct of Research involving Humans	**Chair: Dr Lalita Savardekar (Secretary,FERCI)**
	Ethical Issues in Investigator-Initiated Clinical Trials (Virtual Session)	**Dr Roli Mathur, Scientist G & Head, ICMRBioethics Unit, ICMR-DHR**
	Ethics Oversight in Adaptive Clinical Trials	**Dr Murugananthan K (Novartis, India)**
	Ethical Challenges in Multi-Centric Trials including Provision for Common Ethics Review	**Dr Saibal Das (ICMR-CAMH, Kolkata)**
	From Review to Continuous Oversight – How Can the Ethics Committees Cope with this Changing Role?	**Dr Sumalya Sen (GIMSH, Durgapur)**
11.00 am	LECTURE – I. Continuous Education for Ethics Committee Members	**Dr Lalita Savardekar (Secretary, FERCI)**
11.20 am	**TEA BREAK and Poster Exhibition**	
11.35 am	SYMPOSIUM – II. Enhancing Quality of Ethics Review	**Chair: Dr. Suparna Chatterjee (IPGMER)**
	Quality Issues in the Ethics Committees' Structure and Functioning	**Dr Nandini Kumar (FERCI)**
	Role of Audit in Quality Assurance (Virtual Session)	**Dr Parloop Bhatt (NABH Assessor)**
	Standardizing Review Processes (Virtual Session)	**Dr Medha Joshi (NIG, Mumbai)**
	Ethics Committee Documentation Practices (Virtual Session)	**Dr. Sucheta B Kurundkar (CDSA)**

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DAY 1: November 08, 2024 Friday (Contd.)		
Time	**Session**	**Resource Persons**
01.00 pm	**INAUGURATION**	
	Welcoming Note by Organizing Chairman (2 min)	**Prof Santanu K Tripathi (Org Chair)**
	Inviting Dignitaries to Dias and Felicitation (3 min)	**Dr Shambo S Samajdar (Org Secy)**
	Inaugural Lamp Lighting (2 min)	**All Dignitaries on Dias**
	Host Institute Welcomes (5 min)	**Mr K K Gupta (Chairman, JIMSH)**
	President Speaks (5 min):	**Dr Nandini Kumar (President, FERCI)**
	Inaugural Address by the Chief Guest (20 min)	**Dr T P Sasikumar (JNANAM, Kerala)**
	Vote of Thanks (3 min)	**Dr Paramita Pal (Convenor)**
01.45 pm	**LUNCH BREAK & Poster Exhibition**	
02.30 pm	Dr V Muthuswamy Memorial Oration (30 min)	**Orator: Dr Doris Schroeder (UK)** **Chair: Dr Nandini Kumar (President, FERCI)**
03.00 pm	PANEL DISCUSSION – I Decentralised Clinical Trials, Emerging Technologies and Shifting Ethics Paradigm Chair: Dr Urmila Thatte (Ex-Secretary, FERCI) Moderator: Dr Pradeep Narayan (NABH)	**Panelists: Dr Bikash Medhi, PGIMER-Chd (Regulatory)/ Dr Geeta Jotwani, ICMR Scientist (Genomics Research)/ Dr Murugananthan K, Novartis (Industry)/ Dr Ranajit Guha (Ethics), Dr Amit Dey (AI)**
03.30 pm	**TEA BREAK & Poster Exhibition**	
03.45 pm	LECTURE – II. Ethical and Informative Trials: How COVID-19 Experiences Can Help to Improve Trial Design (Virtual Session)	**Dr Emma Law (UK)**
04.15 pm	LECTURE – III. Ethical Challenges in Research involving Children and How to Address them	**Dr Suparna Chatterjee (IPGMER)**
04.35 pm	PANEL DISCUSSION – II Academic Clinical Trialsin India – Ethical Issues Chair: Dr Ranajit Guha (IGIMS, Patna) Moderator: Dr Santanu K Tripathi (JIMSH)	**PANELISTS: Dr Bikash Medhi (PGIMER, Chd)/Dr Avijit Hazra (IPGMER, Kolkata)/ Dr Pradeep Narayan (NABH)**
05.00 pm	**General Body Meeting**	
06.30 pm	**Cultural Evening followed by Dinner**	

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DAY 2: November 09, 2024 Saturday		
Time	**Session**	**Resource Persons**
09.00 pm	Free Oral Paper Presentation (8 Papers: 7 min each)	**Chair: Dr Shambo S Samajdar (IHS, Kolkata)**
10.00 am	**TEA BREAK & Poster Exhibition**	
10.15 am	SYMPOSIUM – III. Ethical Challenges in Research with the Vulnerable – Case Studies / Experience Sharing	**Chair: Dr Avijit Hazra (IPGMER, Kolkata)**
	Research in Emerging Infectious Diseases andNeglected Tropical Diseases	**Dr Sayantan Banerjee (AIIMS, Kalyani)**
	Research in Psychiatry	**Dr Soumitra Dutta (TMC, Kolkata)**
	Cancer Research	**Dr R Roychoudhury (SGCCRI, Kolkata)**
11.20 am	LECTURE – V. Ethics in Conduct of AyurvedicClinical Trials in India	**Dr Achintya Mitra (CCRAS)**
11.45 am	LECTURE – VI Ethical Concerns in HomeopathyResearch	**Dr Gurudev Choubey, Research Officer (S-4), DACRRIH, Kolkata (CCRH)**
12.00 pm	**TEA BREAK & Poster Exhibition/Evaluation**	
12:15 pm	Panel Discussion – III Data Privacy and Ethics inBiomedical Research Chair: Dr R Roychoudhury (SGCCRI, Kolkata) Moderator: Dr Avijit Hazra (IPGMER, Kolkata)	**Panelists: ThirdEyeData (Data Science)/ Ms Shivangi Rai, C-HELP, India (Law)/ Dr Pradeep Narayan, NH Hospitals, Kolkata (Ethics)/ Dr Bikash Medhi, PGIMER, Chandigarh (Clinical Research)**
01.10 pm	**LUNCH BREAK and Poster Exhibition/Evaluation**	
02.00 pm	LECTURE – VII. Ethical Issues in Public Health Research (Virtual Session)	**Dr Anant Bhan (Sangath, Bhopal)**
02.20 pm	LECTURE – VIII. Ethics in Research Publication	**Dr Shambo S Samajdar (IHS, Kolkata)**
02.35 pm	**TEA BREAK**	
02:50 pm	MINI LECTURE SERIES – Extempore 12 min each	**Chair: Dr Sabnam Ara Begam (RGKMCH)**
	ML-1. Exposing Medical Students to Research Ethics: An Unmet Need – Dr Aditi Aikat (JIMSH) **ML-2. Role vis-à-vis Lived Experiences of Non-Medical Members of Ethics Committees in the Reviewand Oversight Process – Dr Sutapa Biswas (CFI, Kolkata)** **ML-3. Using Patient Registries in Research: Addressing Ethical Issues – Dr Ashis Kumar Saha (JIMSH)** **ML-4. Ethics in Critical Care Research – Dr Rakhi Sanyal (JIMSH)**	
03.30 pm	**PHOTO SESSION**	

DAY 2: November 09, 2024 Saturday (Contd.)		
Time	**Session**	**Resource Persons**
03.40 pm	**VALEDICTORY SESSION** **Chairpersons: Dr Nandini Kumar, President, FERCI & Dr Balram Gupta, Vice Chairman, JIMSH**	
	Summary of Proceedings (10 min)	**Dr Payodhi Dhar (Org Jt Convener)**
	Valedictory Address: "Update on Helsinki Declaration"(20 min) (Virtual Session)	**Dr Dirceu Greco, Professor Emeritus** **UFMG (Brazil)**
	Award Ceremony: Best Oral/Poster Presentations (5 min)	-
	Feedback from Participants (10 min)	-
	Comments and Announcing the next Conference (5 min)	**Dr Nandini Kumar (President, FERCI)**
	Closing Remarks from Organizing Committee (5 min)	**Dr Shambo Samrat Samajdar (Org Secy)**
	Vote of Thanks & Wrap Up Comments (5 min)	**Dr Balram Gupta (Vice Chairman, JIMSH)**
04.40 pm	**FAREWELL TEA**	

The 11th National Conference of

Forum for Ethics Review Committees in India

FERCICON 2024

INAUGURAL Address by Dr T P Sasikumar

BIODATA of Dr. T.P. Sasikumar

Dr T P Sasikumar, MSc, MPhil, PhD, LLB, MBA, MSSpace Scientist, Mathematician, Photogrammetry – Remote Sensing – Image ProcessingExpert, Educationalist, Spiritual - Meditation Director, Exponent on IKS – Indian ScientificHeritage, LIFE Mentor, Motivation Speaker, Writer, Poet, Thought Leader, Image Creator,Management consultant, Blogger and Youtuber

➢ Student of Vedic Scholar – (Late) Brahmasree KPC Anujan Bhatathiripad
➢ Student of Astrology & Vaastu Expert – Payyanur Kesavan Achari
➢ Student of Himalayan Meditation Master (Swamy Rama) – (Late)

Mahamandaleswar Swamy Veda Bharati

- Professor of Practice, ICFAI University, INDIA
- CHANCELLOR, National Education Forum, KOLKATA
- Acharya, SHIKSHA Gurukulam, YOGA University of Americas, Florida, USA
- Honorary International Director at Viswa Humanity International Royal Council
- Deputy Secretary General - Space Technology at Global Sustainable Council, UK
- Advisor, All India Sustainable Development Council
- Director (Research) at Global Foundation for Early Childhood Care Education &

Research & National Foundation Teachers Institute

- Advisor, Mentor, & Counsellor at YES You CAN International, UK
- Mentor, Jyoti Learning, UK
- Bhagavad GITA Acharya & Advisor – World Yoga Community at the UN NGO

Associate, New York

- India Member of the Education & Science Council at Center for Global Auditorium

Advisor, Bridg360, Texas, USA

- Founder, Grandma Child-Care SHIKSHA Gurukulam
- CHAIRMAN & CEO, Shiksha JNAANAM
- Founder, World Social Craft Foundation
- Director, Columbus SHIKSHA Camp
- Founder, Destination IAS & Mission CSAT
- Founder Director, Works at Conscious Living Commune
- Chief Executive Officer (CEO) & Founder at Shiksha Jnaanam Residential Camp
- Chief Executive Officer (CEO) & Founder, International Institute for Advanced

Academics Soft Skills & Life Learning

- Founder Chairman, Rama Dharma Pracharaka Samithy, Hyderabad.

The 11th National Conference of

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INAUGURAL Address by Dr T P Sasikumar

Thank you for this kind invitation and keeping trust on me, Leaders of Forum for Ethics Review Committees in India and Jagannath Gupta Institute of Medical Sciences & Hospital.

I am deeply honoured to inaugurate this important gathering of FERCICON 2024 here in Kolkata. Kolkata, the cultural heart of India, has a rich legacy of intellect, spirituality, and ethical reflection—a fitting setting for FERCI's mission to uphold ethical rigor in clinical research. The theme, "Assuring Quality of Review and Oversight by the Ethics Committees" is timely and crucial. FERCI's efforts in promoting ethical clinical research resonate strongly in a world where the boundaries of science and ethics are continually tested.

Importance of Ethics in Research:

• FERCI's dedication to fostering ethical standards in clinical research echoes a fundamental truth from our philosophical heritage: that true knowledge (*vidya*) must be aligned with compassion and integrity. Indian philosophy emphasizes not just the acquisition of knowledge, but the responsible and ethical application of it, as seen in the ancient principle of *Dharma*—a commitment to righteousness, justice, and duty.

Indian Philosophical Reflections on Ethics - Be with Bhagavad Gita Verses:

• The *Bhagavad Gita* offers timeless wisdom on the ethics of duty and integrity. In Chapter 2, Verse 47, Lord Krishna advises Arjuna, "You have a right to perform your duty, but not to the fruits thereof." This verse highlights our duty to act ethically, without attachment to personal gain or recognition—principles that should guide ethics committees as they review research for its societal impact rather than individual or corporate interests.

• Further, in Chapter 3, Verse 21, Krishna says, "Whatever a great person does, others follow. Whatever standards they set, others adopt." As FERCI's work continues to set high ethical standards in research, it influences practices across India, setting benchmarks for transparency and ethical responsibility.

• The *Bhagavad Gita* also speaks of selflessness as a core aspect of ethical conduct. Chapter 3, Verse 25 says, "As the ignorant perform their duties with attachment to results, the wise must perform theirs with detachment, for the welfare of society." This guiding principle calls upon us to act in service to society, striving for the welfare of all, particularly the vulnerable populations involved in research.

Connecting to Kolkata's Present Context:

• Recent years have seen challenges in Kolkata's healthcare landscape, from concerns in healthcare delivery in general to the ethics in clinical trials,complex socio-medical challenges in recent years, with public trust in healthcare under strain. It is our shared duty to foster trust through transparent, ethical research practices that prioritize patient well-being.As research continues to expand here, it is vital that the trust between the public and the medical community is upheld through rigorous ethical standards. Our ethical responsibilities should align with the *Upanishadic* call for knowledge that is "illumined by truth."

May this conference serve as a beacon of ethical clarity and strengthen our collective resolve to uphold the principles of justice, compassion, and integrity. As we light the inaugural lamp, let it be symbolic of the light of *Jnana* (knowledge) and *Dharma* (duty), guiding us all towards the highest standards of ethical practice.

Let us strive, as Arjuna did, to act with unwavering dedication to truth and compassion. Thank you, and may this event inspire ethical advancements that benefit all of society.

