25.10.2022, updated 28.12.2022

Instructions On Reporting Financial and Other Arrangements Related to Clinical Trials (CTR 536/2014)

This guideline shall also be used when the application of the clinical trial is submitted in line with the Clinical Trials Directive (20/2001/EC).

Background

The Finnish National Medical Research Ethics Committee (Tukija) gives opinions on the ethical acceptability of clinical trials. Examining financial aspects of the trial is part of the review of research ethics. The committee reviews the financial aspects included in the application at a general level. For instance, do financial factors influence the recruitment of research subjects, either through compensations paid to research subjects or rewards paid to researchers, to such an extent that the voluntariness of consent of the research subjects can be compromised? Are the researchers and other research staff's fees reasonable and in appropriate proportion to the amount of work required in the research?

To review the above-mentioned issues, Tukija shall obtain a sufficient explanation of the research's financial resources and their distribution among the various parties, as well as how research subjects are informed about the research's funding. However, Tukija cannot ensure in advance that the funds allocated to research are used appropriately.

Part II of the application shall be accompanied by an explanation of the basis for determining the compensations to be paid to researchers and other research staff, its amount, and its reasonableness.

Detailed explanations or, for example, the exact content of the agreements between the trial sites and the researcher and/or the sponsor do not need to be attached to the application. However, if necessary, Tukija has the right to request a supplement to the explanations already

National Committee on
Medical Research Ethics (Tukija)
Ratapihantie 9
PO Box 43, 00521 Helsinki, Finland

phone (switchboard): 0295209111
email: info@tukija.fi

provided.

In the application, the sponsor shall provide a reasoned assessment of whether the financial arrangements are sufficient and realistic, so that the trial can be carried out according to that plan and that the research subjects can be recruited without jeopardizing their voluntary consent. However, if during the trial it becomes obvious that there will be significant changes to the trial funding and fees, an application for a substantial modification shall be submitted to the EU portal.

Applicable Legislation

The EU Clinical Trials Regulation (Regulation (EU) No. 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials of medicinal products for human use and repealing Directive 2001/20/EC) requires that clinical trials are subject to scientific and ethical review. The permission for the trial is given in accordance with the clinical trials regulation. During the transition period, the Clinical Trials Directive (20/2001/EC) and the Finnish Act on Medical Research (488/1999, version before 31.1.2022) will apply if necessary.

Description of Financial and Other Arrangements

A brief description of the financial arrangements of the clinical trial in accordance with Section 69 of the EU Clinical Trials Regulation Annex I P

The application dossier shall include information on the funding of the trial. In the ethical review of a clinical trial, the ethics committee considers the amount of the reward or compensation to be paid

to the researchers and to the subject, or the criteria for determining it, and possibly related procedures, as well as the key content of the agreement between the sponsor and the trial site.
When reviewing the ethical aspects of the trial funding, Tukija pays particular attention to the sponsor, funding sources, financial resources, total costs, and potential conflicts of interest of the actors (e.g., employment relationship with the sponsor).

The information shall include:

- Sponsor of the study
- Possible conflicts of interest and/or commitments of researchers and/or other research staff
- The total costs of the trial site and the basis for their formation (administration, premises, equipment, laboratory, and other services)
- Researchers' fees, estimated in euros (can be reported either as patient- or visit-specific fees or as "reimbursement fee")
- Remunerations of other research staff, estimated in euros (can be reported as either patient- or visit-specific fees)
- Resources related to recruiting research subjects