International Agency for Research on Cancer

World Health Organization

Scientific Council **SC/61/2**
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BIENNIAL REPORT OF THE IARC ETHICS COMMITTEE, 2023–2024

1. The IARC Ethics Committee (IEC) ensures the protection of the rights and welfare of participants in research lead, participating in or sponsored by IARC, through the consistent application of international ethical standards for research involving humans.

Composition of the IEC

2. The Committee is composed of ten senior individuals and a majority of external members, with diverse backgrounds and nationalities (as of November 2024) representing sciences, ethics, and law. It meets five times per year to evaluate all IARC projects within its competence.

3. Please see Annex 1 for the composition of the IEC over the reporting period.

4. The departure of four members of the Committee (external members Dr J.H. Fregnani, Dr A. Kerasidou, and Dr H.H. Storm, and internal member Dr S. Vaccarella) was balanced by the appointment of three new members (external members Dr F. Lucivero, and Professor S. Pimple, and internal member Dr A. Olsson). The IARC Data Protection Officer (Ms Jolien Jongerius) was appointed as observer. Professor S. Al-Homoud is Committee Chair since November 2018. Professor B. Fervers is Committee Vice-Chair since January 2024. Dr C. Scoccianti is Secretary since July 2015.

Activities of the IEC

Evaluation of research projects

5. During the period 2023–2024 the IEC met 10 times, five times per each year. In addition to new projects, the IEC evaluated re-submissions of projects previously reviewed, including submissions of supplementary information, re-submissions of projects given conditional approval, and amendments. Material evaluated by the IEC included: a questionnaire summarizing the project's aims and potential ethical issues, a study protocol, local ethical approvals, and informed consent forms. When required, IARC Principal Investigators (PIs) were invited to provide additional information or clarification through extraordinary meetings.

6. The total number of new projects submitted during the 2023–2024 biennium was almost equal to the previous biennium, with an approval rate of 80% and a decrease in the number of re-submissions of approximately 50% (see Figure 1). When compared to the previous biennium, an additional 29.5% of projects were cleared in-between meetings through the expedite review and notification procedures to avoid delay and facilitate approval between IEC meeting (see Figure 2).

7. Submission of an annual progress report, addressing any adverse events which may have occurred during the preceding year, was requested for studies presenting potential ethical implications during their implementation, in order for the IEC to take action, if necessary.

8. For clinical trials the Annual Report also included a copy of the Data and Safety Monitoring Board's report, the scheduled inclusion of subjects versus the actual inclusion, the clinical trial registry unique identifier, and the final version of the protocol, as per the IARC/WHO Policy on Clinical Trials Registration and Public Disclosure of Results based on the WHO Information Note 19/2018.

