International Agency for Research on Cancer
World Health Organization

Scientific Council **SC/59/2**
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BIENNIAL REPORT OF THE IARC ETHICS COMMITTEE, 2021–2022

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 eleven senior individuals with diverse backgrounds and nationalities (as of September 2022) representing sciences, medical care, ethics, law, and the general population. It meets five times per year to give an ethical evaluation of all IARC projects within its competence. All meetings were held by videoconference.

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

4. The departure of two members of the Committee (Professor Mutlu Hayran and Dr Michel Baduraux) was balanced by the appointment of two new members (Professor Yawei Zhang and Ms Sandrine Capsalas). Professor Samar Al-Homoud is Committee Chair since November 2018. Associate Professor Angeliki Kerasidou is Committee Vice-Chair since February 2020.

Activities of the IEC

Evaluation of research projects

5. During the period 2021–2022 the IEC met 10 times (February, April, June, September, and November of both years). 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 submitted and evaluated by the IEC included: a questionnaire summarizing the project's aims and potential ethical issues, a full 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. Submission of an annual progress report, including any ethical problems or 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.

7. 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.

8. The total number of new projects and re-submissions during the 2021–2022 biennium was almost equal to the previous biennium, with an approval rate of approximately 80% (see Figure 1).

9. An additional 9.7% of projects were cleared in-between meetings through the expedite review and notification procedures, when compared to the previous biennium (see Figure 2). Given the recorded consistent rise in projects cleared in-between IEC meetings, the Committee agreed to set the maximum number of expedite reviews to two every two weeks.

Figure 1: IEC evaluations over the biennium

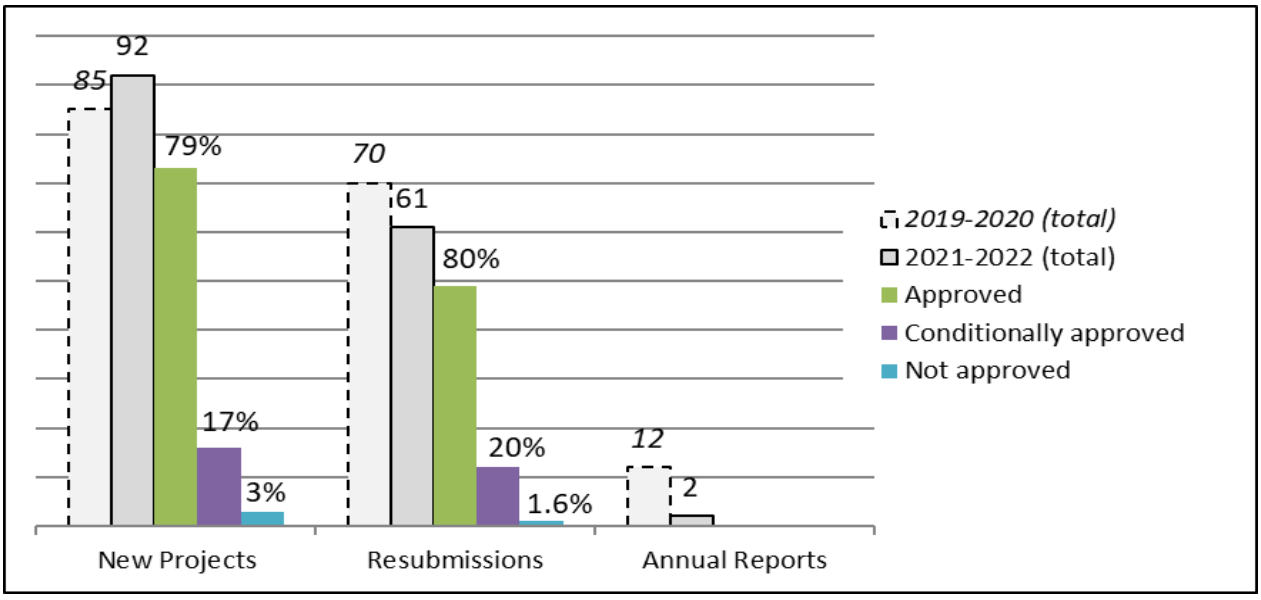
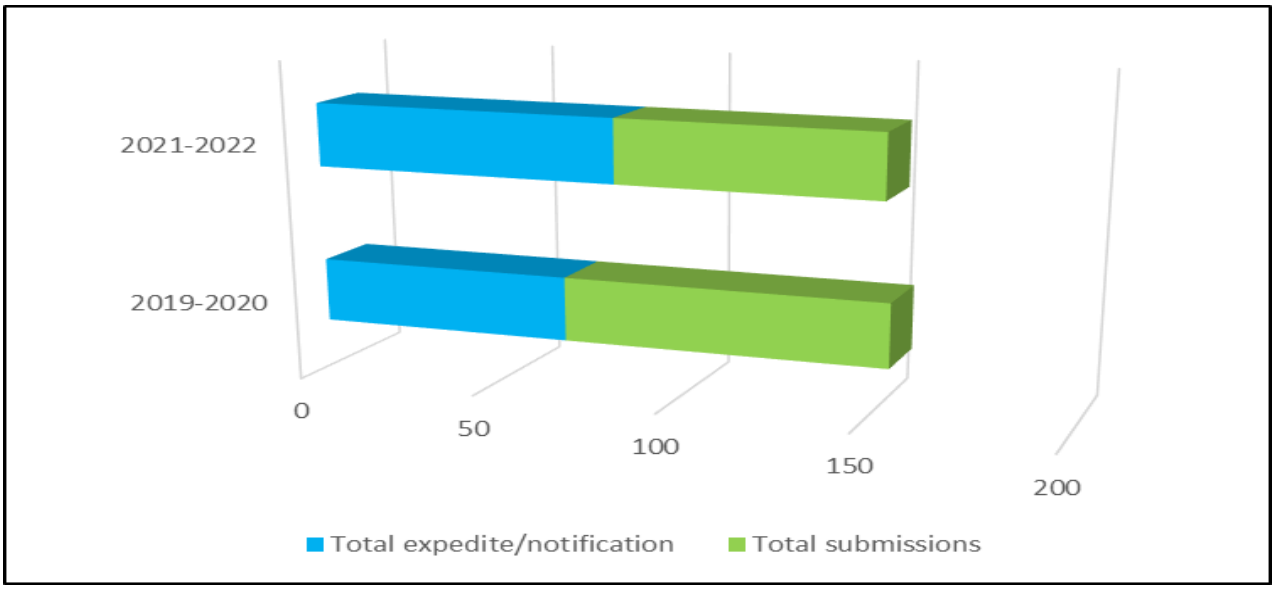