-

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Dr V Muthuswamy Memorial Oration

By Prof. Doris Schroeder, UCLan UK and UCLan Cyprus, 8 November 2024

Introduction

Namaste.

It is a great privilege and honour to give the Dr Vasantha Muthuswamy Memorial Oration at FERCICON2024. Thank you very much for the invitation to the President of FERCI and to the Organizing Chairman.

Dr Nandini, Prof Santanu, Ladies and Gentlemen,

I would like to show my appreciation for having known Dr Vasantha by considering which legacies she left and what she would still want to do.

Dr Vasantha died on the 21st of February 2023 and the last written message I received from her was on 10th of January, about 5 weeks before she went to her heavenly abode.

Amongst other things she wrote: "God has some pending work for me in this world still." And she was right, there is so much still to do for a person like Vasantha, and now she can longer do it herself. Others have stepped forward to carry her legacy, a legacy of promoting ethics and integrity in all medical research in India and beyond.

The main responsibility of carrying forward Vasantha's legacy will fall on Indian shoulders, for instance, on the President of FERCI, Dr Nandini. India is now the most populous country in the world and it has a very large number of Ethics Review Committees. It is an honour to have a speaking slot at the yearly FERCI conference.

The title of this conference is "Assuring Quality of Review and Oversight by the Ethics Committees", an extremely important topic because only good-quality ethics review can prevent harm and exploitation in research.

I want to structure my thoughts on Dr Vasantha across four themes preceded by a short recollection of our collaborations.

Two of the themes refer to the new Declaration of Helsinki, which I believe Dr Vasantha would have welcomed very much. Two further themes refer to Dr Vasantha's achievements.

To conclude, I have a small request on where we could take Vasantha's legacy globally and very practically.

How I have known Dr Vasantha

I first met Dr Vasantha at a UNESCO-hosted meeting, which was organized by our common friend, Dr Dafna Feinholz, the Chief of Bioethics at the UNESCO. This was about 15 years ago. After this meeting, we met regularly at events in Europe or in India.

It was in 2015 that the first opportunity arose to work together more closely.

I invited Dr Vasantha to join a consortium for a grant proposal to the European Commission. The funding call requested that the successful consortium build an ethics framework against 'ethics $dumping$[1]', the export of unethical research practices from higher to lower income countries.

The Wikipedia page on Dr Vasantha says: "She was a recognized expert on ethics dumping in India."

Those who oppose ethics dumping promote equitable partnerships in global research and oppose helicopter research and other colonial practices.

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We were successful and it was a great privilege to work with Dr Vasantha and Dr Nandini for 3.5 years on the TRUST project. For instance, together we published a paper on the six types of ethics dumping.
Schroeder D, Chatfield K, Muthuswamy V and Kumar N (2021). Ethics Dumping – How not to do research in resource-poor settings. Journal of Academics Stand Against Poverty, 1(1), 32–55. https://doi.org/10.5281/zenodo.8089799.

Nairobi May 2016, Dr Joshua Kimani, Dr Vasantha Muthuswamy, Dr Doris Schroeder

The collaboration was excellent and we decided, together with our global teams, to bid for another project from the European Commission. We were successful again.
I now lead the largest ethics project the European Commission has ever funded, with 4.7 million Euros, it's called PREPARED and we are developing a framework for accelerated research during pandemics and other global crises, that does not cut ethics corners.
Dr Vasantha assisted greatly in the team building of the PREPARED group and was very active in the group for four months.
I will return to PREPARED at the end of the oration. Now I would like to come to the four themes that structure my oration. The first two are on the Declaration of Helsinki.

PREPARED team in Amsterdam May 2024

Schroeder D, Chatfield K, Muthuswamy V and Kumar N (2021). Ethics Dumping – How not to do research in resource-poor settings. Journal of Academics Stand Against Poverty, 1(1), 32–55. https://doi.org/10.5281/zenodo.8089799.

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The Declaration of Helsinki

THEME 1 – Respect

26 years after this was recommended by the British Medical Journal, the drafters of the new Declaration of Helsinki have done something that I believe Vasantha would have approved of. They have shown respect to research participants by abandoning the term 'human subjects'.

It was as early as 1991[2], more than three decades ago, that the British Psychological Society noted that psychologists are indebted to those who agree to take part in their research. And as a result, these individuals deserve to be treated with respect. That's why the society recommended that the term 'human subjects' be abandoned and the term 'research participants' used instead.

I have always experienced Dr Vasantha as an extraordinarily respectful person. She was respectful to all those she met irrespective of their class, wealth or standing. In our work together, we met highly impoverished people who struggled to earn their livelihood, some for instance, relying on sex work to feed their children. We also met world famous scholars or politicians. I noticed no difference in Vasantha's kind and polite conduct. She did not judge people on circumstances and showed everybody respect.

That is why I believe she would have congratulated the drafters of the new Declaration of Helsinki on their more respectful use of language.

Chalmers I. People are "participants" in research. Further suggestions for other terms to describe "participants" are needed. BMJ. 1999 Apr 24;318(7191):1141. doi: 10.1136/bmj.318.7191.1141a. PMID: 10213744; PMCID: PMC1115535.

This leads me to a 2nd new feature of the Declaration of Helsinki, which I believe Dr Vasantha would have approved of.

THEME 2 – The recognition of structural inequity

For the first time, the Declaration of Helsinki makes reference to structural inequities in the context of medical research.

Previously, Article 7 simply noted that medical research must promote and ensure respect for all whilst protecting their health and rights. This sentiment was preserved in the new Article 6, but it was also put into context for the first time.

> "Since medical research takes place in the context of various structural inequities, researchers should carefully consider how the benefits, risks, and burdens are distributed."
> (World Medical Association (2024) Declaration of Helsinki, available at: https://www.wma.net/policies-post/wma-declaration-of-helsinki/)

In the drafter commentary on why this reference to structural inequities was made, the drafters noted that they wanted to include an aspirational sentence about global justice, especially after the consultation meetings at the Vatican and Johannesburg.

Chalmers I. People are "participants" in research. Further suggestions for other terms to describe "participants" are needed. BMJ. 1999 Apr 24;318(7191):1141. doi: 10.1136/bmj.318.7191.1141a. PMID: 10213744; PMCID: PMC1115535.

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The result of this recognition of structural inequity is two-fold.
First, the new declaration emphasizes strongly that community engagement is a must and not a maybe.
Second, the regular *exclusion* of participants in vulnerable situations from medical research was reconsidered. In the past, it was argued that those in vulnerable situations should be widely excluded from research to protect them from harm and exploitation. It has now been recognized that such exclusion can "potentially perpetuate or exacerbate their disparities" (Art. 19).
We made a submission to the drafters on behalf of the PREPARED group, and three of our suggestions were incorporated exactly with the wording we suggested. All three were about the articles that focus on individuals in vulnerable situations in a world of structural inequity. I was very grateful for this recognition of our thinking and I was sorry that the PREPARED group at the time did not include Dr Vasantha. The submission was made in June this year.
The result of bringing global justice and structural inequity into the Declaration of Helsinki for the first time is a drive towards more equitable partnerships in research, including much needed medical research.

What would Dr Vasantha have made of this development?
Dr Vasantha is a co-author of the TRUST Code, a Global Code of Conduct for Equitable Research Partnerships. The TRUST Code is featured on the FERCI website under "International Documents".
As the lead author of the code, I know exactly how engaged which co-authors were in the process of writing this guidance, guidance, which has now been widely adopted around the world. It has been adopted by major funders (e.g. the European Commission), top publishers Schroeder D and Pannofino C (2024) PREPARED comments integrated into the Declaration of Helsinki 2024, a blog for PREPARED available at: https://prepared-project.eu/prepared-comments-integrated-into-the-declaration-of-helsinki-2024/
FERCI (not dated) International documents, https://ferci.org/international_documents

(e.g. NATURE), governments (e.g. Poland and the Netherlands), leading universities (e.g. the top two African universities, the University of Cape Town and the University of Witwatersrand in Johannesburg) and major associations (e.g. the Association of Commonwealth Universities).
Dr Vasantha and also Dr Nandini were very much part of the group's push against any type of double standards and any type of extractive helicopter research, which did not involve local communities and researchers, and which had the potential to harm or exploit those who were affected by structural inequities.
Let me give an example.
Together with Dr Urmila, Dr Sandhya, and Dr Nandini, Dr Vasantha organised a major consultation for the TRUST Code in Mumbai in 2016. The cases of double standards, which were exposed at this workshop, have since been quoted around the world to counter inequitable research practices.

World Medical Association (2024) Declaration of Helsinki, available at: https://www.wma.net/policies-post/wma-declaration-of-helsinki/

Schroeder D and Pannofino C (2024) PREPARED comments integrated into the Declaration of Helsinki 2024, a blog for PREPARED available at: https://prepared-project.eu/prepared-comments-integrated-into-the-declaration-of-helsinki-2024/
FERCI (not dated) International documents, https://ferci.org/international_documents

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Most prominently, the 2021 CIOMS Guidelines for "Clinical research in resource-limited settings"[7] referred at length to the case study written up for Dr Vasantha's Mumbai workshop by Dr Srinivasan, Dr Johari, and Dr Jesani.[8]

We also used this case study in a training video clip on ethics dumping. I therefore have very strong reason to believe that Dr Vasantha, who was passionate about addressing injustice, would have welcomed the aspirational thoughts about global justice, which are now part of the Declaration of Helsinki. After these two themes on the Declaration of Helsinki, I would now like to turn to Dr Vasantha achievements in a further two themes.

March 2016, Workshop organised by Dr Vasantha and colleagues to sure equitable partnerships in global research.

Achievements

Theme 3 – Drafting ethics codes

Dr Vasantha was responsible for the release of the main Indian Council of Medical Research (ICMR) ethics guidelines for biomedical research in 2000, 2006 and 2017, in addition to guidelines on animal research, stem cell research and genetically modified food. I want to pause here because it is mind-blowing that one person could be so hard-working to oversee the drafting of ethics guidelines over so many years.

My sincere respect to Dr Vasantha for this major achievement.

Ethics committees need ethics codes. There are so many possibilities for exploitation in research and not every research ethics committee member can know them all. REC members rely as much on ethics guidance as researchers, in my view.

It is also a moving field, as attitudes towards the ethics of research change.

"We have always done it this way" is not a good answer within the context of research ethics. Given that Dr Vasantha was the Indian expert on ethics dumping, I'd like to use it as an example.

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[6] https://www.globalcodeofconduct.org/

[7] CIOMOS (2021) Clinical research in resource-limited settings, https://cioms.ch/wp-content/uploads/2021/06/CIOMS_ClinicalResearch_RLS.pdf

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https://youtu.be/gAP4U0Um0LU&t=4m2s

An example of patronizing conduct as well as helicopter research, both forms of ethics dumping, is the arrival of researchers from abroad with funding in a lower income setting who then demand that their study is pursued exactly as they wish, without or with little input from local researchers or communities, and that it is swiftly approved by a local research ethics committee.

That research in the past has been done this way does not mean it is ethically acceptable.

To recognize this requires vision and forward thinking, which Dr Vasantha had and which is needed to counter persistent claims that "We have always done it this way" is no excuse for unethical conduct.

It is a great achievement of Dr Vasantha's to have recognized and countered the highly unethical practice of ethics dumping years ago in order to make global science more just.

I would now like to come to another great achievement of Dr Vasantha's: her visionary openness to the world.

Theme 4 – Visionary openness to the world

All European countries taken together have half the population of India. Hence, there would always be enough work for an engaged ethicist just working in India. But Dr Vasantha worked around the world.

One of the last video meetings I had with Vasantha was in December 2022, three months before her passing. She was full of energy and joy and very happy to talk to Prof. Ock-Joo Kim from Seoul National University and me about accelerating research during pandemics without cutting ethics corners.

Video meeting December 2022 of Dr Vasantha with Prof. Doris and Prof. Ock-Joo

Notably, India had been one of the first countries in the world to issue specific ethics guidance during the COVID-19 pandemic in April 2020. And whilst the guidance drafting was led by her successor at ICMR, Dr Mathur, I believe she was still involved.

She had a graceful ease and wit when working internationally and crossed cultural boundaries with humility.

She was the Founder Member-Secretary of the Forum for Ethics Review Committees in Asia Pacific (FERCAP) and her links with other Asian bioethics leaders was close. In 1997, she was a World Health Organization (WHO) Visiting Fellow at the Kennedy Institute of Ethics at Georgetown University, a highly prestigious university in the US.

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Here is what some of the PREPARED team members from other countries had to say about Dr Vasantha after we lost her.

> *"Not only a great national leader in research ethics in India she was a warm true friend. I have a grateful heart for Vasantha's triumphant and fulfilled life. May she find eternal peace."*
> Prof. Ock-Joo Kim, Seoul National University, South Korea
> *"When I first met her here in my country, the Philippines, she was already a distinguished persona but she was humble with always an easy and available smile."*
> Prof. Fatima Alvarez-Castillo, University of the Philippines in Manila
> *"We are blessed to have known and worked with her over many years and her legacy will continue to shine as we follow her great example. I am sure that we have a great friend and intercessor in our heavenly home now."*
> Prof. Pamela Andanda, School of Law, WITS, Johannesburg
> *"We have lost a friend and a collaborator, but 'when you lose someone you love, you gain an angel you know'."*
> Dr Joshua Kimani, Clinical Director PHDA, Nairobi
> *"Vasantha was a wonderful person, I wish we could have benefited from her presence among us a lot more, but she now rests in peace."*
> Dr Francois Bompart, DNDI
> *"Adventurous spirit, kind-heart and abundant grace. This is how we shall remember you."*
> Dr Michelle Singh, EDCTP, Cape Town.

