

Application for Human use in Research

| | | | |
|-----------------------------------|--|------------------------------|--|
| Pre conduction بحث لم يبدأ بعد | | Post conduction بحث منتهى | |
|-----------------------------------|--|------------------------------|--|

١. Name of Researcher: _____

٢- Affiliation: _____

Institution: _____ Department: _____

٣. Mailing Address: _____

٤- e-mail: _____

٥- Phone number: _____ Mobile: _____ Fax number: _____

٤. Name(s) of Co-Investigator(s)

٥. Title of the research in English & Arabic عنوان البحث بالعربي و الانجليزي:

٦. Grade of Protocol: (circle your type)

| | | | | |
|-----|-----|----|----------|--------------------|
| MSc | PhD | MD | Research | Scientific project |
|-----|-----|----|----------|--------------------|

٧- The protocol work has been conducted: (circle your type)

| | | |
|---------------|--------------------------|--|
| International | Multicenter within Egypt | Other write (institution , department or Lab name): |
|---------------|--------------------------|--|

٨. Participant: Age: Children (< ١٨ years) _ Adults (> ١٨ years) _ Sex: (M/F)

Vulnerable groups: Yes: _ No: _

If yes, please describe: _____

٩. Quality of research & Sample size (check all that applies):

| | | | | |
|-------------|--------------------|--------------|-------------------|--------|
| Sample size | | | | |
| Drug Trail | Surgical Technique | Blood sample | Review of records | Others |
| | | | | |

١٠. Study Design (check all that apply):

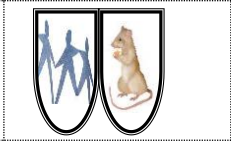
a.Type:Preclinical: _ Phase: (I: _ II: _ III: _ IV: _)

b. Randomization: Yes: _ No: _

c. Placebo: Yes: _ No: _

d. Genetic sampling Yes: _ No: _

e. Stored Tissue Samples



- Will there be any storage of tissue samples (blood/tissues)? ___
- Will there be any genetic analysis of the stored tissue samples? ___
- How long will the samples be stored? _____
- Will any stored samples be shipped out of the country? ___

f. Other _____

11. The research is for the good of society: Yes: _ No: _

12. Facilities for the research are available: Yes: _ No: _

13. List the risks of the study:

Additional information for clinical:

14. Request is being made to waive informed consent: Yes: _ No: _

If yes, please explain why:

15. List the potential benefits, if any, to the subjects:

16. The risks are reasonable to the potential direct benefits: Yes: _ No: _

17. Privacy and confidentiality of subjects are assured: Yes: _ No: _

18. It is clearly stated that the subject of the research could withdraw at anytime without penalty or loss of any benefits to which they would otherwise be entitled: Yes: _ No: _

19. **Informed consent forms must be attached** Yes: _

If No why

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SIGNATURE OF THE RESEARCHER

DATE