International Agency for Research on Cancer

World Health Organization

IARC Ethics Committee (IEC)

Standard Operating Procedures (SOPs)

March 2017

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Introduction

Remit of the IARC Ethics Committee

The IARC Ethics Committee (IEC) is responsible for the ethical review of all applications submitted by IARC staff or external investigators using IARC samples and/or data. Through its international composition and the inclusion of members with a variety of backgrounds, the IEC ensures, to the extent possible, the international consistency and completeness in ethical approval.

These Standard Operating Procedures (SOPs) provide a framework and guidance for the IEC, the Secretariat, and the investigators submitting an application. They should be read in complement with other relevant documents such as the IEC Rules and Procedures.

Section 1

Meetings of the IARC Ethics Committee

1.1 IEC meetings are arranged by the Secretariat, which is responsible for all administrative aspects of the ethics review process. The Secretariat of the IEC is provided by the Director's Office. The IEC Secretariat does not participate in the decision-making process.

1.2 Meetings to review applications are held at least 4 times per year at IARC. Members that cannot be physically present may attend the IEC meetings remotely by videoconference.

1.3 The quorum for IEC meetings is seven members and meetings require the attendance of a majority of external (non-IARC staff) members and of at least one lay member[1]. In the absence of the IEC Chair and Vice-Chair one external member appointed by the other members attending, may act as Chair.

1.4 The Secretariat will keep a record of attendance, indicating which members attended the discussion of each application. IEC members are required to attend at least half of the scheduled meetings. Members may attend by videoconference but should attend at least one meeting per year in person.

Declarations of interest of Committee members

1.5 External IEC members must declare any generic potential conflicts of interest[2] by completing a "Declaration of Interests for IARC/WHO Experts" form once a year. In addition, they must inform the Secretariat if any important changes occur.

1.6 Each member, internal or external, must declare in advance of each meeting and at receipt of the review assignment, any potential conflicts of interest in relation to specific applications being evaluated (e.g. he/she is the Principal Investigator, a collaborator, or is in any other way linked to a specific study), to ensure the independence of the review. Where the Chair has a potential conflict of interest, that item(s) will be chaired by the Vice-Chair or by another external member of the committee in his/her absence.

[1] The composition of the IEC is described in Section III of the Rules and Procedures concerning the ethical review of research proposals at IARC.

[2] The WHO Declaration of Interests for WHO Experts defines a conflict of interest as follows: "A conflict of interest means that the expert or his/her partner ("partner" includes a spouse or other person with whom s/he has a similar close personal relationship), or the administrative unit with which the expert has an employment relationship, has a financial or other interest that could unduly influence the expert's position with respect to the subject matter being considered. An apparent conflict of interest exists when an interest would not necessarily influence the expert but could result in the expert's objectivity being questioned by others. A potential conflict of interest exists with an interest which any reasonable person could be uncertain whether or not should be reported".

1.7 If an IEC member has declared a conflict of interest in relation to a particular study, he/she may be asked by the Committee to leave the meeting room or may be allowed to remain but take no part in the discussion or decisions on that study, except as outlined in paragraphs 1.13 and 1.14.

1.8 The minutes should record all declarations of interest and decisions of the IEC on the procedure followed.

Review of applications

1.9 The review of each application is led by two members of the IEC assigned to act as lead reviewers. The primary reviewer provides a full assessment of the study; the deputy reviewer supplements as needed and acts as primary reviewer in case of his/her absence. If an IEC member has been assigned as a lead reviewer of a study on which he/she has a conflict of interest, they must inform the Secretariat upon reception of the agenda (paragraphs 1.5-1.8).

1.10 The lay members will not be appointed as lead reviewers but will participate fully in all discussions and will evaluate aspects relevant to study participants (e.g., purpose of study, potential risks and/or discomfort for the study subjects, the likelihood of getting useful results, mechanisms put in place to ensure privacy and confidentiality, etc.). In particular they will review in-depth the Informed Consent Forms and Participant Information Sheets, as well as projects with expected high impact on the population and unexpected ethical concerns. They may be appointed as deputy reviewers.

1.11 Whenever possible the Committee should reach decisions by consensus. If a consensus is not achievable, a formal vote should be taken. All members have the right to vote including the Chair and Vice-Chair. In these cases the decision of the Committee should be determined by a two thirds majority of those members present and entitled to vote as in paragraphs 1.6 and 1.7. In the event of a split decision, the Chair has the deciding vote.