As the PREPARED group, we want to dedicate a book about the PREPARED Code, which will be released next year, to Dr Vasantha. But in addition, we want to do something very practical that we hope would have pleased Dr Vasantha.

The first conference of the PREPARED group was in September 2022, when Vasantha still seemed well and definitely able to travel. It would have been her first meeting with the group and as we now know, it would have been her last.

But it was thwarted by something that hampers global science to an extreme extent and that is still very mundane. Dr Vasantha and Dr Nandini could not attend the first conference of the PREPARED group because they were not able to obtain a Schengen visa The conference was in September 2022 and they were given a visa appointment for January 2023, four months later.

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International researcher mobility is essential for research and the world cannot afford to have meetings where important delegates, like Dr Vasantha, are missing simply due to visa hurdles.
In June 2024, the Lancet covered the problem, saying that:

> "Visa issues can undermine the inclusivity of scientific meetings, hindering collaborative opportunities and bi-directional knowledge exchanges. We believe that scholarly organisations have an obligation to advocate for inclusive short-term visa procedures, illustrating the value of wider scientific interactions."

We aim to launch a policy brief on the negative impact of visa hurdles for researchers on global science at the European Parliament in June 2025.
If any of you want to give me examples or statistics of how visa difficulties have impeded global research in your case, please contact me after the conference.
Perhaps this is a small step towards more global justice in research that Dr Vasantha would have approved of.
Let me end this oration by saying that Vasantha is very much missed by the whole PREPARED team, and I still feel a deep personal loss that she is no longer with us.
Thank you again for the privilege of inviting me to give this oration.

Pre-conference Lecture Abstract

ICMR Ethical Guidelines for Investigator-Initiated Clinical Trial (IICT)

Presented by: ***Dr Roli Mathur*****,** Scientist G and Head, ICMR Bioethics Unit, Indian Council of Medical Research, Department of Health Research

Background

Investigator-Initiated Clinical Trials (IICTs) are studies conducted on human participants by academic institutions, collaborative research groups or individual investigators, to explore a new indication, route of administration, dose, or dosage form of an already approved drug. These studies are strictly for research purposes and not intended for commercialization/ or to seek marketing approval. Under NDCT rules,2019 , Academic Clinical Trials are defined as a clinical trial of a drug already approved for a certain claim and initiated by any investigator, academic or research institution for a new indication or new route of administration or new dose or new dosage form, where the results of such a trial are intended to be used only for academic or research purposes and not for seeking approval of the Central Licencing Authority or regulatory authority of any country for marketing or commercial purpose.

India's large and diverse population, trained professionals, and relatively low research costs present significant opportunities for conducting impactful clinical trials. Harnessing these advantages, conducting IICTs can help India address a range of diseases within its population while producing valuable data at a fraction of the cost typically required in developed nations.

The Need

The exploratory nature of IICTs could pose unique risks to participants as the Central Licensing Authority (CLA) is not accountable for their oversight and no permission is to be sought for the conduct of these studies. Lack of adequate budgets could be a significant deterrent to IICTs. Further, providing medical management and treatment, compensating for research-related injuries, and reimbursing participant expenses are perceived by many investigators and institutions as a costly responsibility that discourages participation in IICTs. Ethics committees and institutions have a heightened responsibility to ensure quality and safety in IICTs. There is a need to establish effective mechanisms for monitoring serious adverse events (SAEs) in IICTs, as there is a lack of clarity regarding who is accountable for causality assessment, SAE subcommittee composition and reporting timelines. Additionally, the need for Data and Safety Monitoring Board (DSMB) and its implementation is not clear. In addition to above, often limited funding and absence of external sponsors could challenge the maintenance of ongoing studies and post-trial access/ benefit-sharing. These gaps underscore the need for a comprehensive ethical framework for Investigator Initiated Clinical Trials in India, addressing the unique ethical challenges and ensure participant protection.

The Process

To address the above the ICMR is developing an ethical guideline document which would provide clear direction to researchers undertaking IICTs in India. During the last 6 months, two multidisciplinary expert committee meetings were conducted and valuable inputs have been received. A draft framework has been developed, which is being finalized in consultation with experts. The revised draft will undergo peer review and public consultation before finalization and release.

Expected Outcome

The proposed guideline document would provide a framework for the ethical conduct of Investigator-Initiated Clinical Trials in India, addressing unique ethical challenges.

It is intended for all stakeholders involved in any aspect of IICTs including institutions, ethics committees, investigators, postgraduate students, funding bodies and sponsors, regulators, study participants, patient groups, and the public among others. By addressing these issues, the document seeks to enhance the quality and effectiveness of IICTs, encouraging more researchers and institutions to engage in these important studies, ultimately benefiting public health in India.

Pre-conference Lecture Abstract

Title: Navigating the Common Ethics Review Process in Multicenter Studies: Challenges and Solutions

Presented by: Elna Paul Chalisserry[1], Dileep G[1], Roli Mathur[1]
[1]ICMR Bioethics Unit, ICMR-DHR, Nirmal Bhavan, Bengaluru, Karnataka, 562110.Email: icmrbioethicsunit@gmail@gmail.com

Collaborative efforts in biomedical and health research have grown significantly, enabling researchers to pool resources and expertise toward shared goals. These partnerships whether within departments, between institutions, or across international borders—hold the potential to produce impactful outcomes and engage diverse stakeholders. Multicentre studies, in particular, allow researchers to achieve greater statistical power, enhance the validity and reliability of findings, and improve generalizability, potentially leading to improved outcomes or policy changes. However, these collaborations also present ethical challenges, including complex approval processes, lengthy timelines, communication gaps, data-sharing concerns, ownership and intellectual property issues, and diverse local socio-cultural differences.

In India, all biomedical and health research proposals require review and approval from Ethics Committees (ECs) before the study can commence. Each site involved in the research must obtain approval from its respective EC. While this independent review model promotes accountability and ensures cultural, ethical, and contextual relevance, it often leads to duplicated efforts, inconsistencies, and extended timelines. To streamline this process, the ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017) recommended a common review approach for specific low-risk studies and multicentre research involving anonymized data. This approach designates a primary EC to oversee the study, while representatives from participating ECs collaborate to address site-specific concerns and ensure procedural consistency.

Building on this foundation, the ICMR's 2023 Joint Ethics Review Guidelines for Multicenter Research Studies introduce a structured process for conducting common reviews. Under this model, a Designated Ethics Committee (DEC) coordinates joint virtual meeting with members of local site ECs to review protocols, consider site-specific factors, and approve study protocols, all while outlining steps for monitoring follow-up safety and upholding core ethical standards.

Despite these advancements, common review processes are not yet widely adopted in India. To bridge this gap, the ICMR Bioethics Unit aims to understand the factors that deter Ethics Committees from implementing these processes developing a practical, implementable ethics review approach to tackle the remaining challenges in the joint review process. This workshop aims to facilitate dialogue among participants, including Ethics Committee members and investigators, through group discussions that identify practical obstacles to implementing common ethics reviews for multicenter studies. The goal is to develop actionable solutions that will inform policymakers in streamlining national multi-center ethics review processes. Key areas of focus will include communication barriers, lengthy approval times, varying ethical standards, and the implementation of common review procedures.

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Abstracts from Lectures from the Scientific Program:

Title: Quality Issues in the Ethics Committees' Structure and Functioning

Presented by: Nandini K Kumar, *Former Deputy Director General Senior Grade (ICMR), President, Forum for Ethics Review Committees in India*

Abstract:
The two pillars protecting research participant's rights, safety and well-being are informed consent process and independent decision-making by ethics committee (EC). In order to assure about quality of review and oversight by ethics committees one needs to consider three main factors – institution, researcher and ethics committee. While the institution should have policies for responsible conduct of research pertaining to the researcher and support to the ethics committee in terms of its structure and functioning, the latter should give extra care to see that these policies are implemented and its standard operating procedures (SOPs)are adhered to. For this the EC members need to be trained in the relevant topics and SOPs. They should also be updated as and when newer guidelines and regulations come into force. Registration of ECs is the first paper requirement towards quality. For registering the ECs in the relevant portals of Government (Sugam portal of the drug regulator and Naitik portal of Department of Health Research) training certificates of the members are required to be uploaded. As a result of that the EC members are forced to undergo such training which is only a small beginning of the bigger picture of quality review of research proposals. One needs to see that this training extends to the EC secretarial staff and investigators too for smooth functioning of the EC. Additionally, training in research methodology, GCP, current ethical guidelines, regulations and responsible conduct of research should be imparted to researchers periodically.

Concerning structure of EC, there is still a lack of understanding about the requirements. Considering the number of ECs in the country not many have registered yet which is a grave matter. Many times, it is during the registration process that the EC corrects its membership structure. Another issue is that the regulators do not consider alternate members as acceptable inclusions, whereas National Ethical Guidelines, 2017 do. Alternate members are a necessity to replace absent members who should be part of the quorum as per New Drugs and Clinical Trials Riles 2019 without which the minutes will be considered null and void. This flexibility is needed for the timely review of regulatory clinical trials. Many ECs conduct a meeting for the sake of following the existing norms but without giving serious thought to their responsibilities. There is no discussion on risk-benefit analysis and vulnerability to provide safeguards. Monitoring as a routine or 'for cause' is an integral part of EC functioning despite its mention in the ethical guidelines and the regulations but this is not being paid much attention to. For efficient functioning of EC, one needs to work out a faster turnaround time. All this will be more regular if quality review by external agencies is carried out.

Solutions to address these issues are registration of ECs, continuing education and training for EC members to make them aware of their SOPs and the latest information to justify their decisions in that light; usage of ICMR's fillable forms as annexures in SOP for uniform procedure across the country; monitoring as a routine process and 'for cause'; and internal and external quality assessment. Currently, three agencies do this – one national and two international ones. The national one is the National Accreditation Board for Hospitals to assess ECs. The international ones are the WHO-initiated Strategic Initiative for Developing Capacity for Ethical Review and the American Alliance for Accreditation of Human Research Protection Program. The National Medical Commission, Dental Council and similar Statutory bodies of AYSH (NCISM and NCH)

Abstracts from Lectures from the Scientific Program:

Title: Lessons from COVID-19 experience to improve clinical trial design for better quality?

Emma Law
Head of Clinical Quality Assurance, Protas, UK

Isabel Smith
Senior Research Officer, Protas, UK

During the COVID-19 pandemic, the race to find an effective vaccine or treatment saw an 'extraordinary number' of clinical trials being conducted. While there were some key success stories, not all trials produced results that informed patient care. There was a significant amount of waste in clinical research during the pandemic which is said to have hampered an evidence-based response. Conducting trials which could have been predicted to fail to answer the research question (e.g. because they are not large enough to provide a definitive result) is not only a waste of resources but also a breach of research participants' trust and a violation of research ethics.

The issues seen in COVID-19 clinical trials highlight a broader crisis in trial design, where many trials do not provide informative results. This presentation will explore the ethical concerns of poorly designed trials and discuss how ethics committees and other stakeholders can identify and prevent such trials in the future.

Keywords: Research ethics, research integrity, COVID – 19, clinical trials, trial design

Abstracts from Lectures from the Scientific Program

Title: Ethical issues in decentralised clinical trials

Presented by: Prof. (Dr.) Ranjit Guha, Principal & Professor of Anatomy Indira Gandhi Institute of Medical Sciences, Patna, Bihar

ABSTRACT

Fuelled by adaptations to clinical trial implementation during the COVID-19 pandemic, decentralised clinical trials (DCTs) have been burgeoned. Decentralized clinical trials are conducted in whole or in part at locations other than traditional clinical trial sites. While these trials have the potential advantage of access, participant centricity, convenience, lower costs, and efficiency, they also raise a number of important ethical and practical concerns.

Decentralised clinical trials also involve many digital tools to facilitate research without physical contact between research teams and participants at various stages, such as recruitment, enrolment, informed consent, administering study interventions, obtaining patient-reported outcome measures, and safety monitoring. These tools can provide ways of ensuring participants' safety and research integrity, while sometimes reducing participant burden and trial cost. Research sponsors and investigators are interested in expanding the use of decentralised clinical trials. The US Food and Drug Administration and other regulators worldwide have issued guidance on how to implement such adaptations. However, there has been little focus on the distinct ethical challenges these trials pose including participant safety, privacy and confidentiality, remote consent, digital access and proficiency, and trial oversight. In digital ethics frameworks, the related ethical issues fall under three areas requiring increased ethical vigilance: participants' safety and rights, scientific validity, and ethics oversight. DCTs also raise some other issues, many of which are of considerable ethical significance. These include the implications for the relationship between patients and healthcare staff, for the social dimension of the patient, for data integrity (at the source, during transmission, in the analysis phase), for personal data protection, and for the possible risks to health and safety. Despite their considerable growth, DCTs have only received little attention from bioethicists.

Awareness of these ethical complexities will help foster the development of processes and cooperative solutions to promote safe, ethical trials going forward, optimized to decrease burden and increase access for all participants. Prof. (Dr.) Ranjit Guha Principal & Professor of Anatomy Indira Gandhi Institute of Medical Sciences, Patna, Bihar .0

Abstracts from Lectures from the Scientific Program

Title: Integrating Research Ethics into Medical Education: An Urgent Call for Reform

Presented by: Dr Aditi Aikat[1] and **Dr Santanu K Tripathi** [2]
1. Professor, Community Medicine & Dean , Students Affairs, JIMSH
2. Professor Pharmacology & Principal, JIMSH

Abstract
Clinical research inherently involves complex ethical considerations, especially when human participants are involved. No clinical research can proceed responsibly without prioritizing the rights, dignity, and welfare of participants. Ethical standards in clinical research are not only foundational but mandatory. With clinical research being integral to advancing medical science, understanding these principles must be part of the foundational training for every medical professional. Medical students, the future doctors and researchers, require early and comprehensive exposure to research ethics, yet their current curriculum often overlooks this crucial area.

