CONTINUOUS REVIEW DOCUMENT REQUIREMENTS of
Research Ethics Committee of the University of Tartu

Documents of the approved study for the continuous review should be submitted to the Ethics Committee electronically (to eetikakomitee@ut.ee) with **cover letter (has to be in searchable pdf format or MS Word format)**, which **shall contain at least the following information**:

1. Full title of the Project and Protocol or Study number

2. Principal Investigator(s): first name and surname, workplace, address of workplace, contact e-mail, phone no.

3. Numbers of Approvals given by the Ethics Commitee (number of the initial approval and number of the last approval).

4. List of documents being submitted

5. Correspondent: first name and surname, address, phone, e-mail.

According to the Regulation No. 23 of the Minister of Social Affairs of 17 February 2005 Conditions and Procedure for Conducting Clinical Trials of Medicinal Products § 9, § 10, § 12 and Medicinal Products Act (16th December 2004) § 90 the following documents should be submitted to the Ethics Committee:

- **Protocol amendments and changes in study plan**
- **All reports of SUSARs occuring in clinical trial of an investigative medicinal product in any study site in Estonia.**
  The sponsor shall enter reports on suspected serious unexpected adverse reactions occurring in the clinical trial of an investigative medicinal product or reference medicinal product in Estonia in the European Pharmacovigilance database and notify the Agency of Medicines thereof, bearing in mind the following deadlines:
  1) suspected serious unexpected adverse reactions that are fatal or life-threatening shall be reported immediately, any case no later than seven calendar days after knowledge by the sponsor of such a case;
  2) other suspected serious unexpected adverse reactions which are not fatal or life-threatening shall be reported within fifteen calendar days after knowledge by the sponsor of such a case.

- **Annual safety report of all SUSARs which appeared in any study site of the world** (should be sent by the study sponsor).
  Once a year, the sponsor is required to submit a written report on serious adverse reactions of the investigational medicinal product identified in any country to the Agency of Medicines, and in case of veterinary medicinal products, also to the Ministry of Agriculture.

- **Notification of the end of a study** (If a study is terminated earlier than it was planned, the notification with justification of the termination should be sent within 15 days. If the study ends by the plan, the notification should be sent within 90 days.)
- At least **once a year synopsis of the studies** approved by the committee (should be sent by the Prinicpal Investigator of the study).

NB! Changes in any previously approved document should be marked clearly. →

All documents of the approved study for the continuous review should be submitted to the Ethics Committee electronically to eetikakomitee@ut.ee. The e-mail shall contain Title of the Project, Protocol or Study number, List of documents being submitted. Names of attached files have to be clear and generally understandable.

Any further questions, please contact us!

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