

BIENNIAL REPORT OF THE IARC ETHICS COMMITTEE, 2019–2020

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 twelve senior individuals with diverse backgrounds and nationalities (as of November 2020) representing sciences, medical care, and the general population. It meets five times per year to give an ethical evaluation of all IARC projects within its competence. Meetings take place in Lyon with participation by videoconference for members of the Committee who cannot attend in person.

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

4. The departure of one member of the Committee was balanced by the appointment of two new members with unique expertise in cancer epidemiology and oncology. Professor Samar Al-Homoud is Committee Chair since November 2018. Dr Hans Storm replaces Dr Angeliki Kerasidou, on maternity leave, as Vice-Chair since February 2020.

Activities of the IEC

Evaluation of research projects

5. During the period 2019–2020 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 aims and potential ethical issues, a full study protocol, local ethical approvals, and informed consent forms. The IARC Principal Investigator (PI) was invited to provide additional information or clarification, when required.

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. An increased number of both new projects and re-submissions was overall recorded during the 2019–2020 biennium when compared to the previous one (see Figure 1). During the 2020 COVID-19 lockdown, the IEC strongly supported the IARC PIs by clearing in-between official meetings through the expedite review procedure, 40% additional projects when compared to 2019 (see Figure 2).

Figure 1: IEC evaluations over the biennium

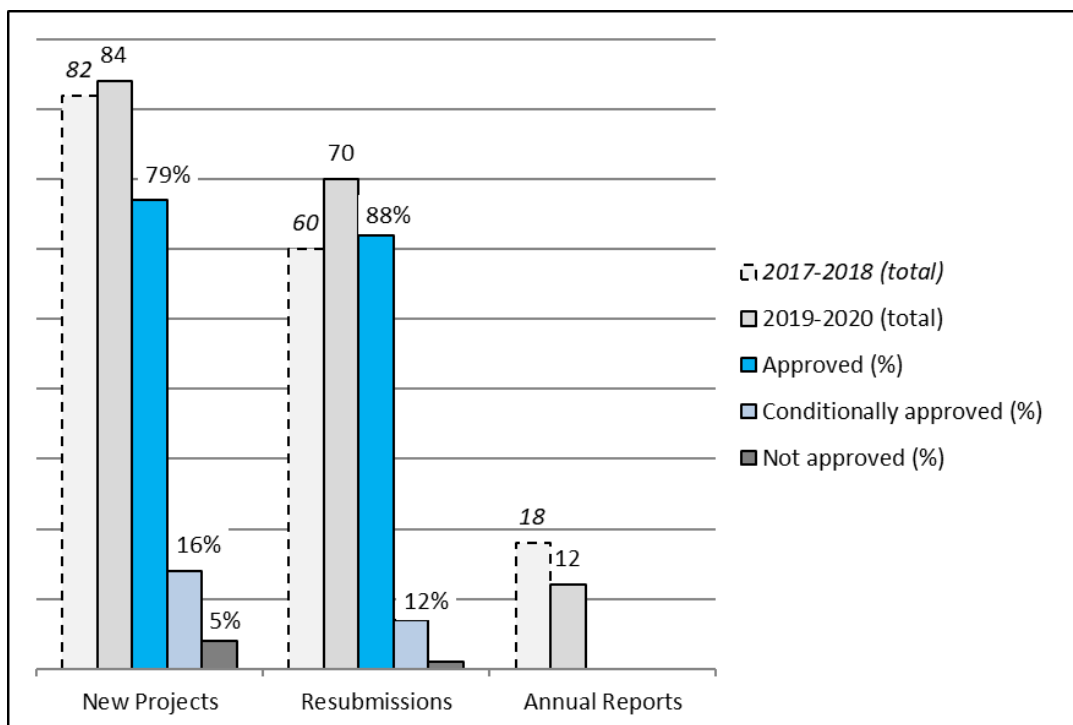
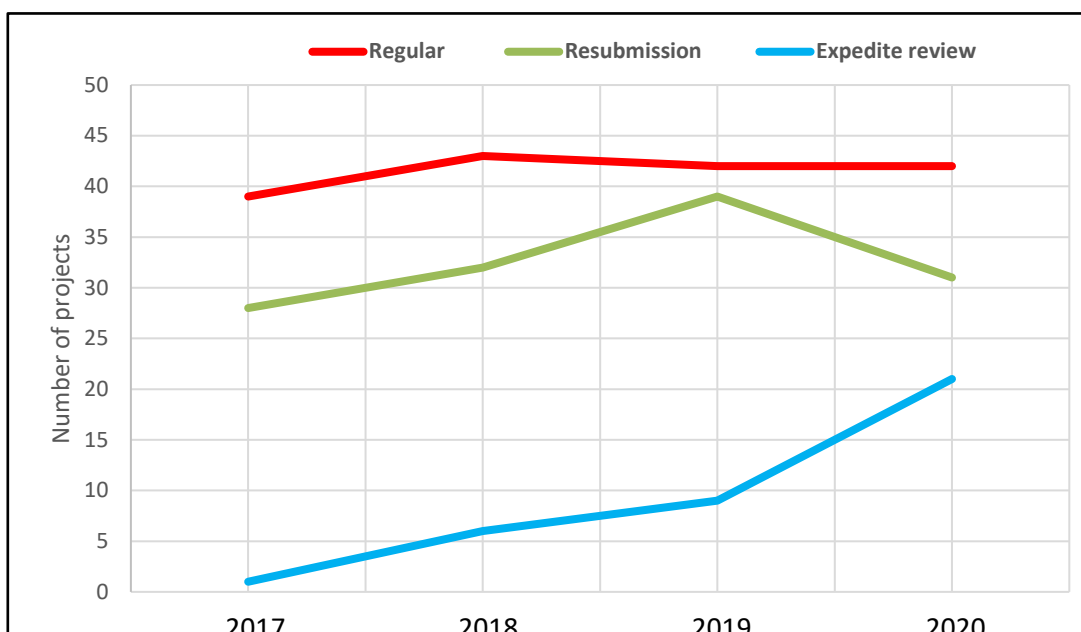