1.12 Any member that wishes to record formal dissent from the decision of the IEC can ask for this to be recorded in the minutes.

Attendance of the PI

1.13 The PI may be invited to attend part of the meeting at which his/her application will be reviewed, in order to respond to requests from the Committee for further information or clarification. The PI should not be present during the deliberations of the Committee.

1.14 The PI's participation may be by remote means if the IEC Chair agrees. When the PI is unable to attend and is not available to participate by remote means, another IARC investigator or collaborator, but not a representative of the sponsor, may attend instead, subject to agreement by the IEC Chair (see also paragraph 2.8).

Confidentiality of proceedings

1.15 Members must be able to discuss freely the applications submitted and the discussions held during IEC meetings must be confidential. Any breaches of confidentiality by members will result in termination of their membership.

1.16 Minutes of the IEC meetings shall remain in restricted circulation and should not attribute particular statements to individual members, except when requested by a member (see paragraph 1.12).

1.17 Documents circulated by the Secretariat should be treated as confidential by the IEC members.

Responsibilities of the Secretariat

1.18 The responsibilities of the IEC Secretariat are as follows:

- preparing and issuing the schedule of IEC meetings;
- issuing announcements and calls for applications;
- receiving applications and reviewing them to ensure completeness;
- contacting PIs in case additional information relevant to the discussion of their application is needed;
- preparing the draft agenda for review/approval by the IEC (assigning the two lead reviewers, listing submitted projects and discussions on specific issues);
- distributing the agenda, project submissions and other meeting documents;
- arranging travel and accommodation for external IEC members;
- meeting logistics;
- recording apologies for absence and attendance to the meeting;
- advising the meeting as necessary on compliance with IEC's RAPs and SOPs;
- providing support to, working in conjunction with, and advising the IEC Chair, Vice-Chair and Committee members on administrative and procedural matters;
- preparing the minutes of the meeting;
- notifying PIs of decisions taken at the meeting;
    - following-up the replies to the requests by the Committee for additional information on approved projects, the annual and final study reports, and on action points;
- maintaining, updating and developing the IEC database and the IEC governance documents (Terms of Reference, Standard Operating Procedures, Rules and Procedures);
- advising and following up on ethics training of IEC members and liaising and maintaining the Ethics Advisory Group (EAV), composed of senior external experts, as support to the IEC; and
- horizon-scanning for possible changes required in the IEC procedures due to changing international practices.

Minutes

1.19 The minutes of the meeting shall contain a record of the following:

- the members present and absent indicating which members attended the discussion of each application;
- any conflicts of interest declared and the decision of the Committee on the participation of the member concerned;
- the submission of written comments by members;
- a summary of the discussion of the main ethical issues considered for each study;
- the decision of the IEC on the applications: 'Approved', 'Conditionally approved' or 'Not approved' (see paragraph 4.1);
- the feedback to be given to the PI and any additional information requested by the IEC;
- the outcome of any vote taken;
- any formal dissent from a decision of the Committee by a named member, with reasons; and
- any other topics discussed by the IEC and action items.

1.20 The minutes are to be presented as the outcome of collective discussion, including written comments made by members following discussion of an application, and should not attribute particular statements to individual members, with the exception of any formal dissent.

1.21 Copies of the approved minutes of the IEC will be made available to the IARC Governing Council upon request but shall otherwise remain confidential.

Section 2

Submission of applications

2.1 Applications for IEC review are submitted by the study's Principal Investigator (PI). The closing date for applications is no later than 15 working days prior to each IEC meeting.

2.2 The IEC will only review complete applications (as detailed in Section 3). Before applications are submitted to the IEC, they will be reviewed by the Secretariat and any incomplete application will be returned to the PI for completion.

2.3 The following categories of application are available to the PIs (see Section 3 for detailed description and documents to be included with each application):

- regular;
- expedite; and
- notification.

2.4 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.