Figure 1: IEC evaluations over the biennium

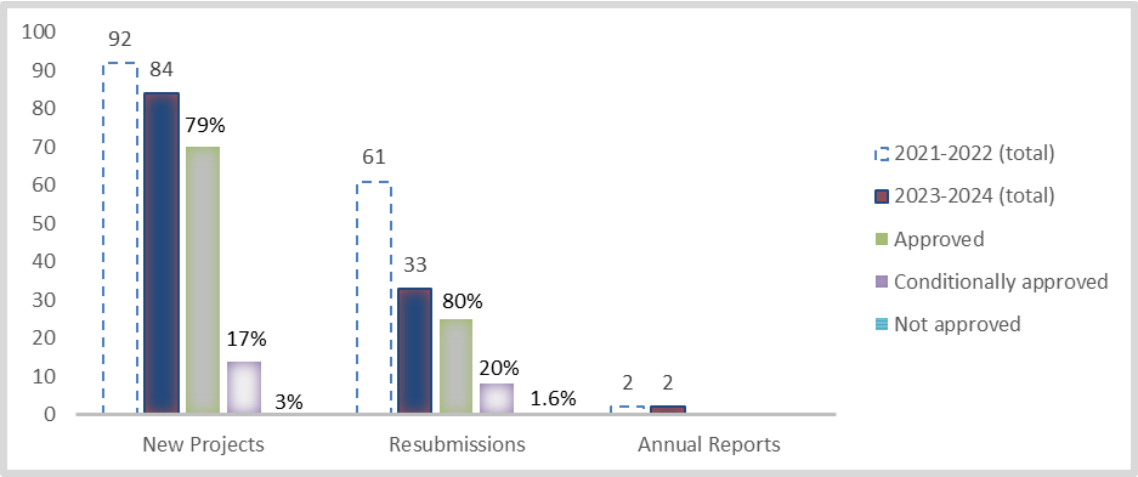
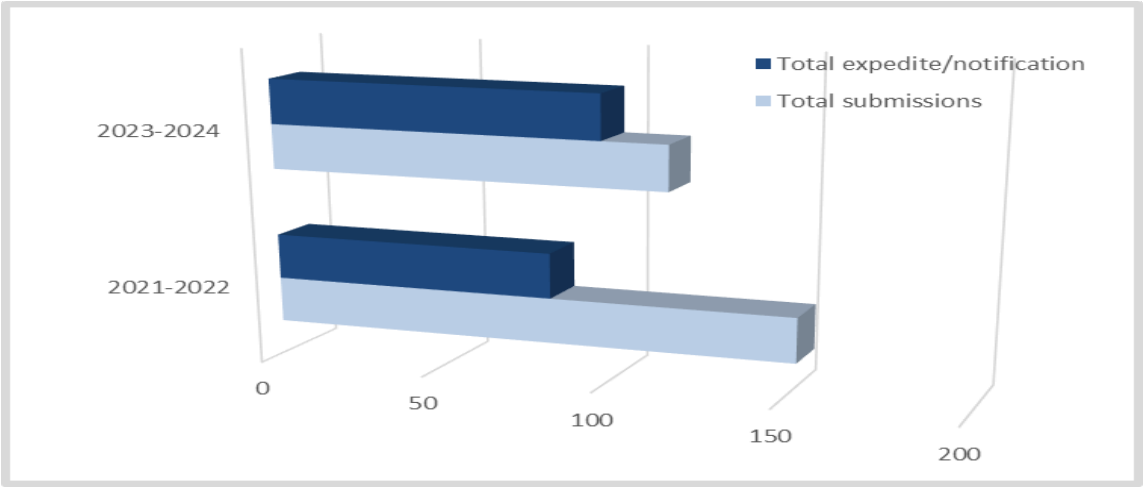


Figure 2: IEC expedite reviews and notifications over the biennium



Update of Procedures

9. The IEC Standard Operating Procedures (SOPs) were updated as follows:

- Section 2 – When applicable, the PI must provide the IEC with official confirmation of the exact provisions under which the project is exempted locally, and the IEC will evaluate whether these align with international ethical standards.
- Section 4 – Multi-center projects not bearing any ethical issue, can be overall approved and the project can start in those centers having collected the local ethical approval or only requiring approval by the IEC.
- Section 3: The following categories of studies were added to Regular Submissions: studies on secondary use of data, studies on data lacking consent for re-use beyond the original purpose or sharing.
- Section3: The following categories of studies were added to Notifications: studies on population aggregated information or making use of summary-level publicly available data or fully anonymised data available in the public domain or commercially available cell lines.

Update of the IEC website

10. The IEC website was updated with:

- A new version of the IEC Template for Informed Consent, and the WHO Template for Informed assent for children/minors;
- Several guidance on ethical aspects of projects involving Artificial Intelligence;
- Recommended trainings, and
- The new version of the SOPs.

Monitoring of conflicts of interest (COIs)

11. The ethics review of research involves consideration of potential COIs referring to situations in which financial or other personal considerations may compromise or be perceived to affect the conduct or reporting of research. Potential COIs were mitigated as follows:

- On an annual basis, external IEC members were required to complete the standard form on “Declaration of Interests for IARC/WHO Experts” and “Confidentiality Undertaking”; and
- Ahead of each meeting, all members were required to declare any potential COI in relation to research projects under evaluation. In the presence of a potential COI, those member(s) were not allowed to participate in the project(s)’ evaluation.