The Current State of Research Ethics Education
Globally, and particularly in India, research ethics in medical education has yet to receive the emphasis it warrants. Medical students are educated extensively in patient care and medical knowledge but seldom gain formal training in ethical research conduct. This oversight leads to a critical knowledge gap regarding key ethical concepts, such as autonomy, non-maleficence, beneficence, and justice, which are pillars of ethical research practice. Further, important concerns like confidentiality, the nuanced distinctions between medical practice and research, conflicts of interest, and the protection of vulnerable participants remain inadequately addressed.

The Urgent Need for Ethical Literacy in Medical Research
Ethical literacy is indispensable for medical students who, as practitioners, may encounter clinical trials, regulatory research, and investigator-initiated studies. They must be equipped to navigate these varied research environments with an ethical compass, understanding both the similarities and distinctions between clinical care and research. Students should be educated on principles guiding pre-market industry-led drug trials, investigator-initiated studies, and the ethical complexities of “off-label” drug uses in research contexts.Without formal education on these matters, medical students may unknowingly perpetuate ethical oversights. To fill these gaps, medical education programs must prioritize research ethics, tailoring the curriculum to include both theoretical foundations and practical applications of ethical principles.

Conclusion
Addressing the ethical dimension of clinical research within medical education is no longer optional—it is a necessity. Developing a curriculum that immerses medical students in ethical principles will ensure that they become responsible practitioners and researchers, prepared to uphold the dignity and welfare of every research participant. It’s time for educational institutions and medical regulatory bodies to prioritize this pressing reform.

Abstracts from Lectures from the Scientific Program

Title: Ethical Challenges in Research with the Vulnerable – Cancer Research
Presented by: Dr. Suparna Chatterjee, Professor of Pharmacology Institute of Postgraduate Medical Education & Research Kolkata

Essentiality of research in children is well perceived by all. The basic principles of research ethics i.e. justice, autonomy, beneficence and non-maleficence hold good for research involving children as well. However, research in children poses unique ethical challenges especially in countries where research ethics practicing standards are heterogeneous. All stakeholders need to be sensitized about these challenges. Excellent international and national guidelines are in place to ensure ethical conduct of research in children. Some of the unique ethical challenges of pediatric research include vulnerability of the research participants and complexities in assessing risk versus benefit of research projects. Other than the general challenges some are also contextual like issues pertaining to socio-cultural sensitivity and age group of the participants.

Measures to address them would include engaging in discussion with children and their caregivers about whether the proposed research would provide and direct or indirect benefit to the participants and the nature, extent and severity of anticipated harm. Ethics committees while reviewing pediatric research protocols should ensure that the best possible research design is selected and the participant selection criteria is scientifically justifiable. Issues like invasive biological sample collection should be carefully reviewed and only those deemed truly essential are allowed. Research involving healthy children with no direct benefit of participants needs special attention. Training of IEC members to mindfully evaluate risk versus benefit of each research proposal is very essential. However, such exercises are not commonly undertaken by most IECs in our country. Review of both the informed consent and assent forms have to be undertaken. Child-friendly language must be used in assent forms and also while communicating with children and their parents during the process seeking consent.

Additionally, issues related to recruitment of children under care of guardians other than parents demand special attention and IECs should stringently monitor ongoing approved studies to ensure that studies are being undertaken as per the protocol and abiding by all applicable ethical principles and norms.

Another complex issue is how to compute what amount of money should be payable to the parents of a child for participation in an interventional research study. For adults this is relatively easy but ensuring that the child gets something either as gifts needs to be looked at. In several developed nations gift vouchers for sole use for children are given. However, such practices are yet to be adopted in our country.

Finally, it is important that all stakeholders must have adequate knowledge about complexities of research ethics in children and strive towards ensuring good quality research is undertaken without compromising with any principles of research ethics.

Abstracts from Lectures from the Scientific Program

Ethics in Conduct of Ayurvedic Clinical Trials in India

Presented by: ***Dr. Achintya Mitra***, *M.D. (Ayurveda)*
Assistant Director In-charge (Scientist-4), Regional Ayurveda Research Institute, Gangtok; Central Council for Research in Ayurvedic Sciences (CCRAS), Ministry of Ayush, Government of India, New Delhi, India

Ayurveda has its roots in India since the time of Vedas and is one the most commonly practised since time immemorial in India and Ascian countries. The use of Ayurvedic medicine has increased tremendously worldwide due to cost-effectiveness and cost-beneficial preference. Nevertheless, of Asian origin, a recent study in the United States of America has shown nearly 59% of the study population used Ayurveda and almost all were aware of Ayurveda. Patients with common ailments, preventive care, chronic pain, and immune deficiency were estimated to use Ayurveda more often.

Ministry of Ayush, Government of India, the then Department of AYUSH published Good Clinical Practice (GCP) guidelines for AYUSH system in 2013 due to the growing demand for Ayurveda and other traditional medical system across India in recent decades. The therapeutic efficacy and safety of the use of Ayurvedic medicines as well as different treatment procedures are to be validated with the latest modern parameters to assure the consumers and beneficiaries. Moreover, the repurposing of the Ayurveda is the major domain in the present day. The classical formulations and new drugs are to be enforced through rigorous scientific studies and clinical trials at par compliance with the rules and regulations of the competent authorities including licensing authorities.

Ministry of Ayush, Government of India has issued the different directives and there is strong vigilance in every possible sector. Central Council for Research in Ayurvedic Sciences (CCRAS) is the apex body to conduct the research programme including clinical trials on Ayurvedic medicines. The clinical trials may be carried out after obtaining approval from the Institutional Ethical Committee of Human Research followed by the CTRI registration. The IECHR should be accredited by the Department of Health Research, Ministry of Health and Family Welfare, Government of India. There are separate State Drug Controllers in each state for licensing after the phase III study. The ministry launched the pharmacovigilanceprogramme under the central sector scheme in the structured networking involving government and private institutes all over the country in 2018.

There are many unique things by the principles and practices in Ayurveda which differ from conventional modern medicines and existing clinical research methodologies. The Ayurvedic physicians are used to treat patients with fundamental doctrines like tridosa theory, saptadhatu theory, panchamahabhuta theory, prakriti assessment as it is considered personalised medicine.

The treatments in Ayurveda include a long history of tradition, observation, faith, availability of resources, etc. The challenges involved in carrying out trials in Ayurveda are well-known such as treatment plan based on prakriti; difficulty many times in using the blinding technique of Ayurveda medicine; comprehensive approach including lifestyle and dietary regimes associated with poly pharmaceutical Ayurveda drugs with enormous phytoconstituents. However, there is lacking of standardization of Ayurveda medicines, and variation in the method and mode of drug administration in many cases. Despite these limitations including lack of infrastructure, and poor governance of licencing authority, the generation of good quality evidence applied to Ayurveda is essential for rational use.

More than 700,000 registered Ayurvedic physicians at more than 250 government-accredited universities or colleges form a major resource for carrying out clinical trials related to the field which is still not enough to meet the requirement for good conduct of clinical trials. Ayurvedic medicine needs more rigorous scientific research to evaluate safety, quality and efficacy in a collaborative and integrative approach to be acceptable to the scientific communities.

ICMR Bioethics unit has taken the initiative to formulate the ethical guidelines for research in integrative medicine with AYUSH system of medicine where the ethical issues have to be sought out in case of integrative research with conventional medicine. The guidelines will be the valuable in near future by the ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017), New Drugs and Clinical Trial Rules (2019), Good Clinical Practice guidelines for clinical trials in Ayurveda, Siddha and Unani (ASU-GCP).

Ministry of Ayush as well as CCRAS has taken much initiative to strengthen the clinical trials with an integrative approach for main streaming for which there is some high-quality scientific evidence of safety and effectiveness. Collaboration is required to ensure the benefits of Ayurveda as an adjuvant or add-on with conventional medicine with synergism, as a standalone intervention for which Ayurveda can be referred, to explore the non-pharmacological measures, and to strengthen the public health programme. CCRAS has collaborated with leading organizations in the country like NIMHANS, CIMR-AIIMS, IMS-BHU, Safdarjung hospitals, NCI Jhajar, Lady Hardings, Ayush department of all AIIMS, TMC-TMH& ACTREC, ICMR, CSIR, DST, DBT, etc. There are regular schemes for clinical trials under the intra-mural for the scientists working in the councils and extra-mural research for any institutions or organizations apart from the Ministry of Ayush. CCRAS has initiated many schemes to boost up the young mind for research like SPARK (200 projects per year), PDF (20 candidates per year), SMART (44 projects, 2023), PG STAR (48 projects, 2023), PhD programme, ARMS for research methodology and scientific writing, AyushDiksha for human resource development, PRAYATNA for fostering scientific writing, etc.

Abstracts from Lectures from the Scientific Program

Title: Continuous Education for Ethics Committee members

Presented by: **Dr Lalita Savardekar** , Scientist F , Department of Clinical Research, ICMR-NIRRCH

Abstract:

The Ethics Committee serves to ensure safety and protection of the rights of the study participants by reviewing and monitoring research studies within the framework of the national regulations and ethical guidelines, both national and international. The core ethical principles of autonomy, justice, beneficence, non maleficence and research integrity are the basic requirements for any research study. National and international ethics guidelines mandate that all the ethics committee members should undergo periodic trainings to keep themselves updated with the latest regulatory and ethics guidelines to effectively monitor and evaluate research. The functions of the multidisciplinary ethics committee members are specific, varied and hence individual EC members need themselves to be abreast with their specialty. In addition, latest advances in the ethics and regulatory scenario will be helpful in critical review and ensures appropriate decision making by the ethics committee and thereby the protection of the study participants.

Ethics Committee functions exclusively based on the Standard Operating Procedures (SOPs) developed by the EC for objective decision making. EC members have a basic responsibility to keep themselves updated with the SOPs and ensure its functioning as per the SOPs; hence any new changes in the SOPs should be explained , deliberated to and by the EC members for a complete understanding and objective functioning by guidelines and regulations.

Modalities for continuous education are online trainings modules, special training for lay person, social scientists, one or two days intensive trainings with challenging scenario case series. Such trainings may be tailormade to ensure that the busy ethics committee members can undergo their training at their own pace, have active discussions and deliberations and exposure to real life or simulated challenging scenarios and ways to handle such events.

Abstracts from Lectures from the Scientific Program

Title: Decentralized Clinical Trials: Emerging Technologies and the Shifting Ethical Paradigm with a Focus on Artificial Intelligence

Presented by: *Amit Kumar Dey[1], Shambo Samrat Samajdar[2]*
[1] Deparment of Diabetology, Apollo Sugar Clinics, Kolkata, West Bengal.[2] Deparment of Pharmacology, JMN Medical College and Hospital, Nadia, West Bengal

The landscape of clinical trials is undergoing a profound transformation, driven by technological advancements such as decentralized clinical trials (DCTs) and the integration of artificial intelligence (AI). This shift holds the promise of expanded access to research, enhanced data accuracy, and improved patient-centered care. However, it also raises intricate ethical considerations that clinical researchers and ethics committees must carefully address. As we explore the convergence of DCTs, emergent technologies, and AI, it becomes essential to consider both the opportunities these innovations offer and the ethical challenges they introduce.

The Emergence and Impact of Decentralized Clinical Trials (DCTs)

Decentralized clinical trials leverage digital technologies to enable remote participant engagement, thereby minimizing the necessity for frequent site visits. Utilizing telemedicine, mobile health applications, and remote monitoring devices, DCTs present multiple advantages, including:

Enhanced Accessibility: DCTs facilitate broader participation across diverse geographical regions, enabling the inclusion of varied patient demographics in clinical research.
Improved Patient Convenience: The ability to participate remotely reduces the logistical burdens of travel, likely increasing study adherence and retention.
Real-Time Data Collection: Continuous monitoring via wearable devices and mobile applications allows researchers to obtain real-time data on participants' health, improving data quality and accuracy.

While DCTs provide these benefits, they also challenge established norms regarding clinical oversight, informed consent, and patient confidentiality. Thus, an updated ethical framework is essential to uphold participant welfare and trust.

Artificial Intelligence in Clinical Trials: Expanding the Scope of DCTs

AI is becoming integral to DCTs, where it supports functions such as patient recruitment, monitoring, and data analysis. Key applications of AI in these trials include:
Patient Recruitment and Screening: AI algorithms can analyze large datasets to identify eligible participants, enhancing the efficiency of recruitment efforts.
Data Analysis and Pattern Recognition: AI's capacity to process complex data allows for the detection of trends and insights that may be beyond human analytical capability.
Remote Monitoring: Machine learning models can identify irregularities in real-time health data, enabling timely intervention when necessary.

However, as AI assumes a central role in trial management, new ethical questions arise around transparency, accountability, and the potential for algorithmic bias. Ethical oversight is crucial to ensure that AI-driven decisions are fair, accurate, and inclusive.

