Fair compensation of subjects in clinical research in Belgium

The basic ethical principle is that participating in clinical research shouldn't cost the participant anything (on top of standard of care costs, if applicable).

As a general rule, all study-related expenses should be reimbursed (when advanced by the participant) or compensated for (when a reasonable fixed lump-sum has been agreed upon).

Rule applies to academic and commercial studies.

Compensation should be reflected in the ICF (payment form, frequency, amount,...).

If the sponsor does not want to bear study-related expenses, this should be clearly justified in the application dossier to the EC. If the EC agrees, this should be clearly reflected in the ICF.

Additional compensation, such as for time investment, inconvenience, or willingness to participate can be offered, but should be well-justified.

If the sponsor wants to include such compensations, these should be clearly justified in the application dossier to the EC which evaluates the acceptability of these costs in view of undue influence. If the EC agrees, compensation should be reflected in the ICF (payment form, frequency, amount,...).

Patients or healthy volunteers have equal rights to compensation although expected therapeutic benefit can be factored in.

A study can only take place if the benefit-risk ratio of such study is positive, meaning that the risks for the individual study participant cannot be higher than the potential benefits for such participant or society.

BAREC

For more information on what are study related expenses or what are considered correct amounts of compensation, please consult the guidance document.