Monitoring of the “ASBEST” Study

12. The large-scale retrospective research of risk of oncological disease caused by occupational exposure to chrysotile asbestos containing dust (ASBEST) study was discussed by the Scientific Council in 2014 (see Document SC/50/12) and the IARC Governing Council was informed of the continued oversight of the study by the IEC (see Document GC/56/5).

13. The IEC was notified of the final publication in 2024 of the final manuscript in the *Journal of the National Cancer Institute*, and Q&A about the study (https://asbest-study.iarc.who.int/). The IEC congratulated the PI and the Asbest Team for the acceptance of this manuscript, and recommended that the communication effort includes ASBEST methodology, procedures and quality insurance put in place for the ASBEST study.

Training for IEC members and IARC staff

14. The IEC attended training on REDCap, a database often used by IARC for data collection, delivered by the IARC Health Info Systems Specialist and focusing on data security and privacy guidelines.

15. The IEC was informed of the revision of the Declaration of Helsinki by the World Medical Association (available at https://www.wma.net/what-we-do/medical-ethics/declaration-of-helsinki/). The new version provides for increased protection for vulnerable populations, improved transparency in clinical trials, and stronger commitments to fairness and equity in research.

16. The IEC Secretary attended training on Artificial Intelligence (AI) and Health, delivered by the WHO and focusing on efforts made in creating harmonized ethical guidance on ethical issues such as reduction in employability, privacy and confidentiality, and the potential of generating fake data. WHO's Approach on AI for Health is available at https://www.who.int/teams/digital-health-and-innovation/harnessing-artificial-intelligence-for-health.

17. The IEC Secretary attended a workshop on Addressing data science challenges for AI in Health (available at https://www.youtube.com/watch?v=bgXMEPPEyKk), delivered by the Global Health Network. The workshop explored AI's transformative impact in healthcare delivery, ethical frameworks, responsible AI strategies, and effective implementation of AI solutions.

18. The Research Ethics Online Training developed by the Global Health Network in collaboration with the WHO (available at https://globalhealthtrainingcentre.tghn.org/research-ethics-online-training-v2/), was made available to IARC staff and as mandatory training for new IEC members. This substantial course covers 10 areas on ethical considerations in international health research.

19. New IEC members also received training by the IEC Secretary on the ethical aspects of research involving human participants, on the application of the relevant international guidelines to the review of the types of research conducted at IARC, and on the roles and responsibilities of research ethics committees.

20. The training on International Council for Harmonization Good Clinical Practice (ICH GCP) (available at https://globalhealthtrainingcentre.tghn.org/ich-good-clinical-practice/) was made available and recommended to IARC PIs performing clinical trials. This training meets the minimum criteria for ICH GCP Investigator Site Personnel Training identified as necessary to enable mutual recognition of GCP training among trial sponsors.

21. Online training opportunities on Policies, Research Priorities, and Ethics Regulations across the world were regularly explored by the IEC Secretary and suggested to the members, including those organized by the WHO.

Collaborations

22. To strengthen collaborative opportunities between IARC and other UN Agencies on bioethics, the IEC Secretary attended remotely the UNESCO Sessions of the UN Inter-Agency Committee on Bioethics. Results of the discussion were shared with the IEC to explore areas of mutual interest such as reflecting on the principle of solidarity and cooperation, as set forth in Article 13 of the Universal Declaration on Bioethics and Human Rights, in light of the increasing prominence of open science and open innovation.

23. To strengthen collaborative opportunities between IARC and WHO, the IEC Secretary attended remote seminars organised by the WHO Ethics Review Committee and the WHO PAHO Regional Program on Bioethics. Results of the discussion were shared with the IEC to explore areas of mutual interest, including research integrity and responsible conduct of research and how to identify and evaluate layers of vulnerability.