Ethical Challenges at the Nexus of AI and DCTs

The integration of AI within decentralized trials introduces novel ethical considerations, demanding attention from clinical researchers and ethics committees:

Informed Consent in the Digital Age: Traditional methods of obtaining informed consent may not suffice in DCTs, where limited face-to-face interaction complicates communication. AI-driven tools employed in consent processes must prioritize clarity, ensuring that participants fully comprehend the study's objectives, risks, and procedures. Ethics committees play a critical role in scrutinizing these processes to safeguard informed and voluntary participation.

Data Privacy and Security: Given DCTs' reliance on digital data, maintaining patient confidentiality is increasingly challenging. AI algorithms require extensive data to function optimally, elevating the risk of sensitive information exposure. Robust data protection protocols and anonymization techniques are thus essential, with ethics committees tasked with enforcing stringent cybersecurity standards.

Bias and Fairness in AI Models: AI models used in DCTs may perpetuate biases inherent in their training data, leading to potential disparities in participant recruitment and clinical recommendations. For instance, algorithms developed with data from limited populations may yield inaccurate predictions for underrepresented groups. To foster equity, ethics committees must ensure that AI models undergo rigorous validation across diverse populations.

Accountability and Transparency: AI-based decision-making in DCTs can be complex and opaque, potentially limiting participants' and researchers' understanding of the reasoning behind certain actions. Transparent, interpretable AI systems are necessary to maintain trust. Ethics committees should advocate for “explainable AI,” whereby algorithmic processes are as comprehensible as possible.

Patient Autonomy and Agency: With AI increasingly involved in health monitoring, questions about patient autonomy emerge. For instance, if an AI system flags a participant as non-compliant based on data patterns, there might be an automatic intervention without consulting the patient. It is essential to balance the need for intervention with respect for participant autonomy, supported by clear policies that regulate AI's role in such scenarios.

Redefining the Ethical Paradigm in Clinical Trials

The convergence of DCTs and AI signifies a shift in the ethical paradigms traditionally associated with clinical trials. To uphold ethical, patient-centered practices, clinical research stakeholders and ethics committees may consider the following strategies:

Development of Updated Ethical Guidelines: Existing guidelines, such as those provided by the of Helsinki, may not adequately address the ethical challenges posed by DCTs and AI. Collaborations among regulatory bodies, ethics committees, and technology developers can contribute to the development of guidelines that are tailored to these novel paradigms.

Continuous Ethical Review: Given that DCTs involve real-time data collection, continuous ethical monitoring may be more effective than periodic reviews. Establishing ethics committees that specialize in DCTs and AI could provide nuanced oversight tailored to these innovations.
Stakeholder Education and Training: Clinical researchers and trial coordinators should receive specialized training on the ethical implications of AI and digital health technologies, covering topics such as AI biases, data privacy best practices, and transparency in AI-assisted decisions.

Conclusion

Decentralized clinical trials, empowered by AI and other advanced technologies, are paving the way for a new era in clinical research. However, this progress necessitates a proactive reassessment of ethical frameworks to confront the unique challenges posed by these innovations. Ethics committees and clinical research professionals must collaborate to develop guidelines that ensure participant safety, data integrity, and inclusivity. By thoughtfully embracing these advancements, the clinical research community can ensure that technological progress aligns with the best interests of participants and society at large.

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Abstracts from Lectures from the Scientific Program

Title: Role of Audit in Quality Assurance

Presented by: Dr. Parloop Bhatt
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Abstract

Quality assurance in healthcare industry ensures compliance and integrity falling in the ambit of global regulations as well as national/ international accreditation standards. Systematic examinations of the processes and procedures governing clinical trials, healthcare industry at large through audits, facilitatesthe identification of discrepancies, enhancing operational efficiency, and promoting adherence to established standards.

The framework of Quality assurance (QA) encompasses policies and practices designed to ensure consistency, integrity and following of ethical practices at all times. Various accreditation bodies, such as the FDA in the United States and the European Medicines Agency (EMA) in Europe , FERCI , NABH have set forth guidelines and standards ensuring the quality assurance. Both internal and external audits contribute to a comprehensive quality management system that fosters continuous improvement and accountability with corrective actions and preventive measures, risk management strategies as well as Quality by Design, to enhance the quality standards.

As healthcare research/ industry continues to evolve, embracing innovations and complexities, the integration of robust audit mechanisms will remain vital for safeguarding the integrity of scientific inquiry and protecting participant rights.

Abstracts from Lectures from the Scientific Program

Title: Role of WHO in Fostering Ethical Conduct of Clinical Research
Presented by: Dr Madhur Gupta, Technical Officer- Pharmaceuticals, WHO India Country Office

Abstract

The World Health Organization (WHO) plays a key role in promoting ethical conduct in clinical research by supporting ethical standards, **reviewing research and develop guidelines on ethical aspects. WHO has published many Guidance documents for research ethics committees for rapid review of research during public health emergencies.**

The World Health Assembly adopted Resolution 75.8, "Strengthening clinical trials to provide high-quality evidence on health interventions and to improve research quality and coordination". This resolution emphasized the urgent need to enhance both global and national clinical trial ecosystems. In response to this, recently WHO published a guideline for best practices for clinical trials. The guidance is a pivotal tool for strengthening the global clinical trials ecosystem, enhancing the efficiency and credibility of clinical research, and promoting public trust in the outcomes of research and in the evidence base for health interventions.

WHO works with Member States and partners to promote ethical standards and appropriate systems of review for any course of research involving human subjects. Within WHO, the Research Ethics Review Committee (ERC) ensures that WHO only supports research of the highest ethical standards. The ERC reviews all research projects involving human participants supported either financially or technically by WHO. The ERC is guided in its work by the World Medical Association Declaration of Helsinki (1964), last updated in 2013, as well as the *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (CIOMS 2016).

WHO India is committed for the area of ethics and biomedical research for strengthen the ethics review of health research in India, and contribute to the rights, safety, and well-being of research participants.

The World Health Organization Collaborating Centres for Bioethics (CCs) are key institutions with relevant expertise distributed throughout the world. The Indian Council of Medical Research Bioethics Unit, National Centre for Disease Informatics and Research Bengaluru has been designated as WHO Collaborating Centre in 2020 and it`s the first one in the South- East Asia Region (SEAR) of WHO.

ICMR-National Institute of Epidemiology and WHO jointly developed the online course on Ethics Review of Health Research for building capacities of ethics committees and researchers and the course provide the fundamentals of ethical issues in biomedical research involving human participants and provide updates on research ethics guidelines in India.

In 2023, WHO introduced a tool for benchmarking ethics oversight of health-related research involving human participants. The tool is intended to assist countries in evaluating their capacity to provide appropriate ethical oversight of health-related research.WHO tool is intended to promote policy convergence and best practices in research ethics oversight, to enhance public trust in health research, and to ensure that the rights and safety of humans involved in health-related research are adequately protected, both in ordinary times and during public health emergencies.

Abstracts from Lectures from the Scientific Program

Title: "Ethics Oversight in Adaptive Clinical Trials".
Presented by: Murugananthan Krishnan, Country Head – Study and Site Operations, Global Clinical Operations, Development, Novartis, Mumbai, Maharashtra, India
E-mail: murugananthan.k@novartis.com

Abstract:
Adaptive clinical trial designs are innovative approaches that allow for modifications to the trial procedures based on interim data. Adaptive clinical trial designs offer flexibility and efficiency by allowing modifications based on interim results. Ethics oversight in adaptive clinical trials is crucial to ensure that the flexibility and efficiency of these designs do not compromise ethical standards. Ethics oversight in adaptive clinical trials includes,

- **Ethics Committees and Institutional Review Boards (IRBs)**: These bodies play a vital role in reviewing and approving adaptive trial protocols. They ensure that the trial maintain clinical equipoise and that any modifications are ethically justified.
- **Interim Monitoring**: Adaptive trials often involve interim analyses, which require careful oversight to ensure that changes based on interim results do not introduce bias or ethical concerns. Data Monitoring Committees (DMCs) are typically responsible for the governance and oversight.
- **Informed Consent**: Maintaining informed consent is more complex in adaptive trials due to potential changes in the trial design. Participants must be kept informed about any significant modifications that could affect their participation.
- **Transparency and Communication**: Clear communication with participants, stakeholders, and regulatory bodies is essential, particularly detailing the adaptive nature of the trial and any changes that occur during its course.
- **Regulatory Guidance:** Regulatory agencies (FDA, EMA) provide guidelines to ensure that adaptive trials are conducted ethically and that their results are scientifically valid.
- **Public and Patient Engagement:** Engaging with the public and patient communities can help ensure that the trial design and its adaptations are aligned with patient needs and ethical standards.

These measures help maintain the ethical integrity of adaptive clinical trials, ensuring that they are conducted responsibly and transparently.

Abstracts from Lectures from the Scientific Program

Title: Ethics Oversight in Adaptive Clinical Trials

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• **Regulatory Guidance:** Regulatory agencies (FDA, EMA) provide guidelines to ensure that adaptive trials are conducted ethically and that their results are scientifically valid.

• **Public and Patient Engagement:** Engaging with the public and patient communities can help ensure that the trial design and its adaptations are aligned with patient needs and ethical standards.

These measures help maintain the ethical integrity of adaptive clinical trials, ensuring that they are conducted responsibly and transparently.

Abstracts from Lectures from the Scientific Program

Title: Ethical Challenges in Multi-Centre Trials including Provision for Common Ethics Review
Presented by: **Dr. Saibal Das,** *MD, DM Scientist D (Medical), ICMR CAMH, Kolkata*

Abstarct:
Multi-centre trials can be a major opportunity to generalize findings or enhance the statistical power of clinical studies. However, such studies also pose vital ethical challenges, including respect for participants' rights and protection of research integrity. An effective approach to such challenges is through a joint ethics review incorporating local variations. The ethical basis of multi-centre trials is founded on some of the most basic principles, such as collegiality, trust, fairness, accountability, and cooperation. Collegiality respects mutual respect among team members, while trust implies a clear sharing of information. Equitable recognition of contributions with special attention towards intellectual property and rights for publication are standard elements in favor of fairness. Accountability concerns responsibility on the part of all parties, and cooperation underlines the need to work with one another toward commonly shared goals of research. The most significant ethical issue in a multi-centre trial would be that it would pose delays, as there is the need for multiple ethics reviews. Every site that participates in the research has its own ethics committee, which might have different requirements applied to it as a result of local ethical standards, thereby making it an inefficient practice. Conflict of interest management among several sites could also make the review process complicated. In order to ensure integrity, the study must force all researchers and members of committees to declare potential conflicts of interest.

The above challenges are resolved through the joint ethics review process. This process establishes a Designated Ethics Committee (DEC) at the coordinating site, which first reviews the research protocol. The Participating Ethics Committees (PECs) of the other sites review it with a concern for local ethics. The DEC harmonizes the communication of the PECs, ensuring that there are uniform ethical standards applied, along with offering a reduction in redundancy for the review process. Informed consent is an important ethical consideration in multi-centre trials. A standardized consent form may be developed, but a number of local differences in language, cultural, and literacy factors should also be considered. The Coordinating Principal Investigator's task is to supervise the general conduct of the multi-centric trial in compliance with the study protocol, coordinate communication between the DEC and Site Principal Investigators, and manage ethical and scientific integrity throughout all sites. To say it in simple terms, every S-PI is responsible for tailoring the consent form to the local setting, ensuring that participants are adequately informed and their rights respected.

The next big challenge is maintaining the privacy and confidentiality of participants across multiple sites. Standardization on sharing and custodianship of data is therefore a must for protecting participant information. A joint ethics committee, therefore, must make adequate provisions regarding data security and address any breaches that would occur. Risk-benefit assessment forms the heart and soul of the Joint Ethics Review. Although the DEC makes an overall risk-benefit assessment of the study, PECs are concerned with particular issues pertinent to the site. Likewise, the protocol amendment and adverse event reporting procedures demand clear communication between all sites to protect the participants as well as the integrity of the study. Post-research benefits: in order to provide participants at all the sites with uniform results of the study. This is very significant in vulnerable populations, who may have different expectations and needs. Best practice standards for multi-centre trials ensure transparency in communications, timely reporting, and respect for core ethical principles. In that respect, ensuring a joint ethics review is necessary to protect participants while enacting valuable collaborative research.

Abstracts from Lectures from the Scientific Program

Title: Ethics in Research Publication

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Introduction

Ethics in research publication are essential for upholding the scientific record and ensuring credibility in academia. Adherence to ethical guidelines helps prevent issues like plagiarism, data fabrication, and undisclosed conflicts of interest, which can harm scientific progress and erode public trust. Organizations like COPE, along with publishers like Wiley and Elsevier, provide frameworks to address these concerns, helping maintain high standards. This article outlines best practices for researchers, editors, and reviewers, incorporating COPE's core practices and recommendations from major publishers to support ethical integrity in publication.

1. Overview of COPE and Ethical Guidelines

1.1 COPE's Mission and Resources

The Committee on Publication Ethics (COPE) is a global non-profit organization that promotes ethical standards in scholarly publishing. COPE's resources include:

COPE Forum: A collaborative platform where editors discuss ethical dilemmas and seek peer guidance.

Core Practices: Guidelines that cover publication ethics, including data integrity, conflicts of interest, and post-publication corrections.

Case Archive: A database of real-world ethical cases that provides insights into handling complex ethical issues.

1.2 Core Ethical Standards by COPE

COPE's standards emphasize transparency, accountability, and integrity. Key principles include:

Transparency and Accountability: Honest reporting to avoid data misinterpretation.

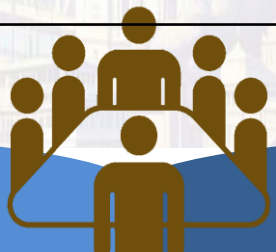
Editorial Independence: Editors should make decisions based on scientific merit, free from external influence.

