International Agency for Research on Cancer

World Health Organization

IARC Ethics Committee (IEC)
Frequently Asked Questions

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Important Note:
For detailed guidance, please refer to the IEC Standard Operating Procedures and Rules and Procedures, available at https://ethics.iarc.fr/Documents/index.php.

All correspondence to the IEC should be addressed via the Secretariat (iec-secretariat@iarc.fr).

Types of projects reviewed by the IEC

The IEC reviews, approves and monitors **all research projects coordinated by IARC scientists orin which they participate**. No such project can be initiated without IEC clearance. 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[1].

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 submission;
- Expedite review; and
- Notification.

Fore detailed guidance, please refer to Section 3 and Annex 1 (below) of the IEC Standard Operating Procedures:

	Type of submission to the IEC		
Type of study	**Regular**	**Expedite**	**Notification**
New study or collection of new material* **including descriptive study, survey, study on cancer registry data, or on outcomes other than cancer.*	X		
Methodological and quality assurance study. Study on population aggregated information. Study on anonymous data* **the protocol must demonstrate that such study is permissible by national law.*			X
Amendment to already approved protocol/study.	Substantial amendment and/or request not given expedite approval by the IEC.	Minor amendment	
Study on previously collected data* where consent for storage and future use was specifically provided. **such as data from questionnaires, previously measured biomarkers, or medical records.*	➢ Only if: • The study is proposed by a non-IARC PI; • Pooled analyses of data from studies not previously approved by the IEC.	EPIC study submitted by a non-IARC PI	X
Study on previously collected data/stored samples that will perform new biological analysis and/or make use of new technologies.	X	EPIC study	

Required documentation for submission of a research proposal

[1] *IARC Ethics Committee Rules and Procedures*, available at https://ethics.iarc.fr/Documents/index.php

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 according to the type of submission to the IEC. Specifically:

For a Regular Submission:

- completed IEC questionnaire[2];
- study outline/protocol (including sample size and power calculations where appropriate);
- informed consent forms, where appropriate;
- 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;
- any other relevant documentation;
- for resubmissions or amendments provide all previous IEC references/registration numbers related to the study; and
- for multicentric studies pooling previously collected data provide, in addition to the generic documents above, a flow-chart showing how data and/or samples will be managed and shared between the different centres, and clearly state in the application the role of IARC in the study.

For an Expedite Review, the PI should submit a memo to the IEC requesting the expedited approval of the study. The memo should be accompanied by:

- the reason of the request for an expedited review;
- any implications of the proposed request for the safety or welfare of participants;
- the detailed proposal (for EPIC Studies: the PF1) and the protocol;
- the relevant national and/or local ethics committees' approvals (for EPIC studies: approval by the EPIC Steering Committee);
- any changes that affect the terms or the appropriateness of the original Informed Consent or of other original information documents given to the study participants;
- in cases whether a re-consent may be required, the possibility of tracing and re-contacting the study participants, or the waiver of consent approved by the local ethics committee; and
- IEC reference of the original IARC study and copies of the ethics approval of the original IARC study and of its Informed Consent forms (if applicable).

For a Notification, the PI should submit a memo to the IEC notifying of the study. The memo should be accompanied by:

- an abstract of the proposed study summarizing its objectives, research hypothesis, scientific rationale and methodology (for EPIC Studies: the PF1);
- power and sample size calculation (if applicable); and
- IEC reference of the original IARC study and copies of the relevant national and/or local ethics committees' approvals (for EPIC studies: approval by the EPIC Steering Committee), and of its Informed Consent forms (if applicable).

Closing dates for submission

The deadlines for submission of projects should be **no later than 15 working days prior to**

[2] *IARC Ethics Questionnaire* available for download at https://ethics.iarc.fr/Submission/index.php (also for Mac users).

each IEC meeting. Dates of IEC meetings and deadlines for submission are posted on:

1) the IEC website;

2) the IEC intranet; and

3) reminded internally with a Memo ahead of a meeting.

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 Secretariat (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 assigns the project to two main reviewers, selected amongst the Committee members scheduled to attend the next meeting and free from any potential conflict of interest on the project.

The IEC meetings' Agendas, Minutes, Decisions, Comments, and full projects' documentation are posted on the IEC's Members website (password protected) at least two weeks in advance of each meeting, to enable all IEC members to review and comment on the submitted projects.

*Simplified Agenda*s are published for consultation on the IEC intranet. To preserve the confidentiality of IEC proceedings, the simplified Agenda does not disclose participating members and reviewers assigned to projects, studies' description, or overall discussions held. Consequently, for any query regarding your submission, please ask the IEC Secretariat.

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 potential ethical issue raised by the proposed study is addressed and discussed. The IARC PI may be requested to attend the IEC meeting, in person or by telephone, to respond to eventual queries and comments on the project submitted.

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, and that these are consistently applied in all IARC research settings. Among others, the IEC evaluates:

- the completeness of the research proposal according to the required documentation;
- 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 issues (e.g. whether the proposal exhibits a favourable balance of benefits and risks to participants, the selection process, the informed consent form);
- any other potential issues.

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

The IEC uses as its reference point for the review of research projects the "International Ethical Guidelines for Health-related Research Involving Humans" (2016) 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)[3].

The Rules and Procedures (RAPs) governing the operation of the IEC 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"[4].

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

The IEC should reach one of the following decisions on each application:

- *Approved (an Annual Report* may be required)*
  - the PI may be asked to submit minor additional information or clarification;
- *Conditionally approved*
  - the PI may be asked to submit additional information or clarification as per IEC requirements, and/or to consider IEC recommendations (advices given by the IEC which do not condition the approval of a study);
- *Not approved*
  - the PI is required to substantially revise and re-submit the project.

*The vast majority of studies conducted or coordinated by IARC consist of observational epidemiological studies where, after IEC approval of the protocol, the potential for causing harm to study participants or for raising other significant ethical or safety issues is negligible. These studies do not warrant a regular follow-up by the IEC during their progress. Some categories of studies do however typically require the submission of an Annual Progress Report (e.g. intervention studies, studies with potential for incidental findings).

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

[3] IEC Guidelines and useful links, available at https://ethics.iarc.fr/useful_links/index.php.