Applications submitted by IARC PIs

2.5 The PI is responsible for:

- submitting a full application, including all relevant enclosures (see Section 3);
- collecting relevant information and documents from all the study sites and in particular the Participant Information Sheets, Informed Consent Forms, local ethical clearances, approval under the applicable national law, and processing MTA/DTA forms[3] with the relevant IARC Units;
- ensuring that the implementation of the study at the local sites complies with the ethical standards and with any applicable good clinical or epidemiological practice standards;
- ensuring that local PIs and project personnel are trained at an appropriate

[3] IARC MTA/DTA Templates available at http://intra.iarc.fr/policies-and-procedures/Standard-Agreement-Templates

level to conduct the study and have been trained in the study procedures;
- being prepared to respond to specific requests from the IEC in person on in writing;
- informing other involved bodies/entities, such as collaborators or funding institutions, of relevant decisions taken by the IEC; and
- accepting responsibility, together with collaborators and their institution(s), for the conduct of the study and ensure that adequate insurance is in place to cover any eventual liability.

2.6 Consideration must always be given to ensuring there are arrangements for dealing with liability if there is loss or injury to participants in IARC studies. The IEC will consider whether special insurance is necessary for particular studies (interventional or observational).

2.7 The IEC should be immediately notified by the PI of any ethical issues that have arisen in the course of the study, for example serious adverse events or concerns raised by local ethics committees.

2.8 In the case of prolonged absence from work, the PI is responsible for ensuring that his/her responsibilities are delegated to a suitable temporary replacement, and that that replacement is identified to the Secretariat.

2.9 Approval by the IEC does not attest compliance with the law of the countries involved. It is the responsibility of the PI to ensure compliance with local legal and ethical requirements, and that administrative approval to proceed with the research has been obtained from relevant organizations (e.g. health services).

2.10 For multicentric studies coordinated by IARC, the PI is responsible for:

- obtaining local ethical clearances;
- storing copies of the specific Participant Information Sheets and Informed Consent forms used in the different centres; and
- submitting documents listed in Section 3 to the IEC, after translation in English where needed.

Applications submitted by non-IARC PIs

2.11 Samples or data collected for IARC studies may occasionally be used for additional studies that have no direct involvement of IARC scientists[4]. In these cases the application for IEC review should be submitted by the external PI of the new study, with support from the IARC staff member responsible for the samples or data, i.e. the PI of the original study or, in its absence, a nominated IARC Custodian.

2.12 In addition to the standard procedures and required documents (see Section 3) applications submitted by external PIs should include:

- the IEC questionnaire completed and signed by the external PI;
- memo to the IEC from the IARC PI/Custodian of the original IARC study confirming his/her agreement for the use of the samples/data;
- IEC references of the original IARC study and copies of the ethics approval of the original IARC study, of its Informed Consent forms and Participant Information Sheets; and
- copy of the 'project registration form' submitted to the IARC Biobank with the request for access to the samples.

2.13 Following the IEC review, the Secretary will forward the project description together with the IEC's decision to the IARC Director, who will determine whether the use of the samples conforms to IARC's mission and objectives.

2.14 The IEC Secretary will communicate the result of both reviews to the external PI and to the IARC PI/Custodian of the original study within 15 working days of the meeting.

[4] See "IARC Policy on Access to Human Biological Materials" and the "Sample access standard operating procedure" (available on the IARC Biobank website - http://ibb.iarc.fr/) for the principles and procedures governing access to samples stored in the IARC Biobank.

Section 3

Type of submission to the IEC (see also Annex 1)

Regular Submission

3.1 The following types of study should be submitted to the IEC through the regular submission procedure:

- new studies or collection of new material (including descriptive studies, surveys, studies on cancer registry data, and studies on outcomes other than cancer);
- studies using previously collected data (including data from questionnaires, from previous biomarker analyses, or from medical records) submitted by a non-IARC PI (for studies on previously collected data proposed by an IARC PI, see paragraph 3.12);
- pooled analysis of data from different studies not previously approved by the IEC;
- studies on previously collected and stored samples from studies approved by the IEC for their initial use/application and that will perform new biological analysis and/or make use of new technologies; and
- amendments involving substantial changes to studies previously approved by the IEC (see paragraphs 3.8, 3.10).

Procedure for regular submission

3.2 The PI should submit a memo to the IEC. The memo should be accompanied by:

- completed IEC questionnaire;
- study outline/protocol (including sample size and power calculations where appropriate);
- participant information sheets, 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;
- for resubmissions, amendments, or pooling of studies, provide all previous IEC references/registration numbers related to the study; and
- any other relevant documentation.