Corrections and Retractions: Prompt correction of errors and addressing of misconduct when necessary.

2. Authorship and Contribution Ethics

Clear authorship criteria are vital for recognizing contributors appropriately and avoiding conflicts. COPE advises that authorship should reflect substantial contributions to study conception, design, analysis, or manuscript drafting.

Authorship Types	Description
Ghost Authorship	Excluding contributors who played a major role, often linked to undisclosed sponsors.
Guest Authorship	Including individuals with minimal involvement, usually to enhance credibility.
Gift Authorship	Assigning authorship based on affiliation or status rather than contribution.



Abstracts from Lectures from the Scientific Program

2.2 Recommended Practices for Authorship

Structured Author Contributions: Use of frameworks like the Contributor Roles Taxonomy (CRediT) for precise role attribution.

ORCID Implementation: Assigning unique IDs for authors to prevent authorship disputes.

Authorship Dispute Resolution: Clarify authorship criteria early; seek institutional mediation if disputes arise.

3. Managing Conflicts of Interest (COI)

Conflicts of interest (COIs) arise when personal, financial, or professional affiliations may bias study outcomes. COPE recommends full COI disclosure for all relevant parties, including authors, reviewers, and editors.

COI Type	Description
Financial COI	Ties to financial entities that may benefit from study outcomes.
Non-Financial COI	Personal beliefs or affiliations potentially influencing objectivity.
Professional COI	Academic or institutional relationships that may affect impartiality.

3.2 COI Disclosure Requirements

Author Disclosure: Authors should declare all funding sources and affiliations to allow readers to assess potential influence.

Reviewer COI Transparency: Reviewers should recuse themselves if COIs compromise impartiality.

Editorial COI Policies: Editors should abstain from decision-making if they have conflicts related to a manuscript.

4. Plagiarism and Redundant Publication

Plagiarism involves using others' work without acknowledgment, while redundant publication refers to reusing previous content without proper citation. Both compromise research originality and integrity.

Plagiarism Type	Description
Direct Plagiarism	Copying text verbatim without citation.
Paraphrasing Plagiarism	Rewording another's ideas without credit.
Self-Plagiarism	Reusing one's previous content without disclosure.

4.2 Strategies to Prevent Plagiarism

Citation Best Practices: Properly cite all references and sources.

Pre-Submission Checks: Use tools like Turnitin or iThenticate to screen for duplicate text.

Avoiding Redundancy: Clearly label and cite any reused data or methods from prior studies

Abstracts from Lectures from the Scientific Program

5. Data Integrity and Image Manipulation

Data fabrication (creating false data) and falsification (altering data) are serious ethical violations. COPE emphasizes that researchers should avoid any manipulation that distorts results.

Allowed Adjustments

Prohibited Manipulations

Equal brightness adjustments

Selective enhancement of image sections to mislead interpretation.

Uniform contrast application

Adding or removing elements to alter findings.

5.2 Data Sharing and Transparency

Data sharing improves reproducibility and trust. COPE and other organizations encourage adherence to the FAIR principles:

Findable: Data should be easily locatable.

Accessible: Data should be open for analysis.

Interoperable: Data should be compatible across systems.

Reusable: Data should be available under appropriate licenses.

6. Ethical Peer Review Process

Peer review is essential for ensuring research quality. Reviewers are expected to provide constructive feedback while maintaining confidentiality and avoiding bias.

Peer Review Model	Description
Single-Anonymized	Reviewers know authors' identities, but authors do not know reviewers.
Double-Anonymized	Both reviewer and author identities are concealed.
Transparent Review	Reviews and reviewers' identities are published with the article.

6.2 Reviewer Responsibilities

Confidentiality: Reviewers should not disclose manuscript details.

Bias Avoidance: Disclose any COIs and decline review if impartiality is compromised.

Objectivity: Provide unbiased, constructive feedback aimed at improving the manuscript.

7. Responsible Use of Artificial Intelligence (AI)

AI tools like ChatGPT can aid productivity but must be used responsibly. Any AI usage should be disclosed, and AI should not alter or generate original research data.

Permissible AI Uses	Prohibited AI Uses
Grammar and style edits	Generating original research data or manipulating study results.
Language refinement	Submitting AI-generated manuscripts without proper oversight.

Accountability: Authors are responsible for AI-assisted content.

Transparency: AI use should be disclosed in the manuscript.

Abstracts from Lectures from the Scientific Program

8. Post-Publication Corrections and Retractions

Corrections, expressions of concern, and retractions address errors or misconduct after publication. COPE provides guidelines on implementing these corrective actions.

Correction Type	Use Case
Erratum	Minor errors not affecting the study's conclusions.
Corrigendum	Author-initiated correction for significant errors.
Retraction	Major ethical issues, like fabrication or plagiarism, invalidate the study.
Expression of Concern	Suspicion of misconduct pending investigation.

8.2 Transparency in Corrections

All corrections and retractions should be linked to the original article to maintain transparency.

9. Clinical Research Ethics

Research involving human subjects requires adherence to guidelines like the Declaration of Helsinki and CONSORT, focusing on participant welfare, informed consent, and ethical approval.

Framework	Description
Declaration of Helsinki	Ethical principles for medical research involving human subjects.
CONSORT	Standards for reporting clinical trials to ensure clarity and reproducibility.
ICMJE Guidelines	Provides guidance on ethics, authorship, and transparency in biomedical research.

9.2 Informed Consent and Confidentiality

Informed Consent: Researchers must inform participants of study goals and obtain consent.

Data Anonymization: Sensitive data should be anonymized to protect participants' privacy.

Conclusion

Ethical practices in research publication are crucial for scientific credibility and public trust. By adhering to guidelines provided by COPE, Wiley, and similar organizations, researchers can ensure transparency, fairness, and integrity in their work. Following ethical standards in authorship, peer review, data management, and COI disclosure helps sustain a robust scientific record, fostering trust within both the academic and public communities.

Abstracts of Oral Presentation

Title: Attitude of medical students, residents, and faculty towards professionalism in a tertiary institution in South India

Presented by: Dr. Jean Fredrick, Associate Professor of Physiology, AIIMS Kalyani, West Bengal

Abstract

Introduction

Current medical education guidelines emphasise teaching professionalism as one of the core competencies for students. With the increasing interest among the medical fraternity in teaching professionalism as part of the curriculum, there is a need to understand the perception of professionalism among the students and faculty. This study would enable us to understand the perception of the medical students and faculty towards professionalism.

Methods

Pennsylvania State University College of Medicine's (PSCOM) professionalism questionnaire was administered online through emails to faculty, residents, and final-year and second-year medical students. The questionnaire comprised six elements (Accountability, altruism, excellence, duty, honor, integrity, and respect), with six items for each element. The participants were asked to rate the degree to which each statement corresponded to their definition of professionalism on a five-point Likert scale (1 = never, 2 = little, 3 = some, 4 =much, and 5 = great deal). The questionnaire was analysed and scored as per the original validation study.

Results

378 participants responded to the questionnaire. Total scores were higher among faculty and final-year medical students compared to second-year students and residents. The groups had no significant difference in mean scores of elements of professionalism. Internal consistency estimates for each element of professionalism were between 0.73 - 0.83.

Conclusion

Participants scored "much" and "great deal" on almost all the items in the elements. There was no difference in the mean score of each element between the groups. This study reveals the level of understanding of professionalism among faculty, residents, and medical students. Structured training sessions for the medical fraternity may help understand the tenets of professionalism in a better manner.

Title: Post- trial access needs a viable solution

Authors: Aarti Halwai[1] ; Vina Vaswani[2]
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2. Director, Centre for Ethics, Program Director, YU-FIC Masters in Research Ethics for India, Yenepoya deemed to be University, Mangalore 575 018, INDIA.

Introduction

Post-approval review acts as an important safeguard mechanism to protect the rights, safety and well-being of participants and ensures continuity in assessing risk benefit analysis. But the exposure to risk does not end with trial completion instead, commences a new uncertainty for post-trial access. Developing countries have been emerging as hotspots to conduct clinical trials through sponsorship offered by international pharmaceutical companies of developed countries. The major incentive being low cost, ease in recruitment of participants, not so strict regulatory framework as compared to developed countries. Thus, achieving a fair distribution of benefit remains a concern. One of the methods to achieve fair distribution of benefits is addressing the need for Post trial access (PTA). Thus who holds this responsibility and for how long needs to be explored.

Objective

This study aims to summarise, through a literature review, the challenges to access post trial benefits.
Methodology: The data is based on a review of the literature on PubMed on Post trial access over the last 5 years (from 2019-2024). The keywords included (post trial provisions) AND (post trial access OR post-trial benefits). Only articles published in the English language were included. A total of 18 articles were retrieved. On reviewing the abstracts, 12 were excluded as they were not relevant to the scope of this review. 6 original articles that discussed post-trial access and patient/participant experiences were included. 1 more article was included through snowballing. Results: Our findings highlight gap in the system concerning current procedures for post-trial management with a few facilitators. These include counselling service by clinical staff, referral letter from study doctor, funding via sponsors, supportive clinical trial team and strong collaboration between stakeholders. Participant centric barriers include lack of awareness among participants, failure to understand implications PTA denial, more focus on short term relief, poor understanding of research, possibility of therapeutic misconception, inability to afford transport related cost, inability to attend clinic visits and difficulty in understanding informed consent document. Other barriers included company's disinterest in seeking approval, regulatory restrictions, lack of insurance coverage, difference in understanding among stakeholders w.r.t responsibility and concept of PTA, power dynamics, inadequate collaboration and poor communication among stakeholders.

Discussion & Conclusion

Findings underscore the need to address these barriers and strengthen the identified facilitators to promote Post-trial access. By just offering trial results to participants will do very little to meet this obligation.

Title: Exploring the Research Evidence Approach and Application of Research Ethics Concepts in Ayurveda Research; A Qualitative Study Based on Researcher's Perception

Authors: Dr. Skanthesh Lakshmanan[1] and Dr. Vina Vaswani[2]

1. MSc Research Ethics Scholar, Yenepoya University-Fogarty International Centre Research Ethics Masters Program for India
2. Professor, Department of Medicine and Toxicology, Director, Centre for Ethics, Yenepoya (deemed to be University) Mangalore PD/PI YUFIC Maters Program (NIH,Grant No 1RTW25010305)

Abstract

Background: Evidence-Based Medicine (EBM) has shifted the focus of clinical practice from expert opinion to systematically conducted research, integrating three components: the best available evidence, clinical judgment, and patient preferences. The hierarchical evidence model (HEM) in EBM, which ranks research designs, faces limitations in evaluating complex interventions such as surgery, psychology, and traditional medicine. In Ayurveda, significant gaps exist in scientific literature regarding appropriate evidence models and the application of research ethics in study design. This study assesses Ayurveda researchers' perceptions of evidence approaches and the applicability of research ethics in Ayurveda research.

Methodology: A qualitative study involving in-depth interviews with seven Ayurveda researchers from South India was conducted. Thematic analysis was used to analyse the data, moving from coding the interviews to creating categories and themes aligned with the research objectives.

Results: The study identified several key themes: EBM perception and application, Ayurveda evidence approaches, status of Ayurveda research, comparisons with modern medicine, and the application of research ethics. Sub Themes included "What counts as evidence in Ayurveda," "Evidence through whose lens?" and "Research ethics in Ayurveda." Participants highlighted the need for research designs that account for Ayurveda's personalized approach. Many researchers felt compelled to follow HEM to gain legitimacy in the scientific domain. Those with experience in more adaptable research models for Ayurveda had greater clarity in designing appropriate research methods and applying ethical concepts.

Conclusion: Ayurveda researchers advocate for more freedom in developing methodologies that reflect personalized, holistic practices. This aligns with Bourdieu's Theory of Symbolic Power, wherein Ayurveda research seeks legitimacy within the dominant biomedical paradigm. Future research could explore bioethical perspectives, particularly the concept of autonomy, in developing adaptable research methodologies for Ayurveda.

Acknowledgement: The Authors acknowledged the specific use of ChatGPT 4o mini for language editing and summarization for the word count of this abstract.

Keywords: Evidence approach, research ethics, ayurveda research, hierarchical evidence model and methodology

The 11th National Conference of
Forum for Ethics Review Committees in India
FERCICON 2024

Title: Exploring Artificial Intelligence-Based Distribution Planning and Scheduling Systems' Effectiveness in Ensuring Equitable Vaccine Distribution in Low-and Middle-Income Countries

Authors: Akuma Ifeanyichukwu,[1] Dr. Vina Vaswani,[2] and Dr. Perihan Elif Ekmekci[3]

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2. Professor, Department of Forensic Medicine and Toxicology, Director, Centre for Ethics, Yenepoya (Deemed to be) University, Mangalore 575018, India
3. Professor, Faculty of Medicine, TOBB University Ankara, Turkey drpelifek@gmail.com https://orcid.org/0000-0001-6592-2960 Abstract

Background: During the COVID-19 pandemic, the global issues of vaccine access and equity, particularly in low- and middle-income countries (LMICs), came to the forefront. Simultaneously, there was notable advancement in artificial intelligence (AI) and its potential applications in vaccine distribution and scheduling. In response to these developments, we gathered insights, lessons, and perspectives to inform future strategies for AI-based distribution planning and scheduling systems' effectiveness in ensuring equitable vaccine distribution in LMICs.

