BASIC FORM

Institute:

Solver:

Project type:

Survey duration:

Submitter or sponsor:

Grant:

Name of the project:

focus of work/thesis:

a) clinical
b) experimental-clinical
c) experimental animals
d) it is not biomedical research

Aim of the project:

EXAMINED SET:

- ill	yes	no
- healthy	yes	no
- minor	yes	no
- mental or physical impaired	yes	no
- it is a selected group (social, ethnic, racial)	yes	no

INVESTIGATED SET OF THE EXPERIMENTAL STUDY

- - laboratory rat – strain SPRAGUE DAWLY yes no

- rabbits yes no
- other (specify which) yes no

STUDY EXPECTS:

- physical risk yes no
- psychological risk yes no
- social risk yes no
- discomfort yes no
- intervention in the private sphere yes no
- disclosure of information which may harm the entity or otherwise yes no

STUDY EXPECTS:

- use of medical records (on illness, etc.) yes no
- use of foetal or embryonic tissue yes no
- use of body fluids (urine, cerebrospinal fluid, blood) yes no
- organ use yes no

INFORMATION FOR SUBJECT:

- the subject will receive information material yes no
- do you have an opinion that the participation of the subject will improve its health condition, or increase his interest in the disease yes no

WILL YOU INFORM SUBJECT:

- that this is a research task yes no
- that participation is voluntary yes no
- what is the purpose of the project (tasks) yes no
- what is the expected duration of the research yes no
- what is the expected benefit for the subject, or for others yes no
- what is the nature of the drug, or intervention yes no
- that the subject may have other treatment yes no
- what would be an alternative therapy yes no
- what risks, or discomfort the subject can expect yes no

- that the subject may refuse to participate without giving a reason and without disruption the quality of medical and preventive care yes no
- that he/she may at any time request to suspend his participation yes no
- that all information obtained is confidential yes no
- that the information obtained will be assessed by authorized persons, or competent specialists yes no
- what procedures are planned in case of an acute event yes no

I further agree:

- that in case of any change in the project (task) which would affect the rights and integrity of the subject, I will request additional consent;
- if the study will last longer than stated in the application, I will announce the change to the Ethics Committee of the Faculty of Medicine UPJŠ in Košice;
- with sending one copy of the final report to the Ethics Committee of the Faculty of Medicine UPJŠ in Košice no later than half a year after its completion.

In Košice, day

signature of the responsible solver