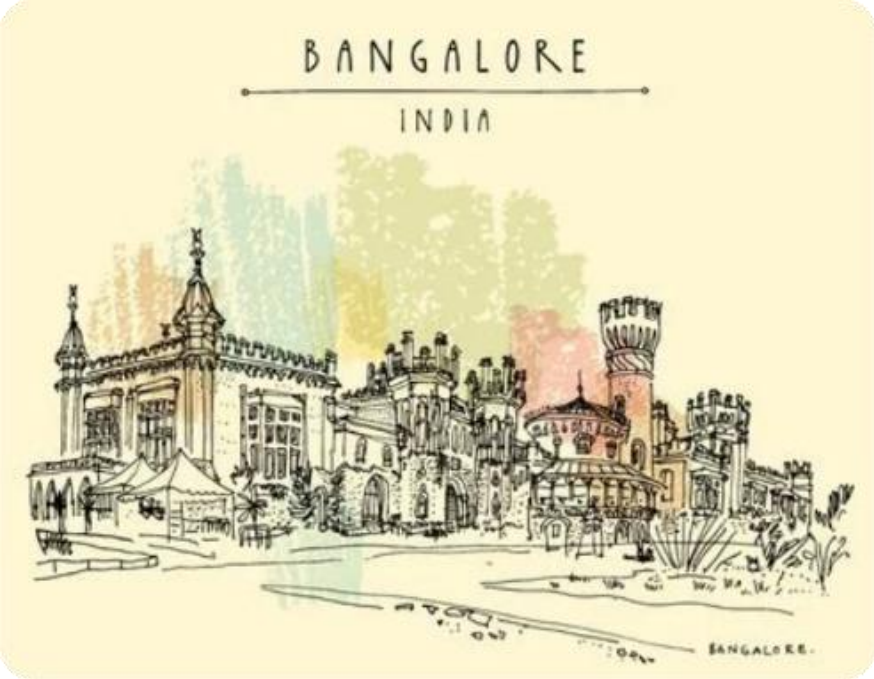
ICMR Bioethics Unit

Report

Draft WHO Tool for Benchmarking Ethics Oversight of Health-Related Research with Human Participants

Date: 6-7 December 2022



Organized by ICMR-Bioethics Unit, Bengaluru

Supported by WHO Headquarters, Geneva

WHO Collaborating Centre for Strengthening Ethics in Biomedical and Health Research

Compiled & Edited by
ICMR Bioethics Unit **,** Indian Council of Medical Research, Department of Health Research, Ministry of Health & Family Welfare, Govt. of India

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Foreword

ICMR Bioethics Unit, works at the national level for the development and updating of National Ethical Guidelines, policies to address emerging ethical aspects of biomedical and health research, review research of national importance with complex issues being led by ICMR and its network of institutions or referred to it by government ministries and departments. ICMR Bioethics Unit promotes ethical conduct of research, improve communication and build capacity of ethical review in institutions across the country.

World Health Organization (WHO) has developed a draft WHO tool for Benchmarking Ethics Oversight of Health-Related Research with Human Participants. ICMR Bioethics Unit, which is a WHO Collaborating Centre for Strengthening Ethics in Biomedical and Health Research took the initiative to undertake an exercise to pilot this draft tool in India . A 2-day workshop was organised in order to deliberate on the draft tool on this and obtain feedback from ethics committess in India. The workshop was attended by the members from about 24 ethics committees across the country and the program was facilitated by 8 national and international facilitators.

A detailed report has been compiled in consultation with rapporteurs in order to collate the suggestions received during the workshop. for each session for submission to WHO. We thank WHO headquarters for its unwavering support and financial assistance for conducting the workshop. I hope that the draft recommendations from India will help to refine this document and will be useful in the finalization of the tool.

Dr. Roli Mathur,
Scientist F & Head, ICMR Bioethics Unit,
Director, WHO Collaborating Center for Strengthening
Ethics in Biomedical and Health Research,
Indian Council of Medical Research
Bengaluru

TABLE OF CONTENTS

Background

ICMR Bioethics Unit, Bengaluru, a WHO Collaborating Centre for Strengthening Ethics in Biomedical and Health Research conducted a 2-day workshop to pilot the draft WHO tool for Benchmarking Ethics Oversight of Health-Related Research with Human Participants in India. The draft Benchmarking tool was developed aiming to assist its Member States in reviewing their current capacity for ethical oversight of health-related research. The tool consists of seven indicators and associated sub-indicators, which were discussed to get insights regarding the applicability of the tool in the Indian context.

