RESEARCH AND ETHICAL COMMITEE

Research Ethics Committees (RECs) are multidisciplinary, independent groups of individuals appointed to review biomedical research protocols involving human beings to help ensure in particular that the dignity, fundamental rights, safety, and well-being of research participants are duly respected and protected. RECs may be established at local, regional or national level. They may be appointed by institutions or by regional or national authorities and are increasingly provided for by law. Their scope as a local, regional or national REC is defined by the appointing authorities.

ROLES AND ACTIVITIES OF RECS IN THE RESEARCH PROCESS

RECs have specific roles before, during, and after a biomedical research project is authorized and conducted, and the research results are evaluated and reported. Their responsibilities and practical responsibilities therefore encompass the entire spectrum of biomedical research – roles aim to fulfil RECs' main objective

– to ensure that biomedical research is conducted ethically. RECs' composition and collective expertise in ethical and scientific issues, as well as their working methods and overall functioning, should provide assurance that they are trustworthy and can carry out their responsibilities effectively and independently.

– complementary activities. There is a general trend, which is to be welcomed, for RECs to take on complementary activities with the aim of improving the overall culture of biomedical research, enhance communication between researchers*/research institutions and society, and raise awareness of ethical issues in biomedical research. For example, RECs or their national organisations may become involved in public dialogue about ethical issues or take on an educational role about research ethics policy and decision making.

	Before research starts		After research has started	
Research phase	Planning, preparation of the project	Review	Conduct	End of the research
Roles	Providing information to researchers*, as needed	Ethics review of the research proposal	Follow up of the research project, in particular ethical aspects; possible re-review	Review reports from the researchers*

Roles of RECs in the research process

ECs' roles before research begins – ethics review of research proposals As their primary objective, RECs ensure that the biomedical research proposals they consider are ethically acceptable before being approved. In this way RECs also provide public assurance that unethical research is avoided and that good quality, ethically sound research is encouraged. RECs fulfil this objective mainly by conducting an ethics review of research proposals

– Independent REC examination of a research project) and by issuing written opinions on their ethical acceptability. They may also, where needed, be consulted by researchers* in the planning and preparation stage of the research project.

RECs evaluate the ethical acceptability of a research proposal from two main standpoints: – from the standpoint of the ethical implications of the research conduct, foreseeable research outcomes, and potential consequences of research results for society. ‘

Society’ can encompass both local and wider contexts and may include the potential interests of future generations. – from the standpoint of the prospective research participants to safeguard their rights, dignity, safety, and well-being. When evaluating a biomedical research proposal

– Independent REC examination of a research project), RECs need to consider the ethical issues involved in accord with applicable ethical principles accepted both by the given society and internationally.

The REC must be satisfied about the scientific quality of the research proposal and of its conformity with national law; scientific quality and conformity with law may be assessed by the REC per se or by other competent bodies.

RECs’ roles during the research RECs should follow up, as appropriate and according to national practice, the conduct of research projects that they have approved and may need formally to re-examine them in view .

- ✓ Research Ethics Committees (RECs) developments and relevant knowledge acquired during the research (This is especially important when the research entails a non-negligible level of risk, or where it is expected to generate clinically relevant information which could affect – positively or negatively – the safety, health or wellbeing of the research participants.
- ✓ The purpose of follow up is to establish whether, in the light of any new developments during its conduct, the research can continue unchanged according to the original proposal, or whether modifications in the project have become necessary, or, even, if the research needs to be discontinued
- ✓ Follow up can usually be achieved by REC review of research reports that the researchers* (or research sponsors* where appropriate) are usually obliged to provide on a regular (at least annual) basis RECs should also have a designated mechanism), that allows them to react as appropriate to any serious information received during the course of the research project – for example, concerning the safety and well being of the research participants including, where appropriate, interim information concerning the efficacy of a medicinal product being studied.
- ✓ This should be done promptly and duly documented. The actions available to the researchers*, research sponsors*, and RECs (in addition to taking immediate measures taken to protect the health and well-being of the research participants) include protocol amendments, or a temporary suspension or termination of the research.

COMPOSITION

1. Chairperson
2. 1-2 basic medical scientists.
3. 1-2 clinicians from various Institutes
4. One legal expert or retired judge
5. One social scientist / representative of non-governmental voluntary agency
6. One philosopher / ethicist / theologian
7. One lay person from the community
8. Member-Secretary

REVIEW OF RESEARCH

- Conduct initial review of research
- Conduct continuing review

Documentation EC members review

- Protocol
- Informed Consent Forms
- Recruitment procedures (e.g., advertisements)
- Written information given to subjects
- Safety information
- CV of Investigator
- Information about payments to subjects
- Other documents can be requested