24. To strengthen collaborative opportunities within IARC and with EU actors, the IEC Secretary attended and contributed to the BBMRI-ERIC Academy Symposium Ethical, Legal and Societal Insights & Outlook for Biobanks and Medical Research organised by IARC LSB. The main topics of shared interest were data protection, genetic privacy, reporting incidental findings, and the management of consent for the use of biological material.

IARC Ethics Advisory Group (EAG)

25. The IARC Ethics Advisory Group (EAG) is a small group of international bioethics experts, established to provide specialist expertise to the IEC to help resolve complex ethical issues. The members are as follows:

    - Professor Angeliki Kerasidou, Professor of Bioethics, The Ethox Centre, University of Oxford;
    - Dr Emmanuelle Rial-Sebbag, INSERM Toulouse, Faculty of Medicine;
    - Professor Giuseppe Testa, University of Milano, European Institute of Oncology.

26. The EAG was not consulted by the IEC over the biennium.

IEC forthcoming perspectives

27. The IEC proposed establishing a working group to develop a position statement on the necessity of obtaining assent forms from minors/children. The IEC will consider several aspects including definitions and age ranges; ethical principles such as respect for the autonomy and evolving capacities of children, beneficence, and justice; cultural and contextual sensitivity; international frameworks (e.g. the UN Convention on the Rights of the Child) and national frameworks; parental/guardian consent interaction; and assess how obtaining assent impacts children, both positively (empowering them) and negatively (causing confusion, stress, or undue influence.

ANNEX 1 – Composition of the IEC

Name		Affiliation	Appointed	End of Term
Past members				
IARC	*Dr S. Vaccarella*	*Cancer Surveillance (CSU) Branch*	*January 2014*	*December 2023*
External	*Dr J. H. Fregnani*	*Oncologist, Head of Education, A.C. Camargo Cancer Hospital, São Paolo (Brazil)*	*September 2019*	*February 2024*
	Professor A. Kerasidou	*Bioethicist, Ethox Centre, Oxford University (UK)*	*January 2018*	*December 2023*
	Dr H. Storm	*Epidemiologist, Chief Medical Officer Danish Cancer Society, Copenhagen (Denmark)*	*June 2014*	*May 2024*
Current members				
External Members	Professor S. Al-Homoud	**IEC-Chair**. Surgeon, King Faisal Specialist Hospital and Research Center, Riyadh (Saudi Arabia)	September 2015	August 2025
	Ms S. Capsalas	Lawyer, Ethics and Corporate Responsibility INTERPOL, Lyon (France)	January 2021	December 2024
	Professor B. Fervers	**IEC Vice-Chair**. Oncologist, Coordinator Cancer and Environment Unit, Centre Léon Bérard, Lyon (France)	January 2010	December 2026
	Dr F. Lucivero	Senior Researcher in Ethics and Data and Director of the Big Data Ethics Forum. Ethox and Wellcome Centre for Ethics and Humanities, University of Oxford (UK)	January 2024	December 2026
	Professor S. A. Pimple	Oncologist, Head of Department of Preventive Oncology, Tata Memorial Hospital Mumbai (India)	November 2024	October 2026
	Professor Paolo Vineis	Epidemiologist, Chair Environmental Epidemiology, Imperial College London, London (UK) / Head Genetic and Molecular Epidemiology Unit, Italian Institute for Genomic Medicine, Torino (Italy)	January 2010	December 2026
	Professor Y. Zhang	Epidemiologist, National Clinical Research Center for Cancer, Cancer Hospital / Chinese Academy of Medical Sciences, Beijing (China)	April 2022	March 2026
IARC	Dr B. Abedi-Ardekani	Genomic Epidemiology Branch (Iran)	January 2016	December 2025
	Dr A. L. Carvalho	Early Detection, Prevention, and Infections Branch (Brazil)	September 2019	August 2025
	Dr A. Olsson	Environment and Lifestyle Epidemiology Branch (Sweden)	April 2024	May 2026
	Ms J. Jongerius	*(Observer)* Data Protection, Legal Officer	November 2023	October 2026