1 Session I-Inaguration

The workshop was scheduled on 6-7 December, 2022 in Bengaluru. More than 24 ethics committee members and experts in the field of ethics in biomedical and health research from Indian Council of Medical Research (ICMR) and non-ICMR institutions (government and private medical colleges/research institutes/non-profit organizations) participated in the event. Director, ICMR-NCDIR, Bengaluru, commenced the inaugural session on 6 December 2022 by stating that the purpose of the session was to familiarize participants with ICMR- Department of Health Research (DHR) initiatives regarding the registration of ethics committees of the country and obtain inputs from all participants that would aid in strengthening ethics committees. Head, ICMR Bioethics Unit presented an overview of the governance framework of ethics committees and ICMR- Department of Health Research (DHR) outreach program, briefing the experts and the participants that ethics is one of the mandates of DHR and ICMR. The capacity-building activities of the ICMR-Bioethics unit were also discussed which includes formulating the National Ethical Guidelines, developing the common ethics review forms, e-training programs, ICMR-DHR outreach program and developing short educational videos, animated videos, infographic posters, and Frequently Asked Questions (FAQs) and posting them on ICMR-NCDIR website. The International facilitators pointed to the global need for setting up high quality ethics committees and the need for measurements, indicators and to measure conformity with standards. It was informed that this tool builds into decades of work of WHO towards helping member states with tools to improve quality.

2 Session II- ICMR-DHR Outreach to understand Ethics Committee Challenges

The session addressed Ethics Committee Registration, with focus on Structure, Functioning, and Challenges of EC in an Indian context followed by a discussion on the Investigator's Perspective & experience with ethics review.

Members from ICMR Central Ethics Committee on Human Research (CECHR) and Joint secretary, Department of Health Research joined the workshop virtually and discussed the latest updates and DHR requirements for ethics committee registration on the National Ethics Committee Registry for Biomedical and Heath Research (NECRBHR). Furthermore, ICMR Bioethics Unit and DHR proposed an outreach program to strengthen the capacity of ethics committees across India and to better understand grassroots challenges in the functioning of ethics committees, especially in non-metro areas. To understand the difficulties of organizations in both government or the private sector and to propose solutions, this initiative is geared towards reaching out to them for a one-on-one interaction.

Representatives of DHR participated in the event and discussed on the overview of structure, functioning, and challenges faced by Ethics committees'. EC registration under DHR through the 'Naitik portal' was demonstrated, and SOP preparation and EC certification were explained. Additionally, DHR representatives discussed challenges faced in reviewing EC registration applications, such as the lack of standard operating procedures (SOPs), absence of ongoing training, an imbalance in the composition of EC, and non-reporting of EC members to DHR.

A discussion was held between participants and experts regarding the investigator's perspective on ethics review, and the main points discussed are outlined below:

- Researchers must receive training in health- related research ethics. Additionally, they may also get trained in the development of SOPs, informed consent forms, research methodology, and protocol writing.
- The presence of scientific reviewers at ethics committee meetings should be mandated in order to bridge the gap between science and ethics.
- When reviewing a student research thesis, it is imperative to involve guides/mentors in the ethics review process. Furthermore, medical students/graduates may also be included in ethics committees to better understand EC functioning.
- Research insurance coverage for researchers and ethics committees may be considered by institutions if any adverse circumstances arise during the study process. Additionally, an honorarium/ reimbursement of expenses for attending ethics committee meetings may be provided at the institutional level.

