International Agency for Research on Cancer

World Health Organization

IARC Ethics Committee (IEC)

Rules and Procedures (RAPs)

Concerning the Ethical Review of Research Proposals at IARC

March 2017

Contents

I. Mission and scope of the IARC Ethics Committee

1. The primary mission of the IARC Ethics Committee (IEC) is to ensure the protection of the safety, well-being and privacy of participants in studies carried out by IARC, and subsequent to this, to enable and promote the conduct of good quality research for the benefit of human health.

2. The IEC has a duty, in light of IARC's research mission and public health role, to ensure that the Agency's studies demonstrate the respect for the most rigorous ethical principles and standards, and more broadly, that these studies are ethically appropriate and reflect the values of an institution that is part of the World Health Organization (WHO) and the broader United Nations family, irrespective of their approval by other ethical review committees (see also WHO Code of conduct for responsible research[1].

3. The IEC reviews, approves and monitors all research projects coordinated by IARC scientists or in which they participate. No such project can be initiated without IEC clearance. In particular, ethical approval from the IEC is required for all research proposals involving individuals recruited especially for the study, collections of human biological materials, or data allowing individuals to be identified, in any study in which IARC is involved in any capacity (see also WHO Manual XV.3.1 paragraph 100[2]).

4. The review process aims to ensure that all of IARC's research is conducted according to the fundamental ethical principles of research involving human participants (e.g. doing no harm, beneficence, respect for autonomy and justice), and that these are consistently applied in all IARC research settings.

5. The IEC uses as its reference point for the review of research projects the "International Ethical Guidelines for Health-related Research Involving Humans" (2016[3]) developed by the Council for International Organizations of Medical Sciences in collaboration with the WHO, which in turn make reference to the Declaration of Helsinki (2013[4]).

6. The Rules and Procedures (RAPs) governing the operation of the IEC detailed here are broadly based on the structure and contents of the WHO's "Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants"[5]. The Standard Operating Procedures (SOPs) of the IEC are detailed in a separate document.

7. These RAPs are expected to evolve and be regularly updated based on comments received from IARC staff and collaborators, and on the experience of the Committee.

---

[1] WHO Code of conduct for responsible research, WHO 2016.
[2] WHO Manual XV.3.1 WHO Research Ethics Review Committee.
[3] International Ethical Guidelines for Health-related Research Involving Humans, prepared by the Council for International Organizations of Medical Sciences in collaboration with the WHO, 2016.
[4] Declaration of Helsinki, adopted by the World Medical Association, 2013.
[5] Standards and operational guidance for ethics review of health-related research with human participants, WHO 2011.

II. Responsibility for the establishment of the IEC

8. An ethical review committee has been in operation at IARC since 1982. In March 2002 at its 43rd Session the IARC Governing Council approved a resolution which sets out the basic principles, scope and procedures for the ethics review process at the Agency (document GC/43/6). The present structure and composition of the IARC Ethics Committee were approved by the IARC Governing Council at its 51st Session in May 2009 (document GC/51/16).

9. The members of the IEC are appointed by the Chair of the Governing Council, following recommendations from the IARC Director, as per document GC/51/R14. The duration of appointment is two years.

10. The IARC Director is responsible for proposing potential new IEC members to the Chair of the Governing Council, and for monitoring the Committee's operation.

11. The IARC Director has agreed to accept the outcome of the deliberations of the IEC.

III. Composition of the IEC

12. The IEC is a committee of senior individuals from a variety of backgrounds, which through its composition and expertise ensures, to the extent possible, the balanced and independent application of the ethical principles and standards, and the international consistency and completeness in the review of IARC's research.

13. The IEC is composed of a minimum of 12 members, including:
    - not more than 1/4 internal (IARC staff) members; and
    - a minimum of 3/4 external members, with at least:
        - one member from the local cancer research community;
        - one general medical practitioner or senior nurse preferably with experience of practice in an ethnically diverse community;
        - one lay member[6];
        - one WHO Research Ethics Review Committee (WHO ERC) member;
        - one member with bioethics background; and
        - two members from low- and middle-income countries with backgrounds in science, law or other relevant areas.

    The quorum of attendance to IEC meetings is specified in the SOPs document.

14. To guarantee the independence of the IEC, both the IEC Chair and Vice-Chair are appointed from amongst the external members of the Committee. In the absence of the IEC Chair and Vice-Chair, members may appoint another

[6] The term "lay member" refers to any individual having no professional experience of science or medicine.

external committee member as Acting Chair to carry out the duties required.

15. The composition of the IEC should ensure:
    - multidisciplinary competence to provide a broad range of experiences and perspectives;
    - international membership to reflect to the extent possible the diversity of the communities taking part in IARC's research;
    - gender balance; and
    - the inclusion of individuals with expertise in the scientific, clinical and methodological aspects relevant to the areas of research most likely to be reviewed.

16. An external Expert Advisory Group composed of a small number of international bioethics experts is available to provide advice in areas outside the competence of the IEC.

IV. Independence of the IEC

17. The IEC is an internal IARC committee but it operates independently.

18. The IEC has the duty and responsibility to ensure that its tasks are carried out free from any bias or influence that could affect their independence.

19. Members are appointed to the Committee based on their personal background and expertise and do not sit on the IEC in any specific representative capacity (institutions, associations, departments).

