Position of the
European Network of Research Ethics Committees (EUREC) on the compensation of research participants

June 3, 2024

Preamble

Human participation in health-related research is integral to the advancement of biomedical sciences. However, clinical research entails significant burdens and potential risks to participants. The widespread use of compensation as a mitigating practice presents ethical challenges. EUREC asserts that RECs should play a proactive role when deciding on compensation matters, excluding the specific issues of compensation for research-related damages according to art. 76 of the Clinical Trials Regulation Nº 536/2014 of the European Parliament and of the Council of 16 April 2014 (CTR) and other applicable laws.

Position

1. For the purpose of this position paper, compensation of research participants may be categorised as (1) *reimbursement* for direct costs related to participation in research; (2) *compensation* for the loss of income, time spent on research, inconvenience, or research-related risks incurred by participants; (3) an *incentive* for participation in research; or (4) a *reward or token of appreciation* for participants.

2. In line with universal principles enshrined in the WMA Declaration of Helsinki (2013) and the CIOMS International ethical guidelines for health-related research involving humans (2016), the CTR (art. 28 lit) states that clinical trials may only be conducted when "*no undue influence, including that of a financial nature, is exerted on subjects to participate in the clinical trial.*" Consequently, the compensation paid to participants must be limited so as not to unduly influence individuals' freedom to choose whether or not to participate in research.

3. Compensation should not be linked to financial gain. Individuals in economically vulnerable situations must not be overrepresented in research due to their vulnerability, according to CIOMS 2016 Guideline 15. RECs are responsible for assessing whether these requirements are respected. On the other hand, balancing the risk of undue influence against potential exploitation, RECs have the authority to ensure that sponsors adequately compensate participants, as these participants should be recognised for their contribution to research without bearing the costs.

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4. CTR (Art. 7) mandates Member States to assess compensation arrangements, with RECs often playing a pivotal role in countries where legislation is not prescriptive. Compensation limits are legally defined in some countries, while others delegate this responsibility to RECs. RECs should exercise their best judgment in navigating the overlap between CTR and national legislation to ensure ethical compensation practices. To make comprehensive and consistent decisions on compensation and to properly inform sponsors, RECs should consider promoting the development of publicly available national guidelines.

5. Determining appropriate compensation is complex, and compensation need not always be monetary. RECs should consider regional factors, site types, and funding sources when deciding whether compensation is adequate. RECs should also be informed about possible other material goods given to participants, such as tokens of appreciation.

6. RECs should recognise the importance of patient and public engagement in ethical discussions to understand diverse motivations and perspectives on fairness; what RECs perceive as fair may not align with participants' perceptions.

7. The ethical link between compensation and risk levels must be deliberated by RECs, especially in clinical trials, where treatments may be ineffective or even dangerous, or when they involve healthy volunteers. RECs should be vigilant to prevent exploitation, inadequate or excessive compensation, or a lack of informed consent.

8. Participants in research should be fully informed about compensation arrangements, including the process for reimbursement, in the informed consent form.

Acknowledging the diverse conditions across European countries, RECs must recognise that a one-size-fits-all formula for compensation is impractical. The responsibility lies with RECs to navigate these complexities and make decisions that respect and protect participants.

This position paper is the result of a survey completed by EUREC members in June–September 2023 and a subsequent webinar series in October–November 2023, which revealed that understandings of compensation vary across Europe. To effectively rule on ethical considerations regarding compensation, research ethics committees (RECs) require a shared understanding of compensation.

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