2.1 General comments pertaining to biomedical and health research ethics in India:

- Legal provisions at the National level to be followed for all biomedical and health research are:
    - ICMR National Ethical Guidelines for Biomedical and Health Research involving human participants, 2017
    - New Drugs and Clinical Trial Rules, 2019 (NDCT Rules,2019)
    - Drugs and Cosmetic Act and Rules 1940 and 1945- classification of drugs under given schedules, guidelines for the storage, sale, display, and prescription of each schedule.
- Department of Health Research (DHR) and Drugs Controller General of India (DCGI), India should verify the ECs that are registered and develop mechanisms for including legal aspects and implementing already existing legal provisions
- In Indian context, chapter 4 of NDCT Rules, 2019 should be followed which provides checklists and recommendations for ECs to comply with protocols and may be mentioned in the tool. Few points that may be considered are:
    - A decision of a public body may be challenged in a court of law if it violates a constitutional right and the violation of that constitutional right need not be related to an abuse of authority. There may be instances when an EC's decision is overturned on constitutional grounds and may not be considered final. While the NDCT Rules provide guidance on how financial compensation for a patient/participant in health-related research is calculated, participants can still seek court intervention if constitutional rights are violated. In light of this, it is necessary to clarify which decisions based on NDCT Rules can be appealed in court.
    - Under the NDCT Rules, 2019, ECs can be suspended or revoked if they do not comply with applicable laws and guidelines.

- There must be at least one permanent member from the AYUSH Department on the EC in order to avoid the protocol being referred back and forth for expert opinion.
- Workshops to train EC members can help and prepare ECs in the event of pandemics.

- Participants and experts discussed whether communications with PI or vice versa can be considered official through WhatsApp.
- Members of the EC were concerned and discussed that revealing their contact details could harm or violate their privacy. The information on public domain could be amended to safeguard the EC members.

2.2 General comments pertaining to draft WHO Benchmarking tool:

- As the word "oversight" is ambiguous, the name of the tool could be changed to another suitable term.
- The tool may include a questionnaire that will help develop mechanisms for the effective functioning of ECs.
- ICH GCP Guidelines and other national-level guidelines of participating countries may be added in the reference
- The WHO Tool may include provision for declaration of conflict of interest in the sub-indicators
- The tool may include a section on publication ethics. There was discussion in the workshop about the need for every institution to have a policy for authorship / authorship guidelines

3 Session III

An overview of the WHO Tool for benchmarking ethics oversight of health-related research with human participants was informed by representatives from WHO headquarters (Geneva)

3.1 General comments

- There have been concerns raised about how well Research Ethics Committees (ECs) handle their role in protecting human participants; therefore, these gaps must be identified.
- Process of developing the 7 indicators was informed in the workshop.
    - A WHO working group was established and involved 20 members from different WHO regions. It covered seven major areas, which included the legal provisions, role of research institutions, etc. The first draft was compiled after public consultation and approximately 200 comments were obtained. It was planned to pilot this tool in 4-5 countries and to understand the practical difficulties of using this tool.

4 Indicator 1: Legal provisions and regulatory framework

The objective of this indicator is to determine whether an adequate legal and regulatory framework exists to support ethical oversight of health-related research involving humans.

4.1 General comments

- A legal and regulatory framework to support ethical oversight of health-related research may be integrated into the WHO tool. The importance of legitimizing the Ethics Committee's functions may also be discussed.
- To make the rating scale more measurable, the term "partially implemented" may be redefined in the tool. For instance, it is uncertain if ECs classified as "partially implemented" can continue to function.
- The term “Lay persons" may be replaced with a suitable terminology (more sensitive) term be used.

4.2 Specific comments

Sub Indicator 1.1	Legal provisions requiring health-related research with humans to be reviewed and approved by ECs
• The tool may consider incorporating some points on how to ensure that legal guidelines are implemented by ECs while conducting health-related research	
Sub Indicator 1.2	Legal provisions requiring ECs to review proposed research to determine whether it is consistent with the ethical standards articulated in WHO guidance.
No additional comment	
Sub Indicator 1.3	Legal provisions requiring ECs to conduct continuing review of ongoing research at intervals appropriate to the risk to humans.[1]
• The EC should continually evaluate progress of ongoing proposals. Therefore, the tool may mention the need of legal provisions for continuing review of ongoing ethical review procedures • Research involving higher risk to human participants will require more ethical oversight and the review process should involve shorter review intervals. Therefore the tool may elaborate further on the need for legal provisions while reviewing research with more than minimal risk or high risk	
Sub Indicator 1.4	Legal provisions allowing ECs to terminate health-related research with humans if they determine that a study no longer meets the criteria that justified its initial approval.
• ICMR National Ethical guidelines states that documents related to regulatory clinical trials must be archived for 5 years and all records must be archived for a period of at least 3 years after the completion/ termination of the study, hence a similar point could be added to the tool. • The WHO Tool mentions, National Regulatory Authorities (NRA) has legal provisions authorizing ECs to suspend or terminate health-related research with humans. Similarly, in the Indian Context, for various states the regulatory authorities have the provision for suspension/termination of research study. For example: o Appeals against the EC's decisions can be filed with the State Board in Karnataka and Orrisa o In certain circumstances, the Data and Safety Monitoring Board (DSMB) may terminate a clinical trial o For Academic Clinical Trial, the EC is the final authority and their decision is considered final	
Sub Indicator 1.5	Legal provisions requiring EC members to declare any conflicts of interest and prohibiting members from participating in the review of any study in which they have a conflicting interest
• There may be a point on the tool that directs EC members to declare and manage conflict of interest during/prior EC meetings.	

