Research Ethics Committees (REC)

Introduction

The Research Ethics Committee (REC) evaluates the ethical acceptability of research before participants can be enrolled in a study. In addition, the REC will examine certain related financial and scientific aspects.

Authority, role and mandate of Research Ethics Committees

The setup, legal status and operation of RECs vary across countries. RECs are usually established by a government or an institutional authority (such as a hospital, research institution or university).

In some cases, RECs may be set up by private organisations, but these may need to be publicly accountable in some way (e.g. through accreditation). There is little evidence to suggest that the quality of ethics review conducted by private RECs varies from those established by a public institution or organisation.

RECs help to ensure the well-being, safety, and protection of persons who participate in research. To achieve this, an ethics review and favourable opinion must be sought before the research can begin and ongoing research will be continually monitored.

Independence of RECs and committee

members

RECs must be independent from sponsors, funders, investigators, and from undue influence (e.g. political, institutional, professional or commercial). This ensures that the interest of research participants is paramount.

Achieving the independence of RECs is a challenge. It requires proper accountability (i.e. making sure the right people are responsible) and balanced membership (i.e. making sure the right mix of people is involved). REC members must be free from, or have properly managed and declared, conflicts of interest. REC members who have conflicts of interest may not be able to participate in decisions concerning a particular study protocol.

Composition and operational aspects

An REC is typically composed of members who together have the qualifications and experience to ensure proper review of the ethical, scientific, medical, and financial aspects of a study. In many countries, non-scientific members are required. Members should be appointed for a fixed term by the recognised authority according to an established procedure. The REC may choose to invite outside experts who are not members to advise on a project.

Properly constituted RECs and standard operating procedures (SOPs)

RECs need to ensure that their written procedures comply with national, local, and/or institutional requirements as well as to their own SOPs.

Guidelines and regulations for some countries specify that REC operating procedures should cover:

- How meetings will be conducted

- How applications to have proposals reviewed should be made
- How the REC will make its decisions at announced meetings, including the minimum quorum (i.e. the minimum number of people required to attend and vote in order to make a decision)
- Details of the process for ethics review
- A rule that no participant should be enrolled before the REC has issued its written favourable opinion of the study
- The investigator’s duty to promptly report to the REC any substantial protocol amendments or safety issues, including serious and unexpected adverse events (AEs).

Ethical deliberation and decision-making

Ethical deliberation

Ethical deliberation refers to careful consideration and discussion of research, and should take into account the principles and values of research ethics from relevant local and international guidelines. All documentation relevant to the review must be examined by the REC before the discussion, during which each member should contribute and provide their expertise and perspectives.

Reaching a decision

Ideally, the REC will reach an opinion that all members find ethically satisfactory (consensus). This decision is valid as long as it emerges from deliberations that are honest, fair, and factually well-informed and follow SOPs.

Making decisions by vote, as opposed to consensus, should be restricted to exceptional circumstances because voting gives priority to the number of people who hold a certain opinion

but does not take into account the reasoning behind those opinions.

Dissenting and abstaining

If a decision is reached that is not accepted by all members, then the number of people who abstain (do not vote) or dissent (do not agree with the majority decision) should be recorded.

Due process

Due process implies that the REC will be impartial and will only make decisions at announced meetings with a quorum. Only members who participate in deliberations are able to take part in decisions; investigators and sponsors should have a fair opportunity to be heard (although they cannot participate in the deliberation and decision-making process).

A decision (favourable or negative opinion) should be communicated in writing to the applicant and to the relevant authorities. The REC must store, and be ready to make available, relevant records of its decisions and SOPs.

Follow-up of ongoing research

RECs re-evaluate approved research at regular intervals, the frequency of which is dependent on the individual REC. This is based on the level of risk the project poses to participants. As part of the continuing review process, the following examples may require follow-up by the REC:

- Any substantial protocol amendments that are likely to have a significant impact on the safety or physical or mental integrity of the participants, or the scientific value of the trial where applicable, accompanied by an updated risk-benefit assessment
- Unexpected AEs and serious AEs related to the conduct of the study or study product

The goal of continuing ethics review

The purpose of continued review is to ascertain if the research is being conducted in compliance with the approved protocol. If the risk-benefit ratio has changed, the participants should be informed of the change and then be asked to re-consent to participating in the research. They may also withdraw from the study.

REC decisions during continuing review

If anything is found to be unacceptable during the follow-up, favourable ethical opinion may be suspended or withdrawn until further information is provided and reviewed. The new information may need to be communicated to participants to enable an informed choice regarding continued involvement in the research. The REC can ask for protocol modifications or changes to the Informed Consent Form, which will require re-approval and subsequent re-consent or refusal from participants.