Figure 2: IEC evaluations by type of submission and by year



Update of Procedures

9. The IEC Standard Operating Procedures (SOPs) were updated with the below changes:
- Section 3 – Procedure for regular submission: in addition to the documents currently required for multicentric studies pooling already collected data from non-IARC primary studies, the role of IARC in the project proposal should be included.
 - Section 3 – Expedite Review: EPIC projects performing new biological analysis and EPIC projects submitted by a non-IARC PI are judged not to present potential threats in terms of the rights and welfare of study participants and may be reviewed and approved by the IEC through the expedite review procedure.

Update of the IEC website

10. The IEC website was updated with:
- Guidelines for good clinical practices, Integrated addendum to International Conference on Harmonisation E(6)R1, 2016;
 - A new version of the IARC Ethics Questionnaire integrating requirements from the IARC Policy on clinical trials registration and public disclosure of results;
 - A new version of the IEC Annual Report Template; and
 - Training on the French procedures on Data Protection.

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 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

12. The *Large-scale retrospective research of risk of oncological disease caused by occupational exposure to chrysotile asbestos containing dust (ASBEST)* study was discussed in 2014 by the Scientific Council (see [Document SC/50/12](#)). Over the 2019–2020 biennium, the IEC continued to monitor advances on the study and potential ethical implications.

13. The IEC noted the 2018 Annual Report on the study and the assessments and recommendations made by the Scientific Advisory Board (SAB) in 2019. The IEC corroborates the recommendations given by the SAB and the Study Team regarding the study progress, mesothelioma deaths, and analysis plan. Also, the IEC thanked the PI for including the methods

and quality assurance in several manuscripts, as recommended by the IEC to strengthen the communication effort on the methodology, procedures, and quality assurance for the study.

