



Code No. : MS/69

Title of research:

Language and cognitive outcome for high risk neonates at the age of 2-3 years.

عنوان البحث:

المآل اللغوية والمعرفية فى الأطفال حديثى الولادة ذوى المخاطر العالية عند عمر سنتين إلى ثلاث سنوات.

Type of Protocol	
Master (M.S.) Thesis	√
Doctorate (M.D.) Thesis	
Philosophy Doctorate (Ph.D.) Thesis	
Research	
Research Project	

Principal investigator	Department	Duty in research
Doaa Mohamed Elshabrawy Elmetwaly	ENT department Unit of Phoniatics	Study of cases subjected to research in regard to history taking, clinical examination and performing language test, collecting data and writing the script of thesis
Mobile 01003304390	Home 050/2239716	e-mail : mhmdzohiri@yahoo.com
Co-investigators	Department	Duty in research
Prof.Dr. Tamer Samir Abou Elsaad	Unit of Phoniatics	The principal supervisor, managing and guiding the duties described above.
Prof.Dr. Hesham Elsayed Abdel Hady	Department of Pediatics	To assess medical condition of infants at age of 2-3 years those were admitted to neonatal intensive care unit.
Dr. Hemmat Mostafa Baz	Unit of Phoniatics	Sharing in supervision of the duties done by the candidate and helping in performing the language test

Protocol is accepted

Protocol should be revised

Signature of ethics committee chairman



Clinical Human Research

Subjects of Research

	Proposed number
Adult Male ♂	
Adult Female ♀	
Child Male ♂	√(The whole number will be 25 cases but gender distribution can't be justified prospectively)
Child Female ♀	√

Materials & Methods of Research

	Mention the type
Invasive techniques:-	
1. Drugs used	No
2. Dyes & materials for medical imaging	No
3. Endoscopy or catheters	No ?
4. Blood or CSF samples	No
5. Tissue biopsy	No
6. Others	No
Non- Invasive technique	<i>Psychometric evaluation.</i> <i>Language assessment.</i> <i>-Audiological assessment (when needed).</i>



Ethical Guidelines to Conduct Research on Human Subject

	Ethical Considerations	Yes	No	Non Applicable
1	Research is for the good of society	√		
2	Research has potential benefit to the subject	√		
3	Informed consent of human subject is taken	√		
4	Research is based on previous animal study		√	
5	Research will lead to unacceptable physical or mental suffering .		√	
6	No risk of unacceptable disability	√		
7	Risks are balanced in relation to benefits	√		
8	Facilities for research are available	√		
9	Investigator is scientifically qualified for this research	√		
10	Privacy & confidentiality of participants are assured	√		
11	Inclusion of vulnerable subjects (old age , children , adolescents , mentally ill , prisoners in custody) is justified i.e. : consent provided	√		
12	Is there a relation between funding authority and research point : * If yes specify on a separate sheet .		√	

Signature of principal investigator

Dr. A. Mohamed Elshabrawy