Sub Indicator 1.6	Legal provisions ensuring that ECs' decisions cannot be overruled except in cases of abuse of authority as determined through a regulatory agency or court
• A EC's decision may not be considered final, particularly when it involves financial compensation for a patient/participant in health-related research. Therefore, the above mentioned point may also be addressed in the tool.	
Sub Indicator 1.7	Legal provisions ensuring that research participants have access to medical treatment for any injuries that directly result from their participation, and that participants and their dependants are protected from any financial consequences that could directly result if they suffer injury or death as a result of their participation.
No additional comment	
Sub Indicator 1.8	Legal provisions requiring clinical trials to be registered on a registry that complies with the WHO Registry Criteria[2] before recruitment of participants begins
No additional comment	
Sub Indicator 1.9	National, regional, and/or local oversight authorities supporting ECs and ensuring that they adhere to applicable ethical and legal requirements
No additional comment	
Sub Indicator 1.10	Legal provisions creating mechanisms for independent authorities to suspend or revoke the authority of ECs that do not adhere to applicable laws, regulations, and guidelines
No additional comment	
Sub Indicator 1.11	Updated, publicly available information on laws, regulations, and official guidelines related to the ethics oversight of health-related research with humans
The WHO tool may discuss points on Data storage and data management such as: • Adequate guidelines can be outlined for the storage of data and data management for health-related research, clinical trials, and student theses and these guidelines should be made publicly available	
Sub Indicator 1.12	An updated, publicly available list of all ECs in the country
• List of ECs should include names, qualifications, compositions, and terms of all their members. EC members should only have their affiliations, appointment and institutional contact information on the updated list. Sponsors and others may exert pressure on EC members if their personal information has been disclosed.	

[1] https://www.who.int/clinical-trials-registry-platform/network/registry-criteria

5 Indicator 2: REC structure and composition

The objective of this indicator is to determine whether ECs have an effective structure and composition

5.1 General comments

- ICMR National Ethical Guidelines, 2017 states that ECs should be multi-disciplinary and multi-sectoral and there should be adequate representation of age and gender. Therefore, the tool may also include the above-mentioned points in this sub-indicator.
- Additionally, the tool may also mention the roles and responsibilities of an alternate member. ECs can also have a set of alternate members who can be invited as members with decision-making powers to meet the quorum requirements.
- An informed consent form may also be assessed by lay persons.

5.2 Specific comments

Sub Indicator 2.1	The EC's membership satisfies the requirements of relevant ethical guidelines
• There should be more representation of younger age groups in the EC, with the minimum requirements of the members being clearly defined	
Sub Indicator 2.2	The roles and responsibilities of EC members are clearly defined
• ICMR National Ethical Guidelines states that EC members either be trained in human research protection and/or Good Clinical Practice (GCP) at the time of induction into the EC, or must undergo training and submit training certificates within 6 months of appointment (or as per institutional policy); • Hence, WHO tool may discuss in this indicator that, upon appointment, new members should have a window of one to two months to complete GCP Certification.	
Sub Indicator 2.3	EC members and chairs are appointed for specific terms, rather than on an indefinite basis
Sub Indicator 2.4	EC members and chairs may not be removed prior to the expiration of their terms, except for legitimate reasons
• SOPs may be drafted stating that EC members who fail to attend meetings will be removed from the EC membership	
Sub Indicator 2.5	The EC invites relevant non-members to contribute to the review of research that raises issues beyond the scope of the members' own expertise
• Non-members and experts who have been consulted on a specific subject/topic should be included in the voting process since they contribute to the final decision-making	

6 Session IV

Indicator 3 REC resources

The objective of this indicator is to determine whether the EC has documented procedures to carry out its ethics oversight activities. The procedures should cover the submission and screening of applications, the protocol review process, the monitoring of ongoing research, and the document management system.

