

## IARC Ethics Committee (IEC) Frequently Asked Questions

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### ***Types of projects reviewed by the IEC***

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, collecting human biological materials, or collecting data allowing individuals to be identified, and for any study in which IARC is involved in any capacity<sup>1</sup>.

### ***Types of submissions to the IEC***

The following categories of application are available to the Principal Investigator (PI) depending on the type of research proposal:

- regular;
- expedite; and
- notification.

The procedure of submission and the documentation required, depend on the type of research proposal (see <http://ethics.iarc.fr/Submission/index.php> for detailed information or contact the IEC Secretary at [iec-secretariat@iarc.fr](mailto:iec-secretariat@iarc.fr)).

### ***Required documentation for submission of a research proposal***

In order to enable the review of research proposals by the IEC, the PI is required to provide detailed information on the project, by submitting the required documentation, as follows:

- completed IEC questionnaire<sup>2</sup>;
- study outline/protocol (including sample size and power calculations where appropriate);
- participant information sheets, where appropriate;
- informed consent forms, where appropriate;

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<sup>1</sup> WHO Manual XV.3 paragraph 100, available at <https://emanual.who.int/p15/s03/Pages/XV31WHOResearchEthicsReviewCommittee.aspx>

<sup>2</sup> IEC questionnaire available for download at <http://ethics.iarc.fr/Submission/index.php>

- national and local ethics committees' approvals, including comments and conditions, or evidence of submission;
- an account of national legislation on human research ethics and data protection, where appropriate;
- for resubmissions, amendments, or pooling of studies, provide all previous IEC references/registration numbers related to the study;
- any other relevant documentation (e.g. IARC MTA, DTA forms); and
- depending on the type of study, the PI may be required to provide an annual report to the IEC.

### ***Closing dates for submission***

The closing dates for submission of projects should be no later than 15 working days prior to each IEC meeting. Dates of future meetings and deadlines for submission are posted on the IARC intranet website<sup>3</sup>.

### ***Language requirements***

The working language of the IEC is **English** and all documents should be submitted in English. Studies conducted in **French** language must submit the IEC questionnaire in English but additional study documents may be submitted in French (given it is also an official language of IARC).

Documents submitted in other languages will not be reviewed by the IEC. Applications will not be considered complete and will not be circulated to the Committee until appropriate translations have been provided.

### ***What happens after I submit my project to the IEC for review?***

Each project should be submitted to the IEC Secretary ([iec-secretariat@iarc.fr](mailto:iec-secretariat@iarc.fr)) who will perform a preliminary screening to confirm that the questionnaire has been properly completed and that all necessary additional documentation have been provided. The Secretary then assigns the project to two main reviewers, randomly chosen amongst the Committee members scheduled to attend the next meeting.

The meeting agenda and the full project submissions (questionnaire and additional documents) are posted on the IEC's Members website (password protected) at least two weeks in advance of the next meeting, to enable all IEC members to review and comment on the submitted projects. The IARC PI should be available on the day of the IEC meeting, in person or by telephone, to respond to eventual queries and comments on the project submitted.

### ***How is a project reviewed at an IEC meeting?***

A brief presentation of the project under review is first made by the assigned reviewers and then discussed by all IEC members. Any ethical risk raised by the proposed study design is addressed and the discussion is opened. The IARC PI is given a chance to respond to all the queries and comments (no formal presentation is allowed), if necessary.

Among others, the IEC members consider:

- the completeness of the research proposal (see "Required documentation for submission of a research proposal");

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<sup>3</sup> <http://intra.iarc.fr/about-us/IARC-Committees/Pages/IARC-Ethics-Committee.aspx#tab1>

- the appropriateness of study design, the overall scientific quality of the research proposal, and how results will be disseminated;
- the quality of collaborators, the funding sources and potential conflicts of interest;
- potential ethical problems (e.g. whether the proposal exhibits a favourable balance of benefits to risks, whether the risks to participants and others are minimized, whether participants are fairly selected, whether the information provided to potential participants is accurate and permits participants to make informed decisions about whether to participate);
- any other potential issues.

### ***What standards or procedures does the IEC use to base its review on?***

There are a number of ethics standards and guidelines for review of research projects involving human subjects (see available 'Ethics Documents' on the IEC's website <http://ethics.iarc.fr/Documents/index.php>). The most important in terms of the broad principles are the Nuremberg Code and the Declaration of Helsinki; for more specific aspects of the ethics review of epidemiological and studies the current reference are the 'International Ethical Guidelines for Health-Related Research Involving Humans', developed by the International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO)<sup>4</sup>.

For more detailed information on the procedures adopted by the IEC, please see the Rules and Procedures (RAPs) and Standard Operating Procedures (SOPs) documents available on the IEC's website at the following address: <http://ethics.iarc.fr/Documents/SOP/index.php>.

### ***What are the different types of decisions given by the IEC?***

The IEC may give any one of the following decisions on a project:

- *Approved* - the PI may be asked to submit additional information/minor amendments;
- *Conditionally approved* - the project has been approved but the PI must submit additional information or make specific modifications in order to receive full approval. Project's start may be subject to additional information, documents or modifications requested by the IEC;
- *Not approved* - to be substantially revised and re-submitted at a subsequent meeting taking into account the IEC's recommendations.

The Secretariat will notify the PI in writing of the decision of the IEC. All notification letters will be in the name of the Chair. Any questions or concerns that a PI might have with regard to the decision on his/her project should be referred directly to the Secretariat.

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<sup>4</sup> CIOMS WHO 2017. International Ethical Guidelines for Health-related Research Involving Humans. Available at <http://cioms.ch/ethical-guidelines-2016/WEB-CIOMS-EthicalGuidelines.pdf>