20. To safeguard the Committee's independence, both the IEC Chair and Vice-Chair must be external members.

21. The IEC has established a set of procedures for dealing with conflicts of interest. IEC members must comply with these procedures (see SOPs document).

V. Membership requirements

22. Members must agree to comply with the rules and procedures of the IEC and must complete a Declaration of Interests prior to their appointment (see SOPs document).

23. Members must attend at least half of all scheduled meetings in each year and to take part in continuing education on ethical review. Members may attend by videoconference but should attend at least one meeting per year in person.

24. All members of the IEC are required to maintain confidentiality on all matters relating to the review process and to complete the Confidentiality Undertaking (see Annex A).

25. The appointment of any member who does not comply with the above rules

will be terminated. Compliance with the rules will be determined by the Chair of the IEC in consultation with the IARC Director.

VI. Support of the IEC

26. The work of the Committee is supported by a Secretariat whose responsibilities are detailed in the SOPs document.

27. The IARC Director is responsible for providing adequate resources to support the efficient operation of the Committee, including Secretariat staff, facilities and financial resources.

VII. The review process

28. The primary role of the IEC is to carry out the ethical review of IARC studies involving human subjects. Special attention is given to the nature of any intervention and its safety or effect on participants, to the process of obtaining informed consent, documentation (e.g. participant or patient information sheet), data generation tools, and to the suitability and feasibility of the protocol.

29. IARC and/or the sponsor of the study are responsible for ensuring the scientific quality of the research. It is not the task of the IEC to undertake scientific review, nor is it constituted to do so. However, as part of the ethics review process the IEC will examine the study design and protocol with respect to their ability to address the study objectives and any issues that give rise to ethical concerns.

30. The IEC must be satisfied that ethical review by other involved bodies e.g. the relevant ethical committees of the external collaborators of the study has been or is being undertaken.

31. Before approving a project, the IEC should determine that the following areas have been appropriately addressed by the applicants:
    - type of project, proposed study duration and principal research question/objectives;
    - who is responsible for the conduct of the study, both in terms of the overall coordination and its implementation in specific centres, and who are the collaborators;
    - financial management of the study;
    - procedures for the recruitment of research participants;
    - procedures for obtaining informed consent;
    - procedures for data and specimen handling;
    - procedures for the interaction with participants such as: structures in place for the care and protection of research participants, including medical treatment and the financial costs of participation, acceptance of liability, insurance, etc.; and
    - ethical issues, such as confidentiality and community issues (e.g. issues potentially affecting the community in which the research is taking place).

VIII. Research Collaborators

32. The PIs have a duty to satisfy the IEC that any external study collaborators are of sufficient academic standing and repute, and have the necessary expertise to efficiently carry out the study protocol. This involves being satisfied that they have the agreement from their institution(s) for their participation in the study.

33. The IEC has a duty to indicate to researchers and their employing institutions that careful consideration should be given to compliance with national regulations and laws, but does not provide specific interpretation of such regulations and laws.

34. The PI must also ensure, to the extent possible, that any external study collaborators and their institutions do not have associations or interests, or have expressed positions, that could be reasonably perceived to represent a conflict of interest or otherwise damage the reputation of the Agency.

IX. Decisions available to the IEC

35. Decisions on research studies submitted to the IEC are made collectively by the Committee after thorough review and discussion during its meetings.

36. Studies involving only minimal risk and burden to research participants may be reviewed on an expedited basis by the IEC Chair and Vice-Chair, rather than by the full Committee, or notified to the IEC (see SOPs document).

37. The following decisions are available to the Committee (see SOPs document):
    - *Approved*: the PI may be asked to submit additional/minor amendments;
    - *Conditionally approved*: the project may start but the PI must submit additional information or make specific modifications in order to receive full approval; and
    - *Not approved*: to be substantially revised and re-submitted at a subsequent meeting taking into account the IEC's recommendations.

X. Monitoring and oversight of the IEC

38. The IEC Chair is responsible for overseeing the compliance with the policies, rules and procedures of the IEC by the Secretariat and the Committee members.

39. The IEC as a whole is responsible for monitoring the quality and consistency in the application of the international standards and guidelines for the ethical review of the research by the IEC.

40. The IEC Chair prepares a written biennial report to the Governing Council and to the IARC Director. The report must include the number and dates of meetings held; the attendance record of members; a list of the proposals

considered and the decisions reached on each; and a report of any training undertaken by members.

XI. Training of IEC members

41. Upon appointment, all IEC members should undergo or justify having received training on the ethical aspects of research involving human participants, in 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.

XII. Standard Operating Procedures

42. The IEC will ensure that Standard Operating Procedures (SOPs) are developed and consistently implemented to address, *inter alia*, the following issues:
    - meetings of the IEC;
    - ethics review and decisions;
    - expedited review/amendments to research previously approved by the IEC;
    - monitoring of research given IEC approval;
    - start of new clinical trials[7]; and
    - appeal process.

43. The SOPs shall be consistent with the relevant Governing Council Resolutions, the provisions in the present document and, where relevant, with Good Clinical Practice guidelines (ICH-GCP[8]).

[7] EU regulations No 536/2014 of the European Parliament and of the Council on clinical trials on medicinal products for human use, 2014.

[8] International Conference on harmonisation of technical requirements for registration of pharmaceuticals for human use, Guideline for Good Clinical Practice E6(R2), 2015.