6.1 General comments

- A well-drafted indicator that discusses whether the ECs have adequate resources, including staff, facilities, technological support, and financial resources, in order to function robustly and effectively.
- A point on annual audits may be mentioned in the tool- ECs can be audited to review their work, budget, budget utilization, and annual status reports.

6.2 Specific comments

Sub indicator 03.01	The EC has sufficient competent staff, with appropriate education, training, skills and experience, to support its activities.
No additional comment	
Sub Indicator 3.02	The EC's members and staff receive training on ethical issues in health-related research with humans
• It would be helpful if the tool indicated the number of staff required in relation to workload. • Mechanisms to assess staff training in (human research protection, EC functions, SOPs conversant with ethical guidelines, GCP guidelines, awareness of legal provisions and other relevant regulations) may be included in the tool. • EC secretariat and EC members need independent and combined training, as well as pre- and post-training assessments. • In order to ensure robust decision-making, non-scientific EC members should receive special training regarding ethical considerations for different types of research	
Sub Indicator 3.03	The EC has adequate facilities and equipment
• The point "EC should be supported with adequate infrastructure and facilities…" in this sub indicator may be replaced with 'EC Secretariat '	
Sub Indicator 3.04	The EC has adequate technological support in light of its needs.
In addition to the existing points, the sub-indicator may also discuss the following points: • Developing a dynamic, free global document management system would be useful to manage the overall ethics oversight process • The ECs webpage may include information on mode of submission of research proposals, relevant forms, SOPs and links to National and International Guidelines • The sub indicator may also mention provisions for storing, archiving and retrieving data electronically	

Sub Indicator 3.05	The EC has adequate and stable financial resources
No additional comment	

7 Indicator 4: REC procedures

7.1 General comment

- The indicator may address procedures for ethics review in research in humanitarian emergencies, Pre-emptive research preparation for future humanitarian emergency and outbreak preparedness

7.2 Specific comments

Sub Indicator 4.01	The EC provides adequate guidelines for the submission and screening of applications for the ethical review of health-related research with humans.
Sub Indicator 4.02	The EC has written procedures to ensure that it explicitly considers the ethical criteria for review identified in WHO guidance.
Sub Indicator 4.03	The EC members have adequate time before and during meetings for meaningful review of research proposals.
• In the workshop experts and participants discussed that longer time is required for review of proposals depending upon the resources and facilities available to the ECs. • Discussions revealed that the turnaround time varied for ethical review procedures. Long delays were attributed to various reasons such as, number of review proposals received annually, types of review, lack of communication among researchers and, and unavailability of EC members to meet quorum for meetings in the peripheries of the country. In this regard, the sub-indicator may stipulate a definite average time for reviewing each research proposal.	
Sub Indicator 4.04	The EC has procedures to ensure that decisions are made in a timely manner and that decisions are promptly communicated to principal investigators.
No additional comment	
Sub Indicator 4.05	The EC has procedures for ensuring the rapid review of research proposals in public health emergencies.
No additional comment	
Sub Indicator 4.06	The EC has procedures for considering relevant previous decisions in its review of protocols.
• "Consideration of relevant previous decisions" is a broad term, and the tool may identify which protocol reviews may be considered.	

Sub Indicator 4.07	The EC engages in and/or contributes to monitoring of ongoing research at intervals appropriate to the degree of risk to humans.
No additional comment	
Sub Indicator 4.08	The EC maintains a good document management system.
• In an additional section, the tool may include an application form for initial review (qualifications of EC members, proposal-related documentation, training, and funding), which may assist ECs across the globe in maintaining consistent standards. • ICMR National Ethical Guidelines mentions that documents related to regulatory clinical trials must be archived for 5 years after the completion/termination of the study or as per regulations. Therefore the sub indicator may also discuss some points regarding the same.	