Figure 2: IEC's increased workload in-between meetings over the biennium



Update of Procedures

10. The IEC Rules and Procedures (RAPs) were updated with the following Secretariat's responsibilities in support of the IEC Chair and Vice-Chair:

- Production of the IEC Biennial Report; oversight of the compliance with IARC relevant Policies, rules and procedures; and regular update of the Standard Operating Procedures.
- Assessment and issuance of Notifications; preliminary assessment of Expedite Reviews.
- Training of new IEC members on the ethical aspects of research involving human participants; on the application of international guidelines to the review of IARC's types of research; and on the roles and responsibilities of research ethics committees.

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

- Section 2 – The PI has the responsibility to ensure that the use of personal data and samples and the conditions for their storage and process, are consistent with the IARC Information Classification Policy, relevant WHO Policies, and with the relevant national regulations; and that they ensure the overall transparency and security about data processing, the participants' right to access, restrict, rectify or erase personal data, and the data protection by design and by default, in agreement with General Data Protection Regulation, Art. 25.
- Section 5 – Requirement to include in the Annual Report of intervention studies, the trial ID or registry identifier code/number; the final version of the protocol; and overall to comply with the IARC/WHO Policy on clinical trials registration and public disclosure of results.

Update of the IEC website

12. The IEC website was updated with:

- A new design by Lektorium (CMS for static websites customized by the external contractor SPHERICAL) and by Amazon Cloud (AWS);
- A new version of the FAQs for staff on the review process; and with
- The new version of the SOPs and RAPs.

Monitoring of conflicts of interest (COIs)

13. 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
- 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

14. 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).

15. Two meetings between the Study Team (ST) and the Scientific Advisory Board (SAB) of the study, were held remotely in March and in June 2021. In September 2021, the IEC acknowledged receipt of the 2021 SAB Report, noted that it contained insufficient elements for evaluation, and requested access to the SAB written list of queries and of requests for supplementary analyses to the ST. In October 2022, the IEC received the SAB queries to the ST and the ST proposed solutions made in 2021, the 2022 SAB Report, and the 2022 SAB comments on preliminary analyses. In the 2022 SAB comments, the IEC noted some potentially critical aspects of the study that might have implications for the IEC evaluation and in November 2022 requested access to the preliminary analyses in order to complete its ethical evaluation.

16. In November 2022, the IEC was informed of a written agreement signed on 13 December 2019 between IARC and the study Funder, the Izmerov Research Institute of Occupational Health of the Russian Academy of Medical Sciences, stipulating that results should not be circulated outside the ST and the SAB until the initial risk assessment report is accepted by a peer-reviewed journal. The IEC noted that the study is now completed and that a manuscript on the main results is now under discussion among the ST and the SAB. Understanding the terms of confidentiality on the final results as agreed with the Funder, the IEC requested access to the final manuscript(s) once accepted by a peer-reviewed journal.

17. The IEC congratulated IARC and the ST for all efforts made in addressing IEC comments for the period 2012–2020 and for having been able to complete the investigation on chrysotile exposure in the Russian Federation. Also, the IEC acknowledges IARC's and the ST's intention and efforts to engage with the IEC. Given IARC's responsibility in the monitoring and implementation of this institutional study, the IEC remains engaged in conducting its independent review and ethical evaluation and looks forward to receiving the final draft(s).