14. The [IARC website of the Asbest Study](#) was updated upon request of the Russian Ministry of Health with more recent information provided on potential COIs by the Russian collaborators. IARC recognizes that COIs exist, has disclosed them, and considers that the potential consequences are addressed through the measures implemented in the study design and its conduct.

15. The IEC will continue to monitor the progress of this study and report to the IARC Director on an annual basis.

Training for IEC members and IARC staff

16. A module on “Ethics and Epidemiology” was delivered by Dr R. Saracci (Senior Visiting Scientist and former IEC Chair) and by Dr C. Scoccianti (IEC Secretary) to participants of the 2019 IARC Summer School.

17. An online training on French Procedures on Data Protection was delivered by Ms O. Perol (Project Manager, Centre Léon Bérard) to IEC members. The training was uploaded on the IEC website for public consultation and guidance to the IARC PIs.

18. 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 substantiated with the obtention of the Research Ethics certificate, produced by the Global Health Network in collaboration with WHO.

19. 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.

20. Contribution to the Ethics Module of the Global Laboratory Leadership Programme, an activity of the International Health Regulations, was provided by the IEC Secretary to WHO Lyon.

External collaborations

21. To strengthen collaborative opportunities between IARC and other UN Agencies on bioethics, the IEC Secretary attended the 17th meeting of the UN Inter-Agency Bioethics Committee (UNIACB) at the UNESCO Headquarter. Results of the discussion were shared with the IEC to explore areas of mutual interest.

22. Comments on an UNESCO discussion paper on the ethical implications of breast cancer management in low- and middle-income countries were provided by the IEC Secretary.

IARC Ethics Advisory Group (EAG)

23. 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).

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

IEC forthcoming perspectives

25. The IEC training on “Biomedical research ethics” targeting early career scientists and doctoral students from the University of Lyon (EDISS) could not be organized during the biennium. The course should be resumed in 2021, offered online and updated to target a wider audience.

26. A discussion paper on “Ethical issues of normal tissues’ analyses” is being considered.

ANNEX 1 – Composition of the IEC

	Name	Affiliation	Appointed	End of Term
Past member				
<i>IARC</i>	<i>Dr Ghislaine Scélo</i>	<i>Genetic Epidemiology Group</i>	<i>September 2012</i>	<i>June 2019</i>
Current members				
External Members	Dr Samar Al-Homoud	IEC-Chair. Surgeon, King Faisal Specialist Hospital and Research Center, Riyadh (Saudi Arabia)	September 2015	August 2021
	Dr Michel Baduraux	Medical Doctor, IARC Staff Physician, Annecy (France)	June 2014	May 2022
	Mr Kris D’Hoore	Assistant-Director Internal Oversight Services, Interpol, Lyon (France)	January 2017	December 2020
	Professor Béatrice Fervers	Oncologist, Coordinator Cancer and Environment Unit, Centre Léon Bérard, Lyon (France)	January 2010	December 2021
	Dr José Humberto Fregnani	Oncologist, Head of Education, A.C. Camargo Cancer Hospital, São Paulo (Brazil)	September 2019	August 2021
	Professor Kadir Mutlu Hayran	Medical Doctor, President Preventive Oncology Department, Hacettepe University Cancer Institute, Ankara (Turkey)	June 2019	May 2021
	Dr Angeliki Kerasidou	IEC Vice-Chair up to January 2020. Researcher in Global Health Ethics, the Ethox Centre, Oxford (UK)	January 2018	December 2021
	Dr Hans Storm	IEC Vice-Chair since February 2020. Epidemiologist, Chief Medical Officer Danish Cancer Society, Copenhagen (Denmark)	June 2014	May 2022
	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 2021
IARC	Dr Behnoush Abedi-Ardekani	Genetic Cancer Susceptibility Group	January 2016	December 2021
	Dr André L. Carvalho	Screening Group	September 2019	August 2021
	Dr Salvatore Vaccarella	Cancer Surveillance Section	January 2014	December 2021