Method: A scoping review was conducted, followed by two separate witness seminars held at different time points. The analyses for each seminar were performed and presented collectively. Participants' statements were transcribed, coded, categorized, and analysed, with the findings organized thematically. These findings subsequently informed the development of the ethical framework.

Results: A total of 28 articles were included in the scoping review. For the witness seminar, there were eight witness participants, three moderators, and two observers, engaging in discussions that lasted an average of one hour and 40 minutes for both seminars. In the transcript of the first witness seminar, 192 codes, 22 categories, and five themes were identified through inductive coding. In contrast, the second seminar's transcript yielded 159 codes, 11 categories, and five themes through open coding. The coding and analysis processes were conducted independently and then collectively validated to minimize bias in judgment and interpretation.
Discussion: Despite AI's potential, several challenges can impede the effective deployment of AI in vaccine distribution, especially in low-resource settings. These challenges include ensuring equitable access and managing distribution priorities, as well as addressing data management issues and technological limitations. Additionally, leveraging data and technology to optimize the distribution process is crucial, alongside evaluating the effectiveness and governance of AI systems. Ultimately, ensuring equity and inclusivity in AI-driven vaccine distribution remains paramount for maximizing its impact.

Conclusion: This study highlights the effectiveness of AI implementation in vaccine distribution and equity, especially during the pandemic in low- and middle-income countries (LMICs), where achieving vaccine equity remains a significant challenge. It proposes an ethical framework consisting of 10 core components along with 11 implications and policy recommendations aimed at promoting the responsible and equitable use of AI support systems to enhance vaccine equity in future pandemics.

Keywords: Vaccine equity, AI in public health, vaccine logistics, ethical implications, and pandemic response

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Title: Perspectives of Indigenous tribal healers regarding their sharing of Indigenous knowledge with researchers- A qualitative study from tribal communities in southern part of Kerala.

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Background: The inseparable relation between human and nature made mankind stronger by acquiring knowledge from nature through continuous interactions including experiences using all his senses. The knowledge that acquired through experiences are transferred from generations to generations by oral teachings, hearing, seeing and other experiences. This knowledge is termed as 'indigenous knowledge' .Indigenous tribal communities in Kerala possess unique traditional knowledge systems, particularly in healthcare. However, sharing this knowledge with external researchers raises concerns among tribal healers.

Objective: This qualitative study aimed to explore the perspectives of indigenous tribal healers in southern part of Kerala, Kani tribal community regarding sharing of their traditional indigenous knowledge of healing with researchers.

Methodology: In-depth interviews of 8 tribal healers from Kani tribal community was carried out, and thematic analysis done and their perceptions regarding sharing of knowledge with other communities, challenges in practice today and type of practice and indication for referral was probed. The data was analysed manually.

Findings: Tribal healers expressed concerns about cultural appropriation, exploitation, Idea plagiarism, Knowledge attrition and loss of control over their knowledge. They emphasized the need for trust, reciprocity, and benefit-sharing in research collaborations. Some healers saw potential benefits in sharing knowledge, such as preserving their traditions and improving healthcare.

Conclusion: This study highlights the importance of understanding tribal healers' perspectives on knowledge sharing. Researchers must prioritize ethical considerations, community engagement, policy initiation by government to enhance the sustainability of knowledge and collaborative approaches to ensure respectful and mutually beneficial knowledge exchange.

Keywords: indigenous knowledge, tribal communities, traditional healthcare, knowledge sharing, research ethics, community engagement.

Title: Confidentiality at the crossroads of healthcare and research: Challenges faced by custodians of data/samples in an academic and research institution.

Authors: Shama U Rao; Dr Uma Kulkarni

Background: Protection of confidentiality of data in healthcare and research stems from the ethical and legal obligations. frameworks. Our study aimed to identify challenges faced by the custodians in maintaining confidentiality of samples/data when research is conducted on patient samples or data.

Methodology: We conducted a cross-sectional questionnaire-based study on the custodians of patient samples/data. After obtaining informed consent, the validated questionnaires containing 10 questions were administered through face-to-face meetings, to 39 custodians (12 sample custodians (SCs) and 27 data custodians (DCs)).

Results:

The DCs belonged to the Medical Records and clinical departments. Majority used secure cabinets/storage (85.18%) and ensured no photographs were taken (55.55%). Majority stated that they provided access after documenting the request (92.6%), verifying the permission from the Medical Superintendent (MS) (81.5%) and Ethics Committee (EC) (74.1%). 25.9% of DCs experienced data breach. 18.5% of the DCs did not go for any training. The challenges identified from the study were time constraints, lack of secure storage space, technology and protection mechanisms, poor staff/researcher cooperation and knowledge.

The SC came from microbiology, pathology, biochemistry and laboratories. 91.7% kept logbook access to storage equipment, 66.7% had lock and key and biometrics to rooms, 58.3% looked the storage equipment and kept logbooks to storage rooms. 3.3% required EC and MS approval, and 33.3% only required MoU in case of researchers from other institutes. None experienced confidentiality breach. All SCs have undergone training. The challenges identified from the study were time constraints, and technical issues.

Conclusion: From our study it was observed that there were several areas that needed improvement like measures to protect samples/data, granting access to researchers both internal and external, data breaches and training. The study also reveals that custodians face challenges for maintaining confidentiality hence making it necessary for introducing more stringent measures to protect the confidentiality of the samples/data.

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Forum for Ethics Review Committees in India
FERCICON 2024

Title – A retrospective audit to analyze protocol deviations that occurred in regulatory clinical trials at a single centre in a tertiary referral center in India.

Authors- Parida R[1], Chaudhari VL*, Hinglaspurkar SS*, Argade AS*, Jagushte S*, Sawant NS*, Gogtay NJ*
Department of Clinical Pharmacology, Seth GS Medical College and KEM Hospital, Mumbai.

Introduction – A protocol deviation (PD) is any departure from study procedures or treatment plans as specified in the IEC-approved protocol. PDs can be minor or may compromise study integrity and participant safety (violations). Auditing PDs provides valuable insights to identify and address areas of deficit. Our study aimed to analyze PDs and compare pre- and post-COVID-19 pandemic deviations.
Methods – The study protocol was IEC-approved with a consent waiver. Anonymized regulatory studies were evaluated, and Trial Master Files and IEC communications regarding PDs were reviewed. PDs were classified as major (violations affecting patient safety, data, or study integrity) or minor, followed by content analysis categorizing them as eligibility, consent-related, investigational product (IP) related, documentation errors, or sample-related. Corrective and preventive actions (CAPA) taken were also assessed. Descriptive statistics were applied.
Results – Of 21 regulatory trials analyzed, 15/21 (71.4%) were pre-pandemic, and 6/21 (28.6%) were conducted during and continued post-pandemic. A total of 526 PDs were reported. Of these, 454/526 (86%) were minor and 72/526 (14%) were major PDs. Amongst the 454 minor and 72 major PDs, 221/454 (49%) and 63/72 (88%) were pre-pandemic while 233/454 (51%) and 9/72 (12%) were during and post-pandemic respectively.
For minor PDs, 220/454 (48%) were due to missed follow-up timelines, followed by 145/454 (32%) related to sample storage/processing, and 45/454 (9%) to documentation errors. Among major PDs, 49/72 (54%) were missed pharmacokinetic timepoints, and 8/72 (11%) were IP administration related. Of the 72 major PDs, 12 (16%) were beyond researchers' control, while 60 (84%) were deemed preventable (e.g., Electrocardiogram taken before consent, delayed Serious Adverse Event reporting).
Among the total 526 PDs, 242 (46%) occurred during and post-pandemic across the six trials, with a significant proportion [205/242 (85%)] linked to pandemic-related challenges.
A total of 204/526 (39%) corrective actions involved re-counselling participants, and 65/526 (12%) involved retraining study teams.
Discussion and Conclusions –PDs may not be entirely avoidable. However, audits such as these suggest areas where researchers can improve to minimize PDs. targeted training in key areas and the implementation of quality checks can address some of the issues identified in this study.

WMA DECLARATION OF HELSINKI – ETHICAL PRINCIPLES FOR MEDICAL RESEARCH INVOLVING HUMAN PARTICIPANTS

Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964
and amended by the:
29th WMA General Assembly, Tokyo, Japan, October 1975
35th WMA General Assembly, Venice, Italy, October 1983
41st WMA General Assembly, Hong Kong, September 1989
48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996
52nd WMA General Assembly, Edinburgh, Scotland, October 2000
53rd WMA General Assembly, Washington DC, USA, October 2002 (Note of Clarification added)
55th WMA General Assembly, Tokyo, Japan, October 2004 (Note of Clarification added)
59th WMA General Assembly, Seoul, Republic of Korea, October 2008
64th WMA General Assembly, Fortaleza, Brazil, October 2013
and by the 75th WMA General Assembly, Helsinki, Finland, October 2024

PREAMBLE

1. The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human participants, including research using identifiable human material or data.

   The Declaration is intended to be read as a whole, and each of its constituent paragraphs should be applied with consideration of all other relevant paragraphs.

2. While the Declaration is adopted by physicians, the WMA holds that these principles should be upheld by all individuals, teams, and organizations involved in medical research, as these principles are fundamental to respect for and protection of all research participants, including both patients and healthy volunteers.

GENERAL PRINCIPLES

3. The WMA Declaration of Geneva binds the physician with the words, "The health and well-being of my patient will be my first consideration," and the WMA International Code of Medical Ethics declares "The physician must commit to the primacy of patient health and well-being and must offer care in the patient's best interest."

4. It is the duty of the physician to promote and safeguard the health, well-being and rights of patients, including those who are involved in medical research. The physician's knowledge and conscience are dedicated to the fulfilment of this duty.

5. Medical progress is based on research that ultimately must include participants.

   Even well-proven interventions should be evaluated continually through research for their safety, effectiveness, efficiency, accessibility, and quality.

6. Medical research involving human participants is subject to ethical standards that promote and ensure respect for all participants and protect their health and rights.

   Since medical research takes place in the context of various structural inequities, researchers should carefully consider how the benefits, risks, and burdens are distributed.

   Meaningful engagement with potential and enrolled participants and their communities should occur before, during, and following medical research. Researchers should enable potential and enrolled

participants and their communities to share their priorities and values; to participate in research design, implementation, and other relevant activities; and to engage in understanding and disseminating results.

7. The primary purpose of medical research involving human participants is to generate knowledge to understand the causes, development and effects of diseases; improve preventive, diagnostic and therapeutic interventions; and ultimately to advance individual and public health.

   These purposes can never take precedence over the rights and interests of individual research participants.

8. While new knowledge and interventions may be urgently needed during public health emergencies, it remains essential to uphold the ethical principles in this Declaration during such emergencies.

9. It is the duty of physicians who are involved in medical research to protect the life, health, dignity, integrity, autonomy, privacy, and confidentiality of personal information of research participants. The responsibility for the protection of research participants must always rest with physicians or other researchers and never with the research participants, even though they have given consent.

10. Physicians and other researchers must consider the ethical, legal and regulatory norms and standards for research involving human participants in the country or countries in which the research originated and where it is to be performed, as well as applicable international norms and standards. No national or international ethical, legal or regulatory requirement should reduce or eliminate any of the protections for research participants set forth in this Declaration.

11. Medical research should be designed and conducted in a manner that avoids or minimizes harm to the environment and strives for environmental sustainability.

12. Medical research involving human participants must be conducted only by individuals with the appropriate ethics and scientific education, training and qualifications. Such research requires the supervision of a competent and appropriately qualified physician or other researcher.

    Scientific integrity is essential in the conduct of medical research involving human participants. Involved individuals, teams, and organizations must never engage in research misconduct.

13. Groups that are underrepresented in medical research should be provided appropriate access to participation in research.

14. Physicians who combine medical research with medical care should involve their patients in research only to the extent that this is justified by its potential preventive, diagnostic or therapeutic value and if the physician has good reason to believe that participation in the research will not adversely affect the health of the patients who serve as research participants.

15. Appropriate compensation and treatment for participants who are harmed as a result of participating in research must be ensured.

Risks, Burdens, and Benefits

16. In medical practice and in medical research, most interventions involve risks and burdens.

    Medical research involving human participants may only be conducted if the importance of the objective outweighs the risks and burdens to the research participants.

17. All medical research involving human participants must be preceded by careful assessment of predictable risks and burdens to the individuals and groups involved in the research in comparison with foreseeable benefits to them and to other individuals or groups affected by the condition under investigation.

    Measures to minimize the risks and burdens must be implemented. The risks and burdens must be continuously monitored, assessed, and documented by the researcher.

18. Physicians and other researchers may not engage in research involving human participants unless they are confident that the risks and burdens have been adequately assessed and can be satisfactorily managed.

When the risks and burdens are found to outweigh the potential benefits or when there is conclusive proof of definitive outcomes, physicians and other researchers must assess whether to continue, modify or immediately stop the research.

Individual, Group, and Community Vulnerability

19. Some individuals, groups, and communities are in a situation of more vulnerability as research participants due to factors that may be fixed or contextual and dynamic, and thus are at greater risk of being wronged or incurring harm. When such individuals, groups, and communities have distinctive health needs, their exclusion from medical research can potentially perpetuate or exacerbate their disparities. Therefore, the harms of exclusion must be considered and weighed against the harms of inclusion. In order to be fairly and responsibly included in research, they should receive specifically considered support and protections.

20. Medical research with individuals, groups, or communities in situations of particular vulnerability is only justified if it is responsive to their health needs and priorities and the individual, group, or community stands to benefit from the resulting knowledge, practices, or interventions. Researchers should only include those in situations of particular vulnerability when the research cannot be carried out in a less vulnerable group or community, or when excluding them would perpetuate or exacerbate their disparities.