3.3 For multicentric studies pooling already collected data from non-IARC primary studies, copies of the study-specific documents (such as initial Information Sheets and Informed Consent Forms) should be provided with the application for ethics approval. In addition to the generic documents, the application for ethics approval of pooled studies should include a flow-chart showing how data and/or samples will be managed and shared between the different

centres.

3.4 For multicentric studies pooling already collected data from IARC primary studies, original Informed Consent forms should be submitted. The IEC will ascertain whether the new use being made of the data/samples and the conditions for their storage and future use, are consistent with the information originally consented by the participants.

Expedited review

3.5 Some specific categories of studies which are judged not to present potential threats in terms of the rights and welfare of study participants may be reviewed and approved by the IEC through an expedited procedure:

- previously approved studies on already collected and stored samples that will perform new biological analysis and/or make use of new technologies, should be regularly submitted (see paragraph 3.1); however on special occasions and on request of the PI, the IEC can use an expedite approval procedure (i.e. if there is an urgent grant deadline); and
- amendments to research previously approved by the IEC (see paragraphs 3.8-3.9).

3.6 In cases where the Chair, Vice-Chair or the acting Chair (see RAPs, paragraph 14) judge there are no potential ethical implications of the amendment (as listed in paragraph 3.8) or new study, they may approve the proposals. Approvals will be communicated to the members of the IEC at the following meeting.

3.7 All requests not given expedited approval by the IEC Chair or Vice Chair (or the acting Chair) will be required to submit a full application and included in the agenda of the next Committee meeting.

Amendments to research previously approved by the IEC

3.8 The PI may propose to amend the terms of an IEC application, e.g. the protocol, Informed Consent or other supporting documentation, after approval has been given or in some cases after the study has commenced.

The ethics review process distinguishes between Minor and Substantial amendments to a research (below and in paragraphs 3.9, 3.10). The PI may submit a memo outlining the amendments which will be reviewed by the IEC Chair and Vice-Chair who will decide whether the proposed amendment is considered Minor or Substantial:

1. Minor amendments (i.e. procedural changes that are unlikely to alter the risk or the potential benefit to study participants and that do not entail ethical implications):

a. small changes of negligible importance that are made prior to the start of study recruitment;
b. minor amendments that do not involve changes to the protocol;
c. small changes to the design or methodology of the study, or to background information affecting its scientific value;
d. small changes to the procedures undertaken by participants;
e. small changes to study documentation such as participant information sheets, consent forms, questionnaires, letters of invitation, letters to GPs or other clinicians, information sheets for relatives or caregivers; or
f. other changes to the protocol or the terms of the original IEC application that do not alter the risk or the potential benefit to study participants.

2. Substantial amendments (i.e. procedural changes that may alter the risk or the potential benefit to study participants and may have important ethical implications):

a. changes in the use and/or quantity of biological samples;
b. a change of sponsor(s) or sponsor's legal representative;
c. appointment of a new PI or key collaborator, either at IARC or at a local research site;
d. a change to the definition of the end of the study;
e. a change in the purpose or objective of the research, such as introduction of additional genetic studies;
a. a substantial change in research methodology;
b. any change relating to the safety or physical or mental integrity of participants, or to the risk/benefit assessment for the study;
c. a change to the responsibility and liability insurance coverage for the study;
d. introduction of new classes of investigations or other interventions (rather than simply re-scheduling or modifying those already approved); or
e. recruitment of a new type of participant (especially if these would be regarded as being from vulnerable groups).

3.9 Minor amendments do not entail ethical implications and may be submitted through the expedited review procedure (outlined in paragraph 3.11).

3.10 Substantial amendments may have important ethical implications. They require regular submission (outlined in paragraphs 3.2-3.4) and are subject to review at the next Committee meeting.

Procedure for expedite review

3.11 The PI should submit a memo to the IEC requesting the expedited approval of the study. The memo should be accompanied by:

- the motive of the amendment, the details of proposed changes and how the proposed changes would affect the research;
- any implications of the amendment for the safety or welfare of participants;
- any changes that affect the terms of the original Informed Consent or other information documents given to the study participants;
- the appropriateness of the original Informed Consent to the new analyses that may be conducted on the collected data;
- the possibility of tracing and re-contacting the study participants in the cases that may require re-consent; and
- IEC reference of the original IARC study and copies of the ethics approval of the original IARC study, of its Informed Consent forms and Participant Information Sheets (if applicable).

