Publication Integrity and Ethics

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P.I.E. Guidelines: Research Ethics Committee review of human-related research

Practice Guidelines

Please read the declaration at the end of this document before applying these guidelines

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Introduction

This document is intended to provide guidance to personnel working in human-related research programmes and in particular to research ethics committees (RECs), who are reviewing a research proposal on humans prior to its implementation. The term 'research' is hereby given to embrace operational, social science, biomedical, behavioural, health systems and epidemiological research. Many organisations rely upon RECs in order to monitor and confirm that research involving human participants is conducted in an ethical manner. It is also useful to researchers who create and conduct various health research studies.

These P.I.E. guidelines have been created to complement existing regulations, rather than supersede present laws and practices. The document can act as a foundation upon which RECs can develop written procedures and methodology, according to their own specifications, raising the global standard of RECs.

These guidelines do not take a stance on the method of resolution, should any difficulties arise during health-related research.

Standards for the review of research ethics

1 *Responsibility for design*

1.1 An appropriate legal structure of support should surround a review of ethics in health-related research.

1.2 RECs must ensure independent reviews of standards are conducted at every level of health-related research, whether national, institutional, private or public.

1.3 Such review systems must be sufficiently maintained in order to ensure appropriate quality and effective strategies.

2 *Avoidance of isolation of RECs*

RECs are an integral part of wider protections in human research and these guidelines can only act as a focus. To avoid subsequent isolation or inefficient performance, RECs must follow a wider systematic approach.

2.1 It is presumed that research involving human participation is afforded REC overview. Specific categories may be exempt or a review is conducted more rapidly. This will be in accordance with national laws, regulations and guidelines.

2.2 Ethical research studies include training REC members and researchers. Efficiency and effectiveness measures are the responsibility of Department of Health of that country.

2.3 Unambiguous and efficient communication, equal standards and co-operation between committees must be instigated. Co-ordination of review and multi-site research should be available, including across national borders.

2.4 A strategy is implemented to ensure REC measures are consistent with monitoring from national authorities. These mechanisms, for drugs and devices, should include national and international clinical trials.

2.5 Allowance is made for input into the ethics review system by others.

2.6 An REC registration system is in place in individual countries.

3 *Standards for establishment of RECs*

3.1 A REC is established according to an official document that sets out how members and the Chair will be appointed. The committee members will be from a wide range of disciplines, with both cultural and social diversity, and a male and female balance, reflecting the backgrounds of participants.

3.2 Individuals whose backgrounds are not associated with human health research are sufficient in number to have input without discomfort.

3.3 Members of REC include those who are not associated with institutions that finance or are involved in research reviews by the REC.

3.4 The REC should incorporate lay and affiliated individuals who offer different viewpoints for discussion about proposed research.

4 *Ethics of research committee*

4.1 The REC is supported with adequate funding, facilities, staff and training to conduct its technical and administrative affairs responsibly.

4.2 The staff has enough resources to perform their duties: office space, equipment, stationery supplies, and secure storage space.

4.3 If necessary, resources are available for compensation of time and effort to members.

5 *REC independence*

5.1 Policies governing the REC include mechanisms to secure independence and avoid conflicting interest from sponsors or institutions where research is conducted.

5.2 By-laws and regulations of the REC stipulate:

5.2.1 Membership of the REC includes a minimum of one member who has nil association with the sponsors or the institution where the research is to be reviewed.

5.2.2 An REC meeting may have researchers, sponsors, and funders in attendance to answer questions regarding research methods but not for decision making.

5.2.3 Individuals who do not serve as members of the REC or its Chair include: creators of the REC at senior level, institutions sponsoring or conducting research under review.

