



The Arab Republic of Egypt  
Ministry of Higher Education  
Health Research Ethics Committee  
Assiut University  
Faculty of Medicine

## **NATIONAL APPLICATION FORM FOR ETHICAL APPROVAL OF A RESEARCH**

The application technical and ethical guidelines format are to be read before completing this form to ensure that the questions are answered appropriately.

You may find it helpful to read both national technical and ethical guidelines and then fill the format. You can add extra pages.

Before requesting an individual's consent to participate in research, the investigator must read chapter three in the Guidelines for Ethical Conduct of Research Involving Human Subjects.

The Arabic version of the informed consent is the form to be used to take the consent from the Egyptian research participants, so you should fill it in details and in a language or another form of communication that the individual can understand the research subject.

Ministry of Higher Education  
2007

**Do not include this page with your application form**




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## NATIONAL APPLICATION FORM FOR ETHICAL APPROVAL OF A RESEARCH PROPOSAL

Please read the technical and ethical guidelines thoroughly before filling the form  
**Technical proposal form**

### **Applicant**

<input type="checkbox"/> Name: Sherifa Ahmed Hamed
<input type="checkbox"/> Institute: Assiut University, Faculty of Medicine
<input type="checkbox"/> Current position: Professor of Neurology
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<input type="checkbox"/> Signature 

### **Title of the study**

**Vestibular function for children with insulin dependent diabetes using cervical vestibular-evoked myogenic potentials (cVEMP) testing**

### **Introduction/methodology/data collection/data analysis**

Healthy vestibular system adjusts balance during static and dynamic conditions which is important for normal development (standing up and walking). Vestibulopathies (central and peripheral) are common complications of adults with diabetes. Related studies are scarce in children with type 1 diabetes (T1D). We aimed to assess the saccular function of the otolith organ in children with T1D and determine predictors for vestibular abnormalities. We used

cervical vestibular evoked myogenic potential (cVEMP) was used for objective evaluation. This study included 40 patients (boys=15; girls=25) and 25 healthy children. Patients had mean age of  $13.63 \pm 1.50$  yrs, duration of diabetes of  $5.62 \pm 2.80$  yrs, frequent attacks of diabetic ketoacidosis (55%) and hypoglycemia (30%), hyperlipidemia (20%), hypertension (12.5%) and peripheral neuropathy (40%). All had normal basic auditory evaluation. Dizziness was reported in 10%. Compared to healthy children, children with T1D had longer cVEMP P1 and N1 latencies and lower P1-N1 amplitude. Bilateral abnormalities cVEMP variables were observed 60% while unilateral abnormalities were found in 25%. Although marked abnormalities were found with longer duration of diabetes (>5yrs), HbA1c >7%, presence of DKA, hypoglycemic attacks and dizziness, however, the only predictors for longer P1 latency and lower P1-N1 amplitude were the duration of diabetes (>5yrs) [OR = 2.80 (95% CI = 1.80 – 5.33), P = 0.01; OR = 3.42 (95% CI = 2.82 – 6.81)] and its severity (HbA1c 7%) [OR = 3.05 (95% CI = 2.55 – 6.82), P = 0.01; OR = 4.20 (95% CI = 3.55 – 8.50), P = 0.001]. We conclude that the results of this study indicate that objective injury of saccular and its pathways are prevalent in children with T1D. Therefore, optimum glycemic control is mandatory.

#### Budget

Personal

#### Confidentiality

As a corresponding author, I declare that written informed consent was obtained from the patients for publication of their clinical, laboratory and neurophysiological data.

#### For office use only

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Approved



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