Notification

3.12 The following categories of studies will only require notification to and registration by the IEC according to the procedure outlined in paragraph 3.13:

- studies having received a previous ethical approval, using only previously collected data (including data from questionnaires, from previous biomarker analyses, or from medical records) for a new purpose or to test a new hypothesis not envisaged at the time the original consent was obtained. This applies to studies submitted by an IARC PI (regular submission is required for studies submitted by a non-IARC PI; see paragraph 3.1);
- methodological and quality assurance studies which do not present any potential ethical implications;
- studies collecting anonymous data without any identifiers associated or linked to an individual and that do not present issues related to privacy and confidentiality. The protocol must demonstrate that such studies are permissible by national law; and
- studies on population aggregated information.

Procedure for notification

3.13 The PI should submit a memo to the IEC notifying the study. The memo should be accompanied by:

- an abstract of the proposed new study summarizing its objectives, research hypothesis, scientific rationale and methodology;
- power and sample size calculation (if applicable); and
- IEC reference of the original IARC study and copies of the ethics approval of the original IARC study, of its Informed Consent forms and Participant Information Sheets (if applicable).

Section 4

Decisions available to the IEC

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

- *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 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.

4.2 Where the IEC decides that further information or clarification are required, the Chair or Vice Chair will ensure that this information is specifically identified and included in the minutes. The wording of the notification to the PI and of the request for additional information should be agreed upon during the meeting, specifying the ethical principles underlying the decision.

4.3 A project that is 'conditionally approved' may be initiated, but the PI must submit a Memo to the IEC within two months from the receipt of the IEC's decision, detailing the actions taken to address the approval conditions and/or providing the additional information requested. If the PI cannot provide a response in this period, a request for extension should be submitted. If not, the application will be treated as a new submission.

4.4 The requested additional information/clarification submitted by the PI in case of a 'conditional approval' or 'approval with minor amendments', will be reviewed by the IEC Chair or Vice-Chair, which may issue the IEC's final approval or alternatively submit it for review at the next Committee meeting.

Notification of the IEC's decision to the PI

4.5 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.

4.6 The decisions should be communicated to the PI within 15 working days of the meeting. In case of delay in preparing the full notifications, PIs may request informal access to the decision from the Secretariat, with the understanding that the full notification will be sent as soon as feasible.

4.7 The following information will be included in the notification letter or its enclosures:

- a list of the members who participated in the discussion of the application;

- the decision of the IEC;
- a summary of the ethical issues considered by the IEC:
    - in the case of an approval, any eventual minor changes requested or advice given by the IEC;
    - in the case of a conditional approval, any specific modifications or additional information/documents requested by the IEC, the timeline for the PI to provide a response to the points raised;
    - in the case the project is 'Not approved', the reasons for the decision and the issues for which further information or action from the PI may lead to a more favorable decision, should the PI decide to resubmit the application.
- requirement for annual reports, if applicable, and the due date for its submission.

Section 5

Monitoring of research given IEC approval

General policy on monitoring of research

5.1 IEC approval applies for the duration of the research. It is the policy of the IEC that approval given to any research study should be kept under review. This normally involves the submission of annual progress reports and final reports.

5.2 However, the vast majority of studies conducted or coordinated by IARC consist of observational epidemiological studies where, after approval of the protocol by the ethics committee, 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 ethics committee during their progress.

5.3 The IEC will decide at the time of granting ethical approval whether each approved study is required or exempted from submitting annual progress reports and will communicate this decision to the investigators. The submission of a final report will be required in all cases.

5.4 Categories of studies that would typically require the submission of an annual progress report include:

- intervention studies (participants may be subject to risks/adverse events);
- studies using new emerging technologies (may lead to incidental findings, false positives/negatives);
- studies with implications on confidentiality (potential identifiability of subjects in genomic studies); and
- studies with potential for incidental findings.

Progress reports

5.5 In those cases where the IEC has requested the submission of annual progress reports, these should be submitted generally within six weeks of the anniversary of the IEC approval. For studies that must also submit an annual report to a Data and Safety Monitoring Board (DSMB) or to the funding agency the PI may request that the calendar of reporting to the IEC be aligned with the DSMB's/funder's schedule.

