International Agency for Research on Cancer

World Health Organization

Scientific Council **SC/55/2**
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BIENNIAL REPORT OF THE IARC ETHICS COMMITTEE, 2017–2018

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

Composition of the IARC Ethics Committee

2. The Committee is composed of ten senior individuals from diverse backgrounds and nationalities (as of November 2018). 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 a new member with unique expertise in bioethics. A new member representing the WHO Research Ethics Review Committee is expected to join the IEC at the start of 2019. Professor Samar Al-Homoud was appointed as Committee Chair in November 2018. Dr Angeliki Kerasidou will replace Professor Paolo Vineis as Vice-Chair in February 2019.

Activities of the Committee

Evaluation of research projects

5. During the period 2017–2018, 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/or amendments.

6. Studies presenting potential ethical implications during their implementation are required to submit an Annual progress Report consisting of a declaration from the Principal Investigator (PI) notifying the IEC of any ethical problems or adverse events which may have occurred during the preceding year.

7. For clinical trials the Annual Report should also include a copy of the Data and Safety Monitoring Board's report, the scheduled inclusion of subjects versus the actual inclusion, the clinical trial registry ID, 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.

Details of the IEC evaluations are shown in Figure 1.

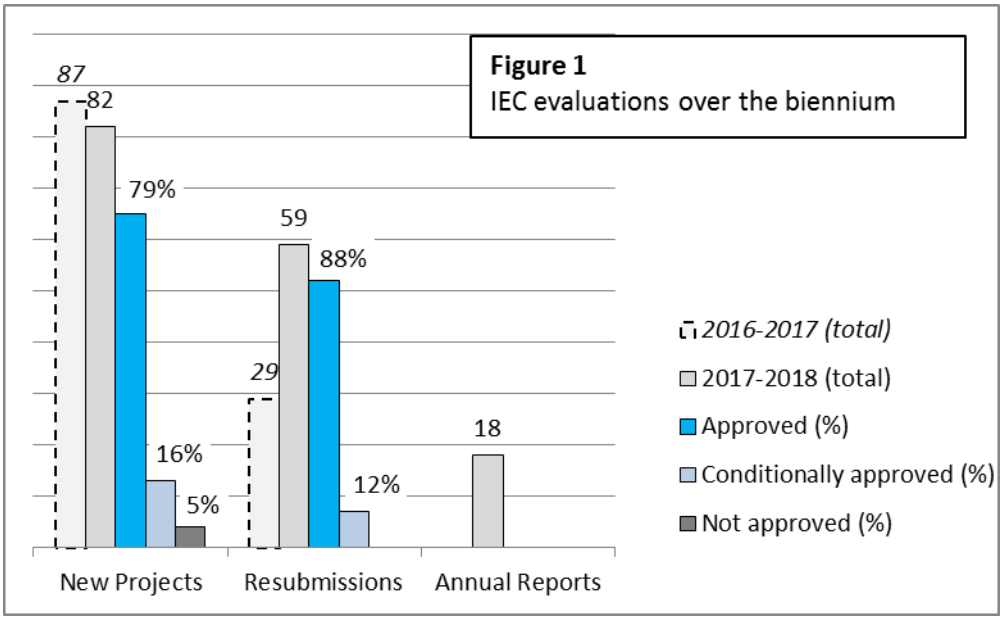

Figure 1
IEC evaluations over the biennium

Update of Procedures

8. The Rules and Procedures (RAPs) now mention the need for an annual update based on comments received from IARC staff and collaborators.

9. The Standard Operating Procedures (SOPs) are being implemented with the below changes:

- Based on comments received from IARC staff, the IEC SOPs and comments to the PI differentiate between a recommendation (which does not condition the approval of a study) and a requirement (to provide the additional information, clarification or modification that conditions the approval of a study).
- Based on the minimum criteria for data protection set by the General Data Protection Regulation (GDPR), the IEC SOPs and standardized Informed Consent Form clarify and monitor requirements of storage of excess samples, safe storage conditions, sharing of research findings, and confidentiality.
- Based on the disclosure requirements set by the WHO Information Note on Clinical Trials, the IEC SOPs and Questionnaire require the PI to register the trial before initiating the first recruitment of subjects and to post on the trial registry the summary results and the latest version of the protocol within 12 months from primary study completion.
- The IEC agreed that the names of members should not appear in the IEC decisions, both to highlight that decisions are taken by the Committee as a whole and to protect the confidentiality of its members.