5.2.4 REC members are protected from acts of revenge relating to research review.

6 *REC training*
Training applying to different types of research is given to REC members upon joining the committee, and regularly thereafter. This focuses on:

6.1 The responsibilities of the REC, and its role with other entities and their policies.

6.2 Ethical considerations relevant to research involving human participants.

6.3 The application of these considerations to different types of research.

6.4 Basic research methodology and creation.

6.5 The impact of scientific designs and objectives.

6.6 The methods used for resolution of tensions.

7 *Transparency, responsibility and standards*

7.1 Actions of the REC must be open and accountable; consistently high quality will be evaluated regarding policies and ethical considerations.

7.2 Regular evaluations are performed by unbiased and skilled persons following a defined format.

Internal assessments are supported by periodic independent external evaluation. Results are studied and followed up.

7.3 The aim of the evaluation is to improve practice rather than apportion blame and to give public reassurance to quality of research procedures.

7.4 All parties involved, including researchers and participants, are able to lodge complaint about the REC.

Complaints are reviewed by a non-REC person and any necessary action implemented.

7.5 REC members are available to discuss concerns from researchers on general issues.

7.6 Decisions made by the REC, other than confidential information, are available to the public via clinical trial registries, newsletters, websites and bulletin boards.

8 *REC quality and guidance*

8.1 Approval or disapproval of the findings of research and supporting material is founded on the acceptance of ethical values with scientific validity and social value.

8.2 The review takes into account a ratio of potential benefits deemed acceptable against harmful risk, consent to procedures with equality measures, protection of vulnerable individuals, fairness in participant selection, due regard to the impact of research on the communities from which participants will be drawn, both during and after completion of research, and any prior scientific reviews and applicable laws.

9 *Basis for ethical decision-making*

9.1 Decisions are founded on unambiguous and consistent adherence to the principles stated in international guidelines and human rights, national laws or regulations.

9.2 The REC decision-making is the basis for specific ethical guidelines which are made available to researchers and the public.

Whereupon this reliance is under the jurisdiction of another REC, the controlling REC ensures compatibility with the other REC decisions, with the same principles, protocol and criteria.

9.3 Historic decisions on a specific ethical decision may be reversed with an appropriate substantiation of reasoning.

9.4 The REC explains its analysis arising from a review when communicating decisions to researchers about significant protocols. Key criteria may involve the following:

9.4.1 Sound methods of scientific analysis essential for ethically acceptable research, to avoid harmful risks without apparent benefit.

RECs will assess qualifications of researchers, adequacy of resources, and methodology of the research under scrutiny.

9.4.2 When research has been conducted in an ethically acceptable manner, risk of negative impact is minimal, in relation to the benefits.

Risk can be assessed in aspects of social, financial, physical or psychological.

9.4.3 In selecting participants for research, strong ethical procedures mean there is no unfair imbalance either way on one set of people in any aspect and in weighing the benefits against the risks, including recruitment.

9.4.4 Individuals participating in research can be reimbursed for travel, child care or loss in earnings. It is not ethically acceptable for payments to be excessive or in the form of free medical care which might encourage participation in research or affect understanding of the research programme.

9.4.5 RECs take breach of confidentiality and invasion of privacy seriously; such elements are disrespectful to participants, often resulting in psychological harm, social, family and community isolation and lost employment or housing opportunities.

9.4.6 RECs must study the information provided for informed consent to research and give serious consideration to participants with respect to their competence to make independent, informed and objective decisions for consent to participation in research. Children or adults whose level of mental capacity renders them unable to give consent should have an authorised surrogate for decision-making. If internal guidelines dictate, RECs may waive the requirement of informed consent; the agreement for participation in research does not preclude an ethically responsible programme of research.

9.4.7 RECs must examine their duties to respect and protect communities where research occurs and to those to whom results may be linked. The aim will be to minimise negative effects such as disgrace and promote positive effects, such as health-related benefits.

9.4.8 Researchers should be sensitive to the cultural, traditional and religious aspects of a community, engaging with community members about conduct of the research.

10 *Decision- making procedures*

The REC summoned to review the research programme bases decisions for protocols on discussion and deliberation except in such cases where expediency has been allowed.