Scientific Requirements and Research Protocols

21. Medical research involving human participants must have a scientifically sound and rigorous design and execution that are likely to produce reliable, valid, and valuable knowledge and avoid research waste. The research must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and adequate laboratory and, as appropriate, animal experimentation.

    The welfare of animals used for research must be respected.

22. The design and performance of all medical research involving human participants must be clearly described and justified in a research protocol.

    The protocol should contain a statement of the ethical considerations involved and should indicate how the principles in this Declaration have been addressed. The protocol should include information regarding aims, methods, anticipated benefits and potential risks and burdens, qualifications of the researcher, sources of funding, any potential conflicts of interest, provisions to protect privacy and confidentiality, incentives for participants, provisions for treating and/or compensating participants who are harmed as a consequence of participation, and any other relevant aspects of the research.

    In clinical trials, the protocol must also describe any post-trial provisions.

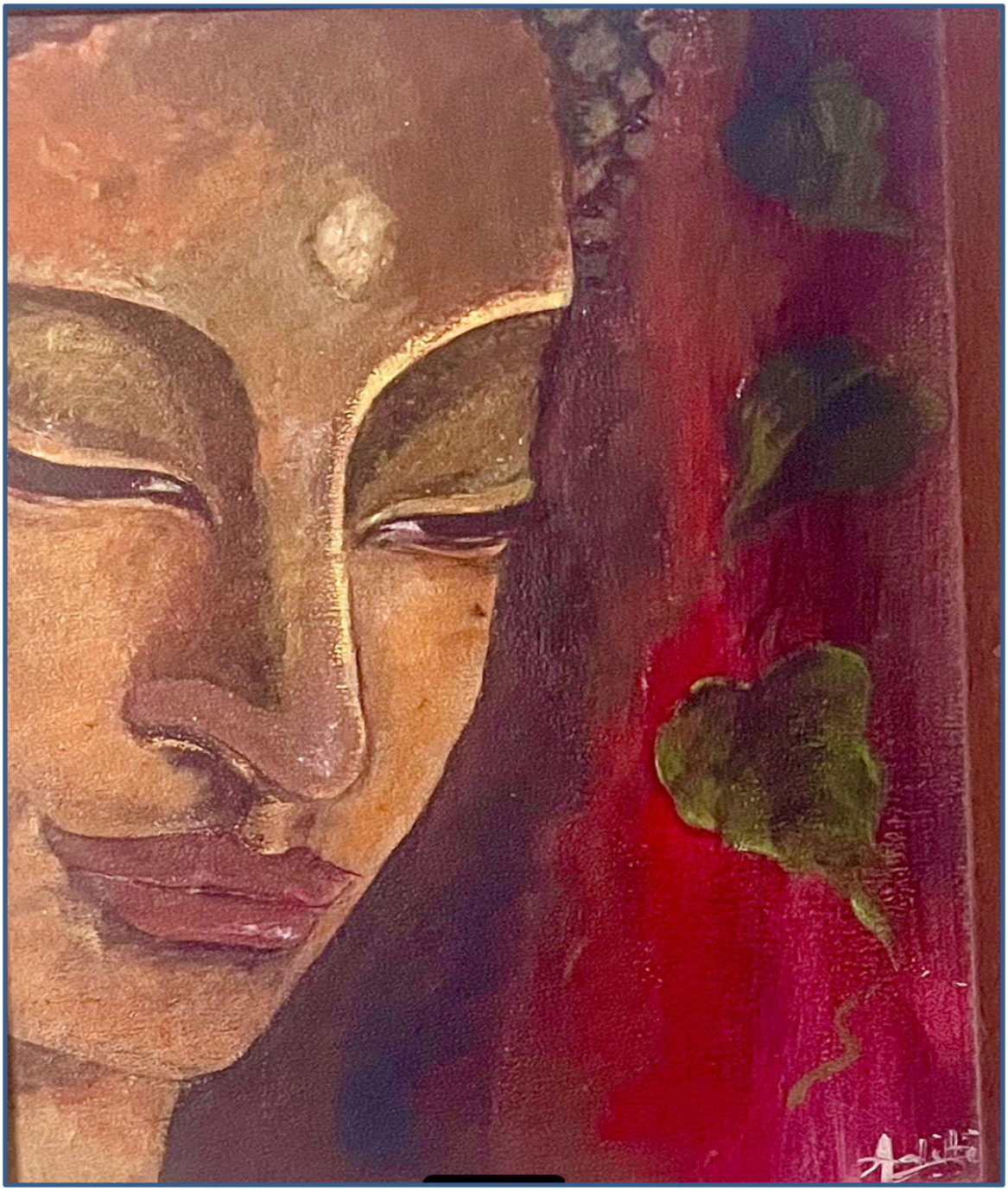
Research Ethics Committees

23. The protocol must be submitted for consideration, comment, guidance, and approval to the concerned research ethics committee before the research begins. This committee must be transparent in its functioning and must have the independence and authority to resist undue influence from the researcher, the sponsor, or others. The committee must have sufficient resources to fulfill its duties, and its members and staff must collectively have adequate education, training, qualifications, and diversity to effectively evaluate each type of research it reviews.

    The committee must have sufficient familiarity with local circumstances and context, and include at least one member of the general public. It must take into consideration the ethical, legal, and regulatory norms and standards of the country or countries in which the research is to be performed as well as applicable international norms and standards, but these must not be allowed to reduce or eliminate any of the protections for research participants set forth in this Declaration.

    When collaborative research is performed internationally, the research protocol must be approved by research ethics committees in both the sponsoring and host countries.

    The committee must have the right to monitor, recommend changes to, withdraw approval for, and suspend ongoing research. Where monitoring is required, the researcher must provide information to the committee and/or competent data and safety monitoring entity, especially about any serious adverse events. No amendment to the protocol may be made without consideration and approval by the committee. After the end of the research, the researchers must submit a final report to the committee containing a summary of the findings and conclusions.



“Believe nothing, no matter where you read it, or who said it, no matter if I have said it, unless it agrees with your own reason and your own common sense.”

Buddha Siddhartha Guatama Shakyamuni

THE ESSENCE OF LEARNING REMAINS THE SAME OVER THE AGES, ONLY THE FORM HAS CHANGED!

Oilpainting On Canvas By **Prof. Dr. Aditi Aikat**, JIMSH, Kolkata

Proceedings of the 11th National Conference of the Forum for Ethics Review Committees in India (FERCICON 2024)

Overview

The 11th National Conference of the Forum for Ethics Review Committees in India (FERCICON 2024) was hosted by the Jagannath Gupta Institute of Medical Sciences & Hospital (JIMSH), Kolkata, from November 7–9, 2024. The conference, themed "Assuring Quality of Review and Oversight by Ethics Committees", aimed to address evolving challenges and innovative solutions in the realm of clinical research ethics. By bringing together a distinguished group of ethics committee members, researchers, investigators, and policy experts from across the nation and abroad, the event provided a unique platform for knowledge-sharing and collaborative problem-solving.

FERCICON 2024 marked a significant milestone in advancing the discussion on ethical oversight within biomedical research, emphasizing the importance of quality assurance in an era where research methodologies, including decentralized and AI-enabled trials, are rapidly evolving. Structured across three days, the conference featured pre-conference workshops, keynote addresses, symposia, panel discussions, and memorial orations. These sessions explored critical themes such as decentralization of clinical trials, ethical dilemmas in research involving vulnerable populations, and innovations in data privacy.

The event highlighted key strategies for integrating international ethical standards with the realities of conducting research in diverse socio-cultural and regulatory contexts. Participants not only benefited from expert-led discussions but also engaged in interactive activities, fostering dialogue on contemporary challenges such as AI biases, research in fragile settings, and ethics in integrative medicine.

Day 1: November 7, 2024 - Pre-Conference Sessions

The pre-conference activities focused on imparting practical knowledge through three specialized sessions, aimed at addressing specific ethical challenges and promoting collaborative approaches in research governance:

Session 1: Common Ethics Review for Multicenter Studies Led by Dr. Roli Mathur and her team from the ICMR Bioethics Unit, this session examined the logistical and ethical complexities associated with multicenter studies. The speakers emphasized the redundancies created by site-specific reviews and introduced the 2023 ICMR Joint Ethics Review Guidelines. These guidelines advocate for a centralized model of ethics oversight via Designated Ethics Committees, facilitating efficient review timelines while maintaining local relevance. The session concluded with actionable strategies for fostering collaboration among institutions.

Session 2: WHO Tool for Benchmarking in Research Ethics Oversight Delivered by Dr. Cristina Torres and Dr. Madhur Gupta of the World Health Organization, this session introduced the WHO Benchmarking Tool, which evaluates the capacity and effectiveness of ethical oversight systems. Emphasizing its utility during public health emergencies, the tool was presented as a resource for promoting global standardization in ethical reviews while ensuring participant protection and fostering public trust.

Session 3: Research in Fragile SettingsPresented by Dr. Doris Schroeder and team, this session highlighted the unique ethical concerns of conducting research in politically unstable or resource-scarce environments. Ethical considerations, including participant safety, data validity, and the contextualization of findings, were discussed in depth. Case studies illustrated both the risks and the adaptive strategies necessary to ensure ethical rigor in such settings.

Day 2: November 8, 2024 - Keynote Lectures and Symposia

The main conference began with a formal inauguration ceremony, where Dr. T.P. Sasikumar delivered an inspiring keynote address. His speech underscored the philosophical roots of ethics in Indian traditions, drawing from principles in the Bhagavad Gita to advocate for selflessness and justice in clinical research.

Symposium I: Contentious Issues in Ethical Conduct of Research Involving Humans
Chaired by Dr. Lalita Savardekar, the session covered diverse topics:

Ethical Oversight in Adaptive Clinical Trials: Dr. Murugananthan discussed the challenges of ethical monitoring in trials with flexible designs, emphasizing the need for dynamic oversight mechanisms. Multi-Centric Trials and Common Ethics Reviews: Dr. Saibal Das highlighted the benefits of centralized ethics reviews for multi-centric studies, which can streamline approvals and maintain uniform ethical standards. Continuous Oversight by Ethics Committees: Dr. Sumalya Sen examined how ethics committees can evolve to manage ongoing responsibilities beyond initial reviews.

Lecture I: Continuous Education for Ethics Committee Members In this lecture, Dr. Lalita Savardekar emphasized the importance of continuous training for ethics committee members to ensure they remain abreast of regulatory and scientific developments.

Symposium II: Enhancing Quality of Ethics Review
Chaired by Dr. Suparna Chatterjee, the symposium explored:
Quality Issues in Committee Functioning: Dr. Nandini Kumar highlighted gaps in committee structure and functioning.
Role of Audits in Quality Assurance: Dr. Parloop Bhatt presented methodologies for conducting audits that enhance operational efficiency and ensure compliance.

Dr. V. Muthuswamy Memorial Oration: Delivered by Dr. Doris Schroeder, the oration reflected on global inequities in research ethics, advocating for inclusive frameworks that prioritize the rights of underrepresented populations.

Panel Discussion I: Decentralized Clinical Trials and Emerging Technologies Moderated by Dr. Urmila Thatte, the panel discussed the ethical implications of decentralized clinical trials (DCTs) and emerging technologies like AI. Concerns such as data privacy, participant autonomy, and the risks of algorithmic biases were critically analyzed.

Day 3: November 9, 2024 – Advanced Discussions and Valedictory
The final day concentrated on specialized topics, offering deeper insights into ethical challenges in niche research areas:
Symposium III: Ethical Challenges in Research with Vulnerable Populations Chaired by Dr. Avijit Hazra, this session provided case-based discussions on:
Infectious Disease Research by Dr. Sayantan Banerjee, addressing issues of consent and equitable access.
Psychiatry Research by Dr. Soumitra Dutta, focusing on patient dignity and data confidentiality.
Cancer Research by Dr. Roychoudhury, exploring ethical dilemmas in balancing patient hope with trial integrity.

Lecture V: Ethics in Ayurvedic Clinical Trials, Dr. Achintya Mitra explored the challenges of conducting Ayurvedic trials, emphasizing the need for standardization and integration with evidence-based medicine.
Panel Discussion III: Data Privacy and Ethics in Biomedical Research This discussion addressed ethical concerns in managing data privacy in the digital era, particularly in AI-assisted research. Speakers highlighted the need for robust security protocols and regulatory compliance.

Valedictory Session

The conference concluded with a valedictory address by Dr. Dirceu Greco, who updated attendees on the latest developments in the Helsinki Declaration. Awards for best presentations were announced, and the event concluded with remarks from the organizing committee.

Key Takeaways

Capacity Building: Emphasizing the importance of training and collaboration among ethics committees to maintain high standards in ethical oversight.

Innovative Paradigms: Advocating for updated ethical frameworks to accommodate innovations like DCTs and AI.

Focus on Vulnerable Groups: Ensuring that research in fragile settings and with vulnerable populations adheres to stringent ethical standards.

Data Security: Promoting robust protocols to address emerging challenges in data privacy and AI transparency.

By facilitating these discussions, FERCICON 2024 strengthened the collective resolve to uphold the integrity, equity, and safety of clinical research across India and beyond.

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FERCICON 2023, PSG Institute of Medical Sciences and Research, Coimbatore

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FERCICON 2018, Mangalore

FERCICON 2024

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Conference Theme:

Assuring Quality of Review and Oversight by the Ethics Committees

7-9 NOV 2024

Jagannath Gupta Institute of Medical Sciences & Hospital (JIMSH), Budge Budge, Kolkata

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