Update of IEC website

10. The IEC website was enhanced by the addition of guidance to IARC staff for project submission and frequently asked questions, ethics guidelines and templates of key ethics documents (e.g. standardized Informed Consent Form).

Integration of the IEC workflow into the Project Portal

11. With the objective of creating a single scientific project management platform which would integrate data on all IARC scientific projects, the IEC workflow (as well as other relevant workflows, e.g. CRAs, MTAs, DTAs) are being integrated into the "Project Portal" initially created to manage IARC grants and direct contributions. The main advantages are as follows:

- The PI will enter the main details of a project only once (i.e. description and financial management and the listing of partner institutions) required by both the Resource Mobilization and the IEC;
- Colleagues at IARC will be able to check if and when a project has been granted ethical approval;
- The IEC will have knowledge of those projects submitted for funding and requiring ethical review, and will directly access the final reports as provided to the funder.

12. IEC projects reviewed over the biennium and which were submitted for funding have been uploaded into the Project Portal.

Monitoring of conflicts of interests (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. The IEC manages potential COIs as follows:

- External IEC members must declare any generic potential conflicts of interest by completing a "Declaration of Interests for IARC/WHO Experts" form once a year.
- All members are required to declare any potential COI in relation to specific submissions or any matter for consideration at IEC meetings, and are not allowed to participate in their discussion.

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 in 2014 by the Scientific Council (see Document SC/50/12). The IEC continued to monitor the ASBEST study on an annual basis and noted the assessments and recommendations made by the Scientific Advisory Board (SAB) and by the Scientific Council.

15. The 2017 Annual Report and SAB Report were received in January 2018. Both documents were reviewed by the IEC and the PI provided further clarifications. The IEC thoroughly monitored advances in the study and potential ethical implications. The IEC considered essential that the PI puts in place a communication effort on the methodology, procedures and quality assurance for the ASBEST study well ahead of the external communication of any study results. The IEC further

recommended defining a strategy reporting results internally ahead of publication. These recommendations were reported to the IARC Director.

16. The IEC's monitoring of the ASBEST study was also discussed with the Ethics Advisory Group (EAG). The EAG acknowledged the Report on the ASBEST study prepared by the IEC and noted the sensitivity of this study with regard to the Agency's reputation. The EAG acknowledged the quality exposure assessment performed in the study, reflecting the efforts made by the PI and the study team within the historical and local context of the study. It was considered that it would be useful for the SAB to play a more active role in advising the IEC on how to proceed in relation to the methodological issues discussed.

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

Training for new IEC members and IARC staff

18. An introductory course on "Biomedical Research Ethics" particularly aimed at IARC Early Career Scientists was delivered by Professor B. Fervers (former IEC Chair), Dr R. Saracci (Senior Visiting Scientist and former IEC Chair) and Dr C. Scoccianti (IEC Secretary); and a science café on "IARC Procedures for Ethical Review" was delivered by the Secretary.

19. A "Research Ethics" page suggesting training opportunities and online courses to IARC staff has been developed on the Learning and Development Portal.

20. Several possible avenues for continuous training of IEC members on ethical conduct and review of research involving human participants, were explored. The following certificates were obtained by the Secretary and the courses suggested to the members:

- White Hall Training's "Practical Implementation of International GCP". The course provides a comprehensive guide to International Conference on Harmonisation-Good Clinical Practice principles and their practical application in the workplace;
- Global Health Network's "Introduction to reviewing genomic research". The course identifies the specific ethics issues to consider when reviewing genomic research;
- Global Health Network's "Research Ethics". The course is adapted from an e-Learning course and resource package designed and produced by the WHO to create awareness about the ethical issues in conducting research, especially in developing countries; and
- UN Ethics Office's "Ethics and Integrity at the United Nations". The course is designed by the UN Ethics Office to strengthen staff awareness of their ethical rights, duties, and obligations.

