

Region:

REK sør-øst / REK KULMU

Saksbehandler:

Telefon:

Vår dato:

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Vår referanse:

To whom it may concern

GUIDELINES ON COMPENSATION IN CLINICAL TRIALS CONDUCTED IN NORWAY UNDER REGULATION (EU) NO 536/2014, CLINICAL TRIALS REGULATION (CTR)

By *compensation*, we refer here to a monetary amount paid to a participant as compensation for time spent and discomfort experienced by taking part in a clinical study, and which is provided in addition to reimbursement of actual expenses related to travel, co-payment, and any loss of income.

The general rule in clinical trials should be that **no compensation is given beyond reimbursement of actual expenses**.

In studies involving healthy volunteers, however, participants are expected to be compensated.

If the sponsor wishes to provide compensation, this must be justified. Acceptable justifications may include improving recruitment or compensating participants for painful or demanding study procedures that are not part of standard care.

The compensation must reflect the time involved and the level of discomfort and must not be so high that it could compromise voluntary participation. This includes a thorough assessment focusing on whether the amount offered could lead to unequal participation based on socioeconomic status, resulting in nonrepresentative findings and poor scientific quality or lead individuals to take on a greater risk than they otherwise would.

The amount must be provided **per visit** or **per procedure**, rather than as a reward for completing the study. This structure should also be clearly reflected in the informed consent form. The amounts should be rounded sums and as simple and understandable set up for the participant as possible.

According to CTR Article 31 (d), Article 32 (d), and Article 33 (d), no incentives or financial inducements can be given to incapacitated subjects, minors, pregnant or breastfeeding women, or their legally designated representatives, except for compensation for expenses and loss of earnings directly related to the participation in the clinical trial.

Participation in clinical trials should, however, be free of charge for the participants, which means that all actual expenses related to study visits, beyond what they would ordinarily incur for treatment of their illness, must be reimbursed. This includes all actual travel expenses, co-payments, any loss of income, and funds for meals if visits last several hours or require the participant to attend in a fasting state. Set limits and max amounts to be refunded for such expenses should be avoided. As all patients should have equal opportunity to participate in clinical trials, it is not acceptable to exclude eligible patients because of their place of residence or the travel distance required to reach the study site.

It is sponsor's responsibility to ensure all information regarding participant compensation and refund of expenses is correctly described in the Informed Consent Form and the Compensation of trial participant document.

Regards,



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The ethics committee for Clinical Trials on Medicinal Products and Medical Devices (REK KULMU)
www.rekportalen.no