8 Indicator 5: Mechanisms to promote REC transparency and accountability

The objective of this indicator is to determine whether mechanisms are in place to promote EC transparency and accountability. These mechanisms should provide the public with information about the ethics review process, the sources of ECs' funding, the composition of ECs, and all research proposals that EC approves. In addition, they should enable research participants, prospective research participants, and investigators to pose questions to ECs and to obtain a response

8.1 Specific comments

Sub Indicator 5.01	Updated information on the EC's own guidelines and procedures is publicly available.
Participants and experts in the workshop discussed that ECs across the globe lack a standard website for communication. • In this regard, it was suggested that the WHO benchmarking tool may provide a template for the requisite web page requiring the necessary information for the EC and their members. Having standardized information on websites around the world will help maintain consistency. • Additionally, the tool may include a Checklist for EC website information	
Sub Indicator 5.02	Information about the EC's sources of funding is publicly available.
• There has been a suggestion that a set of predefined questions may be added to the tool for the EC to use when providing funding information publicly. For example: The amount of funding allocated to secretariat, equipment, etc.	
Sub Indicator 5.03	An updated list of all the EC's members is publicly available.
No additional comment	

Sub Indicator 5.04	A list of the titles, principal investigators, and dates of approval of all research proposals approved by the EC is publicly available.
The participants discussed few points that may be included in this sub-indicator for a better understanding: • On the point that stated "Evidence that the list is publicly available, such as publication on a website, in an annual report, or in other publicly available documents", concerns of copyright, conflicts of interest, privacy and confidentiality, and rights of participants were raised. • The experts recommended only essential details such as title and retrospective study be published on the website. In addition, prospective studies, the names of principal investigator, informed consent forms, and a list of research participants may be omitted. • Along with the list of approved projects, list of non-approved projects should also be available publicly	
Sub Indicator 5.05	The EC facilitates the ability of research participants or prospective research participants to ask questions raise concerns, or lodge complaints about their rights as research participants and about the ethics review process, and it provides timely responses to those questions, concerns, and complaints.
• The participants and experts proposed that there may be an annual auditing system. This would ensure that concerns and complaints are addressed by an external evaluator in a fair and transparent manner.	
Sub Indicator 5.06	The EC facilitates the ability of investigators to ask questions, raise concerns, or lodge complaints about the ethics review process, and it provides responses to those questions, concerns, and complaints.
• Researchers and EC members should be provided equal opportunity, and consideration should be given when filing a complaint	

9 Indicator 06: Mechanisms for ECs to monitor their performance

The objective of this indicator is to determine whether the EC has mechanisms in place to ensure their adherence to ethical standards and to assess and improve the quality of their performance

9.1 General comments

- Need for inclusion of annual report from the principal investigator as part of the review process for analysing and further inputs to be given by EC members.

9.2 Specific comments

Sub Indicator 06.01	The EC proactively solicits feedback from investigators and research participants about their experience of research.
The indicator may mention the type of feedback (verbal/written/audio-visual) that should be obtained from investigators and research participants about their experience of research. Sub-indicator 06.01 is similar to sub-indicators 05.05 and 05.06 and may be merged.	

Sub Indicator 06.02	The EC monitors its adherence to its standard operating procedures.
• The word “self-audit” is ambiguous in nature and may be reframed. • The conduct of the research should be monitored through questionnaires and interviews with investigators. A personal interview with the participants was also recommended regarding their awareness of their participation in clinical trials.	
Sub Indicator 06.03	The EC conducts internal audits of its performance on a regular basis.
• The fourth point in this sub indicator- “Number and nature of complaints received by the EC” have been discussed previously and may be omitted • There may be a need to rephrase "Outcomes of surveys" in a way that is easier to comprehend. Additionally, it may be helpful to discuss how ‘outcomes surveys assessing participants' comprehension/experience’ in internal and external audits, will be implemented.	

10 Indicator 07: Responsible Research Institutions

The objective of this indicator is to assess whether research institutions fulfil their responsibility to ensure that any health-related research with humans affiliated with the institution adheres to internationally recognized ethical standards. This indicator is not designed to provide a comprehensive assessment of research institutions; instead, it focuses on a few key issues that are illustrative of institutions’ commitment to the protection of research participants.

