



**INTERNATIONAL AGENCY FOR RESEARCH ON CANCER
CENTRE INTERNATIONAL DE RECHERCHE SUR LE CANCER**

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PROPOSED CHANGES TO ERC/IRB STRUCTURE

BACKGROUND

1. In 1982, the first 'Committee on Ethical Review Procedures for Research Involving Human Subjects, ERC' was established at IARC. The Scientific Council reviewed the initial period of activity during its 23rd session in 1987 and was satisfied with the procedures followed by the Agency for studies involving human subjects (Report of the Scientific Council on its 23rd session – Document SC/23/11, page 17). A comprehensive report on this subject was then presented to the Governing Council at its 43rd session in 2002 (Document GC/43/6). This report, which showed a steady increase in the number of proposals reviewed (1996: 8; 1999: 11; 2001: 20), was discussed at length and the Governing Council recommended that periodical reporting on this matter be established.

2. In 2004, the ERC Chair, Dr Rodolfo Saracci, presented his report for 2002–2003 to the Scientific Council at its 40th session (Document SC/40/WP2, Rev.1). At that time, the ERC met twice a year and was composed of 10 members, the majority of whom were external to IARC. Telephone and e-mail exchanges were regularly used for issues that needed and could be adequately dealt with between meetings. 43 projects had been reviewed over the two-year period of which 35 had been cleared either unconditionally or after satisfying certain conditions whilst the remaining seven were pending while awaiting additional information. These projects were subsequently cleared. The Scientific Council made the following recommendation in its report: '*The IARC ERC should itself be reviewed by the Director to ensure that it accords with international conventions, standards and procedures.*' (Document SC/40/5, page 6).

3. At its 45th session in May 2004, the Governing Council endorsed the recommendation of the Scientific Council and asked the IARC Director to report on the matter in the following year (Resolution GC/45/R4).

4. Professor Charles Gillis, former Chairman of the National Multicentre Research Ethics Committee for Scotland, was invited to review the IARC ethics procedure. His conclusions were as follows (Document GC/47/12 Rev. 1, page 1): '*IARC, as a sponsor of research as well as a practitioner, had a duty to show leadership in ensuring that its studies were beyond ethical reproach*' and that to this end an independent system of ethical appraisal was needed.

5. The Agency proposed a two-tier system to provide for ethical review (Document GC/47/12 Rev 1, page 3). The Governing Council approved a resolution based on these recommendations and requested the Director to proceed with the establishment of the two-tier system (Resolution GC/47/R9).

CURRENT SITUATION

6. In 2006, the new IARC ethics review system was created with two distinct components:

- **The IARC Institutional Review Board (IRB):**

The IRB is composed of nine members from a variety of backgrounds. Five members come from outside the Agency and four from the Agency staff. The Board meets every two months in Lyon for ethical evaluation of all IARC projects within its competence.

- **The IARC Ethics Review Committee (ERC):**

The ERC is composed of nine senior members from the international community. The Committee ensures, to the extent that is possible, that international consistency and completeness in ethical approval is achieved. This committee also plays a guiding role when the IRB consults it for its views and advice.

7. Since 2006, the IRB has met five to six times per year in Lyon and reviewed 94 proposals, out of which one proposal was classified outside the scope of the IRB and three more were rejected.

8. The ERC has met twice per year, one meeting held in Lyon in conjunction with one of the bi-monthly IRB meetings to enable the two committees to consult on matters of concern. The other annual meeting has taken place in one of the WHO Regions where IARC has on-going scientific activity. Since January 2006, the ERC has met in Peru (11–12 January 2007), Mumbai (16–17 January 2008) and Kuwait (15–16 December 2008). Four joint meetings of the ERC and IRB have also been organized at IARC: 9–10 January 2006, 8–9 June 2006, 11–12 October 2007 and 23–24 June 2008.

9. No formal reports have been developed from these meetings and the degree of direct interaction between the two committees in relation to the work of the IRB is unclear.

10. Professor Charles Gillis initially advised IARC staff and IRB members on any matters of ethical concern. The IARC Scientific Coordination Office has been responsible for ensuring that all relevant IARC project proposals go through the ethics process and provides the secretariat for both bodies.

11. The ERC members' terms of office are due to end in December 2009.

FUTURE STRUCTURE

12. The incoming Director asked the Scientific Council in its 45th Session in 2009 to review the work of the ERC. The question as to whether there was an ongoing need for a two-tier system of ethical review was discussed (see Document GC/51/4). The ongoing need for the ERC was questioned, given the existence of other international expert ethics bodies. It was not clear exactly what value the ERC has added although some specific issues such as clarifying "informed consent" and the engagement of very influential international stakeholders were noted.

13. The Scientific Council therefore invited the Director to prepare recommendations to the Governing Council to adapt the ethics review process to its new needs.

14. The IARC needs to ensure it adheres to the highest ethical standards in its research. It therefore needs an effective IRB which is aware of the specific international context of the research conducted by the Agency.

15. A new structure of ethical review is proposed which will allow the incorporation of both objectives of the current IRB and ERC:

- To provide an ethical evaluation of all IARC projects, and
- To ensure international consistency and completeness regarding ethical approval.

16. The proposal is to establish a single committee, the **IARC Institutional Review Board (IRB)**, but with a modified membership from the current IRB. This committee would be assisted where necessary by a group of experts available to support the IRB with additional advice on specific ethical issues regarding research projects which it has to review.

COMPOSITION

17. The new Committee shall comprise 12 members from diverse backgrounds: an independent chair and vice chair (both external), three members of IARC staff and seven additional members external to the Agency. Among these it is proposed that one should be from the local cancer research community, one should be a general medical practitioner or senior nurse preferably with experience of practice in an ethnically diverse community, one lay member having no professional experience of science or

medicine, one from the WHO Research Ethics Review Committee (WHO ERC), one member with a bioethics training and two members from low- and medium income countries with backgrounds in science, law or other relevant areas. The members of IARC staff appointed to the committee will have to withdraw from the discussion of protocols in which they had involvement (personally and from the same Group). This will be documented in the minutes.

18. Previously attendance at regular meetings of the IRB in Lyon has been seen as a barrier to inclusion of members from low and middle-income countries. However, planned investment in modern video-conferencing facilities at the Agency should help circumvent this problem. It is envisaged that these external members from outside of France and the immediate surrounding countries would only attend some of the meetings in person.

19. The appointments to the new IRB will be made by the Chairman of the Governing Council. The new structure would be implemented for January 2010 and current arrangements would continue until the end of 2009.

20. To deliver certain specific expertise which might on occasion be required but not be available within the IRB, a small group of international experts will be formed. Their advice will be sought on demand and they will be invited on an *ad hoc* basis to the IRB or to provide written advice.

21. All other basic principles and established processes as defined by the Rules and Procedures and Standard Operating Procedures will remain unchanged. Both documents shall be modified by the new Committee to reflect the current proposal after its approval.

22. The Governing Council is requested to endorse this proposal and to request the Director to proceed with the establishment of this committee.