Annex to Minister of Social Affairs Regulation No. 17 of 17 February 2005 "Rules of procedure of medical ethics committee for clinical trials, a list of data to be submitted for obtaining approval, procedure for adoption of resolutions and format of application for obtaining approval"

APPLICATION FOR OBTAINING APPROVAL FROM ETHICS COMMITTEE FOR CONDUCT OF CLINICAL TRIAL

To be completed by the ethics committee:

Filing date of application: Filing date of request for supplements to application: Filing date of supplements to application: Granting consent: Yes ... No ... Date:

To be completed by the applicant:

1. DATA CONCERNING CLINICAL TRIAL

EudraCT number[2] Title of the trial: Sponsor of the clinical trial, number, version and date of the trial protocol: Abbreviated title of the trial where available:

ISRCTN number[3] (if available):

2. PERSONS CONDUCTING CLINICAL TRIAL AND TRIAL SITES

2.1. Principal investigator:

given name and surname:

scientific degree:

profession:

place of employment:

address of place of employment:

telephone number and other contact details:

signature:

2.2. Subinvestigators:

given name and surname:

scientific degree:

place of employment:

profession:

signature:

2.3. Name and signature of the head of the health-care institution of principal investigator (concerning consent with the conduct of the clinical trial) and date.

3. FUNDING OF TRIAL

source:

total cost of trial, including distribution of remuneration payable to subjects conducting the trial (to whom to what extent):

payment of compensation to clinical trial subjects:

conditions of insurance of clinical trial subjects:

4. SHORT SUMMARY OF CLINICAL TRIALS CONDUCTED IN THE SAME FIELD UP TO PRESENT DATE

5. DETAILED SUMMARY OF PLANNED CLINICAL TRIAL AND REASONS FOR CONDUCT THEREOF

6. TIME OF CONDUCT OF CLINICAL TRIAL

7. DETAILED DESCRIPTION OF CLINICAL TRIAL SUBJECTS AND THE METHOD OF THE RECRUITMENT OF THE PARTICIPANTS (number of participants, how and from among whom the selection is made)

8. DETAILED DESCRIPTION OF RESEARCH METHOD

9. DESCRIPTION THE ETHICAL ASPECTS OF TRIAL BY CO-ORDINATING OR PRINCIPAL INVESTIGATOR

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[1] RTL = *Riigi Teataja Lisa = Appendix to the State Gazette*

[2] Confirmation of EudraCT number to be added

[3] International Standard Randomised Controlled Trial Number