

**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<br>Elshabrawy Elmetwaly  | ENT department<br>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<br>Abou Elsaad   | Unit of Phoniatics                   | The principal supervisor, managing and guiding the duties described above.  |
| Prof.Dr. Hesham<br>Elsayed Abdel Hady | Department of<br>Pediatrics          | To assess medical condition of infants at age of 2-3 years those were admitted to neonatal intensive care unit.   |
| Dr. Hemmat Mostafa<br>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><br><i>Language assessment.</i><br><i>Audiological assessment (when needed).</i> |



## Ethical Guidelines to Conduct Research on Human Subject

|    | <b>Ethical Considerations</b>  | <b>Yes</b> | <b>No</b> | <b>Non<br/>Applicable</b> |
|----|--|------------|-----------|---------------------------|
| 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 :<br>* If yes specify on a separate sheet .                                     |            | √         |                           |

Signature of principal investigator

*Dr. Mohamed Elshabrawy*