10.1 General comments

- The tool may elaborate on the exact definition for “adequate” legal support in this sub-indicator
- For annual assessment of the IECs a facility-based, process-based, and study-based audit should be conducted.
- The tool may harmonize the language used in indicators 7.1 and 7.2. "Researcher affiliated with the institute" seems ambiguous in its interpretation.

10.2 Specific comments

Sub Indicator 07.01	The institution verifies that all proposals for health-related research with humans are submitted to an REC if any part of the research will be conducted by a researcher affiliated with the institution.[3]
This sub indicator may discuss a point on: • Evidence that the ECs ensure that all research proposals are verified and comply with the institutional policies.	
Sub Indicator 07.02	The institution has policies and procedures related to the declaration and management of conflicts of interest of researchers affiliated with the institution and of the institution itself.

[3]Whether a research is “affiliated with” an institution should be determined according to local laws and policies

• Additionally, a point may also be included stating- The institution needs to clarify the names of the researchers affiliated with it.	
Sub Indicator 07.03	If the institution has its own EC, it has policies and procedures related to the declaration and management of conflicts of interest of EC members and non-member participants in EC meetings
• There should be a mandate and policies regarding conflict of interest at the institutes, and these should be regularly updated.	
Sub Indicator 07.04	The institution has a policy requiring all researchers affiliated with it to be trained on their responsibilities related to the ethical conduct of research.
• This sub-indicator may be redrafted to emphasize the importance of training non-affiliated members in ethical conduct of research.	
Sub Indicator 07.05	The institution facilitates the ability of research participants and prospective research participants to lodge complaints about studies conducted by researchers affiliated with the system, either through the institution itself or at the national or regional level. If the complaint system is established within the institution, the institution has a process for reviewing and responding to complaints.
Sub Indicator 07.06	The institution has a process for investigating allegations of unethical conduct by researchers and imposing consequences in cases where unethical conduct is determined to have occurred.
Sub Indicator 07.07	If the institution has its own EC, it ensures that the EC has adequate legal support.
No additional comments for the above sub-indicators	

Report on Draft WHO tool for Benchmarking Ethics Oversight of Health –Related Research with Human Participants

ANNEXURE – I

AGENDA

Venue: Dome Hall, Royal Orchid Convention Centre, Yelahanka, Bengaluru
Expected Outcomes: To receive recommendations on improving the tool & self-benchmark ethics oversight in India
Facilitators: Joseph Ali, Andreas Reis, Carl Coleman & Roli Mathur

6th December 2022 TUESDAY **Session I- Inauguration**		
9:30- 9:35am	**Welcome by Head ICMR Bioethics Unit**	*Roli Mathur*
9:35- 9:40am	**Remarks by Director, ICMR-NCDIR**	*Prashant Mathur*
9.40- 9.55am	**Round of Introduction**	*All Participants*
9.55- 10.00am	**Remarks by WHO Facilitator**	*Joseph Ali*
10.00- 10.05am	**ICMR-CECHR Chairperson's Remarks**	*Vasantha Muthuswamy/ N. K Arora*
10.05- 10.10am	**Remarks by Joint Secretary, DHR**	*Anu Nagar*
10.10- 10.15am	**Vote of Thanks**	*Dileep G*
10:15- 11.00am	**National Anthem, Group Photo and Tea**	
Session II- ICMR-DHR Outreach to understand Ethics Committee Challenges **Chairperson: Anu Nagar and Prashant Mathur, Facilitator: Roli Mathur and Rapporteur: Anita Nath**		
11.00- 11.15am	**Governance Framework & ICMR-DHR Outreach program**	*Roli Mathur*
11:15- 11:30am	**Ethics Committee Registration**	*Sujata Sinha / Balu V Gopal*
11:30- 11.45am	Discussion	
11.45- 12.00pm	**Overview of structure, functioning & challenges of EC**	*Vidhya Krishnamoorthy* *R Swaminathan* *Salik Ansari*
12.00- 12.15pm	Discussion	
12.15- 12.30pm	**Investigator's Perspective & experience with ethics review**	*G. Narendran* *Seshadri Reddy Varikasuvu*
12.30- 12:45pm	Discussion	
12:45- 1:00pm	**Animated videos on Ethics Review**	
1:00- 2:00pm	**Lunch**	
Session III- Indicators 1 & 2 **Facilitators: Joseph Ali and Andreas Reis, Chairperson: Dhvani Mehta & Rapporteur: Bency Joseph**		
2:00- 2:10pm	**An Overview of the WHO Benchmarking Tool**	*Andreas Reis*
	Indicator	**Discussants (2-3 min each)**
2:10- 2:20pm	**Indicator 1: Legal provisions and regulatory framework**	*Arun Kumar Yadav* *Sandhya Ravi*
2.20- 2.30pm	Discussion	
2:30- 2:40pm	**Indicator 2: EC structure and composition**	*Sandip Mukhopadhyay* *Mohammad Shameem*