Accountability

RECs must demonstrate accountability towards researchers and the broader public and are immediately accountable to their constituting authority whether a government, institutional authority or private organisation. RECs must promote the transparency of its activities and decisions, including the official announcement of meetings.

Which research requires ethics evaluation?

All research that involves humans must be evaluated by a REC before any prospective participants are recruited. This also applies to research conducted with personal information (e.g.

medical records), or with human tissue and genetic material. Research with human gametes (i.e. sperm or eggs), embryos, and foetal tissue also require prior ethics review in addition to other requirements (see section on particular cases below).

Certain research may qualify for exemption from ethics review, for example, when there is no foreseeable risk of harm or discomfort, and it involves no more than inconvenience to participants (negligible risk). This is also the case for research that involves the use of existing collections of data or records that contain only non-identifiable data about people (e.g. public records, archives, or publications).

Particular cases

Clinical trials are a type of research that has additional requirements. For example, in Europe, sponsors of clinical trials for medicines must have approval from the National Competent Authority and a favourable opinion by the REC before a trial can start.

Research involving human reproductive material (e.g. stem cells, gametes, embryos) requires review by the national oversight committee in addition to the REC.

Ethical aspects

Research that is not scientifically sound is not ethically acceptable. This is because it will expose participants to the burden and potential harms of research without having the possibility of yielding benefits to the participants and/or to society. Thus, the REC must ensure that appropriate scientific evaluation has occurred. If research does not pass scientific evaluation, then it should be denied ethics opinion as well.

Levels of evaluation

RECs can adopt a proportionate approach to ethics evaluation: the greater the burden of research, the greater the scrutiny. An evaluation can be completed by the REC's full committee or by a sub-committee (expedited review). Expedited review is allowed by certain RECs for research that poses only minimal burden to participants (when the amount of harm expected in the research is less than that ordinarily encountered in daily life, or in routine medical, dental, or psychological exams).

SOPs for expedited reviews of research should specify:

- the nature of the applications;
- amendments and other considerations;
- the quorum requirements; and
- whether or not the opinion reached will need to be confirmed by the full committee.

Ethics review of international collaborative research

Internationally collaborative research, like any multi-centre trial, may require a number of ethics evaluations in the respective countries.

Regardless of where the research is conducted, the EU requires that it follows the principles of the Declaration of Helsinki[1] if the research is to be used for marketing authorisation in the EU.

Documents subject to ethics review

Owing to the differences between individual research projects and the evolution of ethics evaluation practices over time, it is difficult to establish a definitive list of documents that the REC needs in order to conduct a full evaluation.

Therefore, the REC may ask to be provided with any document it considers important.[2]

Disclosure to prospective participants

Prospective participants should be fully informed of all aspects of the study, including the aims and methods, sources of funding, and identification of the researchers and sponsors, the anticipated benefits and potential risks. Participants will receive an official invitation to take part in the research and will be informed of the right to abstain (withhold) from participation, or to withdraw consent at any time without reprisal. All measures that are taken to ensure the privacy of participants should be highlighted. The address of who to contact for information at any time should be provided, together with the reassurance that access to free treatment (and compensation, in the event of impairment, disability or handicap) will be available in case of injury from research procedures. Participants will also be informed of the type of reimbursement that they will receive for taking part in the research (where applicable).

Detailed guidance on the application format and documentation to be submitted in an application for an ethics committee opinion on the clinical trial on medicinal products for human use.

Further Resources

- European Commission (2006). *Detailed guidance on the application format and documentation to be submitted in an application for an Ethics Committee opinion on the clinical trial on medicinal products for human use*. Brussels: European Commission. Retrieved 12 July, 2021, from:

https://ec.europa.eu/health/sites/default/files/files/eudralex/vol-10/12_ec_guideline_20060216_en.pdf

Articles References

1. World Medical Association (2013). *Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects.* Retrieved 12 July, 2021, from: https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/
2. European Parliament and the Council (2009). *DIRECTIVE 2001/20/EC on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use*. Retrieved 12 July, 2021 from: https://ec.europa.eu/health/sites/default/files/files/eudralex/vol-1/dir_2001_20/dir_2001_20_en.pdf

Attachments

- Presentation: Research Ethics Committees
  Size: 391,227 bytes, Format: .pptx
  A presentation on research ethics committees, which can be adapted for own use.

A2-4.15-V1.1