10.1 REC members discuss all varied concerns, beliefs and opinions, regarding the protocols and the associated documents under consideration. The Chair adopts an inclusive strategy allowing time for thought and has adequate preparation time. Participation and decision-making is by REC members present at the time of discussion. Responsibility for decision-making rests with the Chair.

10.2 REC members accept their knowledge has limitations, seeking input from external sources if necessary, particularly where life experiences are significantly different from members of the REC.

10.3 Either a vote or consensus determines the decision; it is not a pre-requisite that all REC members are in agreement but all members should accept the final decision.

11 *Guiding principles for the REC*

The REC's membership, review procedures, decision-making, communications, monitoring, archiving, training, quality assurance, and co-ordination procedures with other RECs will be specified in written policies, available to the public and performance levels reviewed at intervals.

11.1 The authority, policies, procedures and terms and conditions of appointment for the REC's are set out in writing, allowing for fresh thinking.

11.2 The policies and procedures of the REC's define the conditions in which they may ask independent consultants to impart special guidance to the REC on detailed protocols or topics requiring their expertise.

11.3 The policies of the REC detail the requirements for submission of review applications, the process for review, co-ordination with others, approval of minutes and invitation to non-members.

11.4 The REC policies specify the allowable time between the decision-making and communication with the applicant.

11.5 RECs follow up approved reviews and monitoring for a proposed study with standard operating procedures and timing.

11.6 The REC has written procedures detailing the recording and filing of documents for archiving, with sufficient security measures in place, for hard or electronic format.

11.7 Staff is given adequate training for record keeping, access and confidentiality.

12 *Responsibility of researchers*

The REC establishes that only individuals with appropriate clinical and scientific qualifications and familiarity with ethical standards for research and submission of information with full knowledge of compliance should be accepted.

12.1 Upon submitting an application for review, the researcher is responsible for the ethical and scientific nature of the study, together with submission of issues regarding conflicting interests.

12.2 A qualified, appropriate member of the faculty oversees student applications and co-signs the work.

13 *Conduct of research*

13.1 Full adherence to the REC protocol is given without deviation unless prior approval is given by the REC. If immediate risk is apparent, an exception can be justified.

13.2 Should a change occur at the site such as closure of facilities, whereupon the conduct, benefits, protections or risk of the trial are affected, the REC is informed.

13.3 REC policy states that any unexpected events or risk elements that affect the research are reported promptly to the committee and other relevant bodies.

14 *Reporting and follow-up procedures*

14.1 A written report of the research status is submitted annually, or as requested, to the REC.

14.2 The REC is informed when a research is completed or terminated.

14.3 Whereupon a study is prematurely suspended the REC is notified with reasons, a summary of work to date and the strategy for participant after care.

14.4 Upon termination of a project, the facility where the research is conducted, sponsors or other interested parties are informed by the researcher.

14.5 Any amendment(s) to the research protocol would require REC approval before implementation.

15 *Informing research participants*
Participants in research receive suitable jargon free communications from the researchers about changes, termination, completion and availability of results.

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Declaration

The Publication Integrity & Ethics and the contributors to these guidelines acknowledge that many institutes and universities around the world have their own guidelines that deal with research ethics. These establishments expect their researchers to follow their guidelines and comply with them. The Publication Integrity & Ethics confirms that its guidelines on research ethics should not replace any existing guidelines of any establishment nor be followed by any of its researchers. However, P.I.E. is happy for any institute or university in the world, with existing guidelines on research ethics, to adapt part or all of the P.I.E. guidelines if the head of that establishment decides to do so and proper acknowledgement of P.I.E. is given.

The Publication Integrity & Ethics recognise that many institutes and universities in the developing world lacks guidelines on research ethics. P.I.E. is happy for any institute or university, who lack these guidelines, to construct their own guidelines based on this document as long as the head of that institute or university approves this decision and proper acknowledgement of P.I.E. is given.

Please note that you may require contacting the Medical, Dental or Pharmacy Council or the Department of Health in your country to seek approval before using these ethics research guidelines.