		Bindu Kutty
2:40- 3:00pm	Discussion	
Session IV- Indicators 3, 4 & 5 **Facilitators: Joseph Ali and Carl Coleman, Chairperson: Bikash Medhi, Rapporteur: Elna Paul**		
	Indicator	**Discussant (2-3 min each)**
3:00- 3:10pm	**Indicator 3: EC resources**	*Luxmi Singh* *Girish N*
3:10- 3:20pm	**Indicator 4: EC procedures**	*Esther Vise* *Barathane Datchanamurthy* *Rajlakshmi*
3:20- 4:00pm	Discussion	
4:00 to 4:10pm	**Animated Videos on Ethics Review**	
4:10 to 4:30pm	**High Tea**	
4:30- 4:40pm	**Indicator 5: Mechanisms to promote EC transparency and accountability**	*N.P. Sireesha* *Pallavi Shindhaye* *Kavitha Dhanasekaran*
4.40- 5.15pm	Discussion	
5.15- 5.30pm	**Educational Videos and End of Day 1**	
7:00 pm	**Banquet Dinner in the Lawns**	
7th December 2022 WEDNESDAY **Session V- Indicators 6 &7** **Facilitators: Joseph Ali and Roli Mathur, Chairperson: Medha Joshi & Rapporteur: Amrita Natarajan**		
	Indicator	**Discussant (2-3 min each)**
9:30- 9:40am	**Indicator 6: Mechanisms for ECs to monitor their performance**	*Anuradha HV* *Avijit Hazra* *Vikrant Bhor*
9:40- 10:10am	Discussion	
10:10- 10:20am	**Indicator 7: Responsible Research Institutions**	*Bishnu Ram Das* *Rajesh B Sawant*
10:20- 10:50am	Discussion	
10:50-11:30am	**Teatime**	
11.30- 11.40am	**Overall feedback on the use of tool**	*Joseph Ali*
11.40- 11:50pm	**Summary and next steps**	*Roli Mathur*
11.50- 12.15pm	**Certificate distribution**	
12.15- 1.00pm	**Feedback from Participants & Closing**	
1:00- 2:00pm	**Lunch**	
THANK YOU		

ANNEXURE II

List of Participants attended – Draft WHO Tool for Benchmarking Ethics Oversight of Health-Related Research with Human Participants

Name	Organization
Dr. Andreas Reis (Virtually)	Co-Lead, Health Ethics & Governance Unit Research for Health Department WHO, Geneva, Switzerland
Dr. Joseph Ali	Associate Director for Global Programs, Johns Hopkins Berman Institute of Bioethics, USA
Dr. Carl H. Coleman (Virtually)	Professor of Law Academic Director, Division of Online Learning Seton Hall Law School One Newark Centre Newark
Ms. Anu Nagar	Joint Secretary, Department of Health Research, Ministry of Health and Family Welfare, New Delhi
Dr. Vasantha Muthuswamy (Virtually)	Chairperson ICMR Central Ethics Committee on Human Research (ICMR-CECHR)
Dr. Narendra Kumar Arora (Virtually)	Executive Director, The INCLEN Trust International, New Delhi
Dr. Prashant Mathur	Director, ICMR- National Centre for Disease Informatics and Research, Bangalore
Dr Roli Mathur	Scientist- F and Head ICMR Bioethics Unit, ICMR Headquarters

Participants/Experts

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Mr. Salik Ansari	Assistant Coordinator and Co-Member Secretary, Sangath, Bhopal
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