External collaborations

21. To further engage with WHO as well as highlight the work of the IEC, a summary report of activities was shared with the WHO Global Health Ethics Unit.

22. To strengthen collaborative opportunities between the IARC and other UN Agencies on ethics, the Secretary attended the 17th meeting of the UN Inter-Agency Bioethics Committee at UNESCO as an observer, with a view to assessing the interest for IARC to eventually join as a full member.

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 in 2017, and the following was discussed in 2018:

- *Potential ethical implications of study design and methods*. The EAG recommended the IEC to review both potential ethical issues and methodological issues that may affect the quality and appropriateness of IARC studies, as deemed necessary. The IEC will more explicitly distinguish in the feedback to the IARC PI the ethical and/or scientific nature of its comments.
- *Ethical issues related to data collected on religion, ethnicity and language*. The EAG observed that the logic of protection of sensitive data is subordinated to the logic of non-discrimination and of confidentiality. The IEC was recommended to monitor the inclusion of the option for a study participant not to answer to these questions, and the compliance from the PI to strict data storage conditions and rights to access.
- *IEC position on the ASBEST study* (see above).
- *Future topics for ethics discussion papers*. The EAG acknowledged the previous topic investigated by the IEC on the management of Incidental Findings in genomic studies. It was agreed that the ethical aspects of conflicts of interest in research studies might be the next topic to be investigated.
- *General recommendation*. The EAG recommended an increased involvement of the IEC in networks with other research ethics committees and conferences on ethics issues to avoid duplication of effort.

Forthcoming perspectives

Ethics training activities

25. A training on “Ethical issues of new cancer screening technologies in LMICs” will be delivered to the IEC members by Professor R. Sullivan (Kings College London).

26. Ethics training and research activities will be developed in collaboration with the Ethox Centre of the University of Oxford, the WHO Global Health Ethics Unit and the UN Inter-Agency Bioethics Committee.

27. An Online Course mandatory to all staff as part of an induction package will be developed in 2019 on ethics and on ethics in research, in collaboration with ETR. The course will introduce the IEC Procedures and the IARC Ethics Policies.

ANNEX 1 – Composition of the IEC

	Name	Affiliation	Appointed	End of Term
Past members				
External Member	*Dr Beatrice Wiafe Addai*	*Surgeon, Peace and Love Hospitals Breast Care International, Kumasi (Ghana)*	*September 2015*	*September 2017*
WHO	*Dr Abha Saxena*	*Secretariat of the Research Ethics Review Committee*	*January 2010*	*December 2017 (retirement)*
Current members				
External Members	Dr Samar Al-Homoud	IEC-Chair (from November 2018). Surgeon, King Faisal Specialist Hospital and Research Center, Riyadh (Saudi Arabia)	September 2015	August 2019
	Dr Michel Baduraux	Medical Doctor, previously IARC Staff Physician, Annecy (France)	June 2014	May 2020
	Professor Béatrice Fervers	Oncologist (France), Centre Léon Bérard – University Claude Bernard Lyon 1, Lyon (France). Previous IEC Chair.	January 2010,	December 2019
	Mr Kris D'Hoore	Due Diligence Officer, Interpol, Lyon (France)	January 2017	December 2018
	Dr Angeliki Kerasidou	Researcher in Global Health Ethics, The Ethox Centre, Oxford (UK)	January 2018	December 2019
	Dr Hans Storm	Epidemiologist, Danish Cancer Society (Denmark)	June 2014	May 2020
	Professor Paolo Vineis	IEC Vice-Chair. Epidemiologist, Imperial College London (UK).	January 2010	December 2019
IARC	Dr Behnoush Abedi-Ardekani	Genetic Cancer Susceptibility Group	January 2016	December 2019
	Dr Ghislaine Scélo	Genetic Epidemiology Group	September 2012	December 2018
	Dr Salvatore Vaccarella	Infections and Cancer Epidemiology Group	January 2014	December 2019