Serial Number:

Date Received:

Investigator Application Form

1. Name of Researcher		
2- Qualification of Researcher	☐ BSc ☐ MSc ☐ PhD ☐ Other	
3. Name of Institution/ Department		
4. Address of Researcher		
Email address		
Phone/Mobile no		Fax no.
5. Name(s) of Co-Investigator(s)		
6. Grade of Protocol	☐ MSc ☐ PhD ☐ Research paper	
7. Title of the Research Project		
8. Type of Research Design (check all that apply)	☐ Experimental ☐ Descriptive ☐ Observational	

9. Subjects of Research	☐ Children (< 18 years) ☐ Adults (≥ 18 years) Vulnerable groups ☐ Yes ☐ No If yes, please describe…… …… ……
10. Request is being made to waive informed consent	☐ Yes ☐ No If yes, please describe…… …… ……
11. The research is for the good of society	☐ Yes ☐ No If yes, please describe …… …… ……
12. Facilities for the research are available	☐ Yes ☐ No
13. List the risks of the study	…… …… ……
14. List the potential benefits, if any, to the subjects:	…… …… ……

15. The risks are reasonable to the potential direct benefits to the subjects, if any, or to the knowledge to be gained …….. ☐ Yes ☐ No

16. Privacy and confidentially of subjects are assured …….. ☐ Yes ☐ No

17. It is clearly stated that the subject of the research could quit at anytime without penalty or loss of any benefits to which they would otherwise be entitled …… ☐ Yes ☐ No

18. Informed consent form is attached …… ☐ Yes ☐ No

Silverman *et al* (2006). Enhancing Research Ethics Committees in Egypt Guidelines for Standard Operating Procedures. ***The Monitor***, 49-52.

REC Review Checklist

Title of Research	
Principal Investigator	
Primary Reviewer for the SRRC	

Social Value	**Yes**	**No**	**N/A**
1. Does the research have the potential to enhance the future health of society?			
2. Has the community been involved with the planning of the research?			
Scientific Design			
3. Will the research be performed by qualified investigators and at proper facilities?			
4. Is the research design appropriate for answering the research question?			
5. Does the control group adequately represent the local standard of care?			
6. Are the experimental procedures adequately described?			
7. Are there any other scientific issues that need to be addressed?			
Subject Recruitment			
8. Is it clear who will be enrolled as research subjects or whose records will be used in the research?			
9. Is the selection of subjects fair and equitable? *(Consider purpose, setting, inclusion and exclusion criteria)*			
10. Does the study have the potential for enrolling subjects who might be decisionally impaired? If yes, a. will there be proxy consent? b. should the investigator assess the capacity of subjects to make their own decisions?			
11. Does the study involve any vulnerable groups? *(e.g., pregnant women and fetuses, children, prisoners, decisionally impaired, institutionalized, socially or economically disadvantaged, employees, students)?* If yes, a. are additional safeguards needed to protect the rights and welfare of the vulnerable groups?			

	Yes	No	N/A
b. state which ones are needed …… …….			
12. Does any compensation for participation (e.g., financial, prospects of free medical care, etc.) represent an undue inducement to participate?			
13. Does the recruitment setting present any potential for coercion?			
14. Were all recruitment materials submitted? *(posters, brochures, contact letters, TV, radio, newspaper, ads)*			
15. Are the recruitment materials acceptable as submitted?			
Risk / Benefit Analysis			
16. Are there physical or medical risks related to study participation?			
17. Are there psychological or emotional risks related to study subjects?			
18. Are there social, economic, or legal risks related to study participation?			
19. Are there risks to society in general?			
20. Are risks adequately minimized?			
21. If not, how can risks be further minimized? …… ……			
22. What is the risk level of the research? ☐ Minimal risk ☐ Above Minimal Risk ☐ Too Risky			
23. Are there potential direct benefits to individual research subjects?			
24. Are there potential for the future health of society?			
25. Will the community/country benefit from the results of the research after the research is over?			
Analysis of Risk and Benefits			
26. Are the risks to subjects reasonable in relation to the anticipated benefits to the subjects and/or society?			
Confidentiality			
27. Are there adequate safeguards to protect subject privacy?			
28. Are there adequate provisions to protect the confidentiality of the data?			

Stored Tissue Samples	Yes	No	N/A
29. Will there be any storage of tissue samples (blood/tissues)?			
30. Will there be any genetic analysis of the stored tissue samples?			
31. Will a code be used to label the stored tissues? If yes, will the code contain any information that can potentially identify the subject?			
32. Will subjects have the option to withdraw their samples at any time?			
33. How long will the samples be stored? ……			
34. Based on questions 32-34, are there safeguards to protect the privacy and confidentiality of the stored samples and the information from the stored samples?			
35. Will any stored samples be shipped out of the country?			
Informed Consent			
36. Is the researcher requesting access to records without informed consent? If yes, explain why this is justifiable ……. ……...			
37. Is the informed consent checklist completed, and is the consent form adequate?			
38. Is the short consent form needed for individuals who are illiterate?			
Safety Monitoring			
39. Are there procedures to monitor the safety data (i.e., serious adverse events, reasons for withdrawal/discontinuation) collected to ensure the safety of subjects?			
40. Is there a Data and Safety Monitoring Board (DSMB)?			
41. Are there any planned interim analyses?			

Recommendation

Approval

List nonbinding suggestions, if relevant: …….

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Approval with Modifications

List modifications ……..…….

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Deferral

List issues …….

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Disapproval

List issues …….

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Informed Consent Form

Elements of Informed Consent	Yes	No	N/A
1. Description of Research: - An statement that the study involves research - An explanation of the purposes of the research - Expected duration of the subject's participation - A description of the procedures to be followed - Probability of random assignment to each intervention - Identification of any procedures that are experimental			
2. Risks and Discomforts: A description of any reasonably foreseeable risks or discomforts to the subjects.			
3. Benefits: A description of study benefits to the subjects or to others.			
4. Alternatives: A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subjects.			
5. Confidentiality: A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.			
6. Compensation for injury: For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether medical treatments are available if injury occurs.			
7. Subjects' Questions and Queries: An explanation of whom to contact for answers to pertinent questions about the research, whom to contact for questions regarding research subjects' rights, and whom to contact in the event of a research-related injury to the subject.			
8. Voluntary participation: A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.			

Additional Elements of Informed Consent (When Appropriate)

☐ 1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.

☐ 2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.

☐ 3. Any additional costs to the subject that may result from participation in the research.

☐ 4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.

☐ 5. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.

☐ 6. The approximate number of subjects involved in the study.

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REC Statement of Confidentiality

_____ agrees, subject to the conditions below, to disclose information in confidence to

_____ relating to projects being evaluated by _____

_____ agrees as follows with respect to the confidentiality of such information.

1. _____ will not disclose or use any such confidential information (other than to the extent reasonably to perform obligations as directed by _____ unless:

   1.1 the subject matter was or becomes generally public knowledge; or

   1.2 the subject matter was or becomes generally public knowledge; or

   1.3 the subject matter is made known to _____ by a third party who by such a disclosure is not in breach of duty or obligation toward _____.

2. Neither _____ nor _____ agents or employees shall distribute or disclose any such confidential information without the prior written consent of RECRC.

3. For purposes of this Statement, _____ considers and will treat as confidential information all business, clinical and procedural information shared by _____.

_____ _____

Signature of REC Official Signature of Recipient

_____ _____

Date Date

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