Training for IEC members and IARC staff

18. A generic module on "Ethics and Epidemiology" was published online for the 2021 IARC Summer School, which was held fully online for the first time, offering a unique opportunity for epidemiologists, statisticians, physicians, oncologists, and other public health specialists to learn and benefit from IARC's expertise from anywhere in the world. The course is available at https://video.iarc.fr/channels/2021IARCSummerSchoolEPI/.

19. The IEC has identified an increasing number of issues on projects run in collaboration with the EU and with other countries having established relevant data protection regulations. The need to obtain new consent, a waiver of consent approved by the local ethics committees or a new legal basis to further processing the data, were among the recommendations given by the IEC on these issues. The Committee consequently felt the need to further familiarize with the IARC Data

Protection (DP) Policy and a meeting was organized with the IARC DP consultant and the Director of Administration and Finance (DAF), in October 2021. The training focused on the DP regulations and UN DP principles applicable to IARC/WHO and clarifications on the ethical and legal responsibilities of the IEC when reviewing projects sharing data with the EU.

20. It was agreed that the IEC remains the reference mechanism for checking overall DP adherence on each scientific project, while legal adherence to DP on all incoming and outcoming Data and Material Transfer Agreements remains the responsibility of the DAF Office.

21. The IARC DP Officer joined the IEC to clarify the definition and implications of pseudonymization versus anonymization to all IARC personnel.

22. New IEC members received training 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. Training was delivered by the IEC Secretary, and it will be substantiated with the obtention of the Research Ethics certificate, as soon as resumed by the Global Health Network in collaboration with WHO.

23. 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. In particular, a collection of available ethical guidelines on Artificial Intelligence (AI) is ongoing.

Collaborations

24. To strengthen collaborative opportunities between IARC and other UN Agencies on bioethics, the IEC Secretary attended remotely the UNESCO 20th Session 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 the Ethics of AI.

25. The IEC is engaged in discussions with the WHO to produce a common ethical framework for the review of studies on AI, taking the WHO publication on "Ethics and governance of artificial intelligence for health" as a reference guide to identify the ethical challenges and risks with the use of AI for health.

IARC Ethics Advisory Group (EAG)

26. 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 Michael Parker, Professor of Bioethics and Director, 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;
- Dr Rodolfo Saracci, Senior Visiting Scientist at IARC and former Chair of the IARC Ethics Review Committee (1982–2005).

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

IEC forthcoming perspectives

28. Following discussion on a number of projects bearing the potential for incidental findings (IFs), the need for a possible update of the IEC discussion paper on the management of IFs in genomic research studies was acknowledged. The discussion paper addresses the ethical and practical issues associated with the management of IFs and offers a proposal for dealing with studies where IFs may occur.

29. An IEC training on “Biomedical research ethics” targeting Early Career Scientists and new IARC scientists, will be developed in collaboration with the IARC Learning and Capacity Building Branch. The course will be offered in a hybrid format, composed of pre-recorded and live sessions.

ANNEX 1 – Composition of the IEC

	Name	Affiliation	Appointed	End of Term
Past members				
IARC	*Dr Michel Baduraux*	*Medical Doctor, IARC Staff Physician, Annecy (France)*	*September 2012*	*June 2021*
External	*Professor Kadir Mutlu Hayran*	*Medical Doctor, President Preventive Oncology Department, Hacettepe University Cancer Institute, Ankara (Turkey)*	*June 2019*	*May 2021*
Current members				
External Members	Professor Samar Al-Homoud	**IEC-Chair**. Surgeon, King Faisal Specialist Hospital and Research Center, Riyadh (Saudi Arabia)	September 2015	August 2023
	Ms Sandrine Capsalas	Lawyer, Ethics and Corporate Responsibility INTERPOL, Lyon (France)	January 2021	December 2022
	Professor Béatrice Fervers	Oncologist, Coordinator Cancer and Environment Unit, Centre Léon Bérard, Lyon (France)	January 2010	December 2023
	Dr José Humberto Fregnani	Oncologist, Head of Education, A.C. Camargo Cancer Hospital, São Paolo (Brazil)	September 2019	August 2023
	Dr Angeliki Kerasidou	**IEC Vice-Chair**. Associate Professor in Bioethics and NDPH Senior Fellow, Ethox Centre, Oxford University (UK)	January 2018	December 2023
	Dr Hans Storm	Epidemiologist, Chief Medical Officer Danish Cancer Society, Copenhagen (Denmark)	June 2014	May 2024
	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 2023
	Professor Yawei Zhang	Epidemiologist, National Clinical Research Center for Cancer, Cancer Hospital / Chinese Academy of Medical Sciences, Beijing (China)	April 2022	March 2024
IARC	Dr Behnoush Abedi-Ardekani	Genomic Epidemiology (GEM) Branch	January 2016	December 2023
	Dr André L. Carvalho	Early Detection, Prevention, and Infections (EPR) Branch	September 2019	August 2023
	Dr Salvatore Vaccarella	Cancer Surveillance (CSU) Branch	January 2014	December 2023