



Etická komisia Detskej fakultnej nemocnice v Bratislave

ETHICS COMMITTEE of Children Hospital in Bratislava

Limbova 1, 833 40 Bratislava, Slovakia

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ROZHODNUTIE DECISION

SCHVÁLENIE NOVÉHO PROJEKTU NEW PROJECT APPROVAL

1. Názov projektu: Mutačná analýza génov ovplyvňujúcich štruktúru a funkciu primárneho cilia a ich význam pri autozómovo dominantnej polycystickej chorobe obličiek (ADPKD).

Project Title: Mutational analysis of genes affecting the structure and function of the primary cilium and their role in autosomal dominant polycystic kidney disease.
2. Vedúci projektu: prof. MUDr. László Kovács, DrSc. MPH
Principal Investigator
3. Spoluriešitelia: RNDr. Katarína Skalická, MUDr. Gabriela Hrková, Mgr. Anita Vaská, Mgr. Ágnes Baranyaiová, MUDr. Pavol Janega, CSc., MUDr. Zuzana Žilinská
Sub-investigators
4. Pracovisko: Laboratórium klinickej a molekulovej genetiky 2. Detskej kliniky LFUK a DFNSP
Trial Site: Laboratory of Clinical and Molecular Genetics, Department of Paediatrics, Faculty of Medicine, Comenius University and University Children's Hospital
5. Vedúci pracoviska: prof. MUDr. László Kovács, DrSc. MPH
Principal Workplace
6. Kód projektu: APVV-14-0234
Project Code
7. Sponzor projektu: Agentúra na podporu vedy a výskumu
Project Sponsor: Slovak Research and Development Agency
8. Ciele projektu:
The goal of project:
 1. to consider the integrity of primary cilium structure by identification of genetic alterations affecting its length
 2. to evaluate the status of ciliogenesis and sensory function of the primary cilium by molecular analysis of genes encoding the proteins of transport mechanism
 3. to identify the defects in signaling pathways of the primary cilium by the molecular analysis of genes encoding a key signaling proteins
 4. to evaluate the importance of the confirmed genetic alterations in respect to ADPKD pathogenesis

The analysis will be made using polycystic kidney tissues obtained by nephrectomy. The study will include native tissues or formalin-fixed paraffin-embedded tissues polycystic kidney and matched normal kidney tissues.

Informed consent must be given on a consent form which must be signed by participants before the start of any project. Participants should then be provided with a copy of their signed consent form.

The results of research project may provide a new source of information on the causes of polycystic kidney disease and to form the basis for subsequent pharmacogenomic analysis.

The results of the project will be presented at home and international conferences and will be published in current contents journals or in SCI indexed journals. The research results will be presented anonymously, in accordance to the protection of personal data of the research participants.

Po preskúmaní vyššie uvedených dokumentov z hľadiska dodržiavania etických noriem a platných medzinárodných dohôd o realizácii experimentálneho a klinického výskumu rozhodla takto:

After reviewing above mentioned documents from the point of observance ethic norms and valid international agreements on realisation of experimental and clinical research decided to

schvaľuje / ~~neschvaľuje~~ uskutočnenie vyššie uvedeného projektu
approve / ~~disapprove~~ realisation of the above mentioned project

Komisia berie na vedomie, že projekt sa nezačne skôr, ako komisia obdrží súhlasné stanovisko zo ŠUKL-u.

The committee understands that the investigator undertakes not to start the clinical trial before the committee has received a copy of the written approval of ŠUKL.

Prehlasujem, že táto etická komisia pracuje podľa požiadaviek ICH GCP 135/95 a príslušných právnych noriem a nariadení.

I hereby confirm that this Independent Ethics Committee is organised and operates according to ICH GCP 135/95 requests and the applicable laws and regulations.

MUDr. Júlia Horáková, PhD
Predsedníčka etickej komisie



Dňa: 15.6.2016
Date

Podpis predsedu EK alebo zástupcu
Signature of chairmen or Vice chairmen of the EC