5.6 The annual progress report consists of a simple declaration from the PI notifying the IEC of any ethical problems or adverse events which may have occurred during this period. For clinical trials the annual report should also include a copy of the Data and Safety Monitoring Board's report and the scheduled inclusion of cases/controls versus the actual inclusion.

Safety reporting

5.7 In research, a Serious Adverse Event (SAE) is defined as an untoward occurrence that either:

- results in death;
- is life-threatening;
- requires hospitalization or prolongation of existing hospitalization;
- results in persistent or significant disability or incapacity;
- consists of a congenital anomaly or birth defect; or
- is otherwise considered medically significant by the investigator.

5.8 A SAE occurring to a research participant should be reported as soon as possible by the PI to the study's DSMB and to the IEC, together with his/her assessment of whether the event was:

- "related/unrelated" – i.e., it resulted from administration of any of the research procedures; and
- "expected/unexpected" – i.e., the type of event is not listed in the protocol as an expected occurrence.

5.9 The IEC will review the DSMB's assessment of the SAE and determine if the study's ethics approval needs to be reconsidered.

Protocol deviations and violations

5.10 Protocol deviations are accidental or intentional changes to the approved study protocol to deal with unforeseen circumstances, which do not increase risk or decrease benefit to the research participants and do not have a significant effect on their rights, safety or welfare and/or on the integrity of the data. Such deviations do not need to be routinely reported to the IEC.

5.11 Protocol violations are accidental or intentional changes to the approved study protocol which may increase risk or decrease benefit to the research participants and that may affect their rights, safety or welfare and/or on the integrity of the data. Protocol violations should be promptly reported to the IEC. In particular, where the change is made to protect subjects from an immediate hazard to health or safety, this should be notified to the IEC as an urgent safety measure and reviewed accordingly.

Final reports

5.12 The IEC should receive a final report within one year of the research terminating. The format of the final report can be: a) the resulting peer-reviewed paper, b) a short memo including information on whether the study achieved its objectives, the main findings and arrangements for publication, if applicable, or dissemination of the research including any feedback to participants.

Section 6

Appeal process

6.1 A PI who considers that a decision of the IEC is flawed, and who believes there are substantial and compelling reasons to challenge that decision, may appeal in writing to the IEC within one month of receipt of the decision, stating the precise issues upon which the appeal is based.

6.2 The IEC will have the option of inviting the PI to explain his case and, if necessary, referring the appeal to an external group of experts for an opinion (see RAPs document).

6.3 The IEC will provide a written reply to the PI within 15 days addressing the issues raised, and either confirming and justifying its position or issuing a revised decision.

Acknowledgement:

The first version of this document (18 May 2006) was originally adapted from the UK Central Office for Research Ethics Committees (June 2005, available at http://webarchive.nationalarchives.gov.uk/20130107105354/http://dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4112417.pdf).

Annex 1: Types of submission to the IEC

New studies	Regular Submission	Expedite review	Notification
New studies or collection of new material (including: descriptive studies, surveys, studies on cancer registry data, studies on outcomes other than cancer).	X		
Methodological and quality assurance studies which do not present any potential ethical implications.			X
Studies collecting anonymous data without any identifiers associated or linked to an individual and that do not present issues related to privacy and confidentiality. The protocol must demonstrate that such studies are permissible by national law.			X
Studies on population aggregated information.			X (Optional)

Studies previously approved by the IEC	Regular Submission	Expedite review	Notification
Amendment to already approved protocol/study.	➢ Substantial amendments and requests not given expedite approval by the IEC Chair or Vice Chair (given the potential ethical implications); ➢ otherwise expedite review.	X	
Studies on previously collected data where consent for storage and future use was specifically provided **(i.e. data from questionnaires and/or previously measured biomarkers).**	➢ Only if: • The study is proposed by a non-IARC PI • Pooled analyses of such data from different studies (not previously approved by the IEC); ➢ otherwise notification.		X
Studies on medical records in line with the previously approved project.	➢ Only if: • The study is proposed by a non-IARC PI • Pooled analyses of such data from different studies (not previously approved by the IEC); ➢ otherwise notification.		X
Previously approved studies on already collected and stored samples that will perform new biological analysis and/or make use of new technologies.	X	On special occasions, on request of the PI the IEC can use an expedite approval procedure (i.e. if there is an urgent grant deadline).	