HUMAN RESEARCH
APPLICATION SUBMISSION FORM

Principal Investigator's name (including title):

……

Project Title:

……..

Simplified Project Title (Optional)**:**

……...

Part A. THE INVESTIGATORS

Principal Investigator's Name : (This is the person with overall responsibility for the conduct of the project and reporting against it. If this is a student project, including a PhD project, then the student's main supervisor should be listed as Principal Investigator on this ethics application.)			
Qualifications :			
Organisational Affiliation :			
Position :			
Phone : **Mobile:**		**Fax:**	
Work Email :			

2nd Investigator's Name:			
Qualifications :			
Organisational Affiliation:			
Position :			
Phone : **Mobile:**		**Fax:**	
Work Email :			

3rd Investigator's Name:			
Qualifications:			
Organisational Affiliation:			
Position :			
Phone : **Mobile:**		**Fax:**	
Work Email :			

Copy and Paste tables to include more Investigators as necessary.

Part B. THE PROJECT

Title:

1. Type of project:
Formatting Tip: Tick all relevant boxes by double-clicking on the box and marking 'Default Value' as 'Checked'.

☐ **Funded research (complete Q34)**

☐ **Un-funded research**

☐ **Commercially Sponsored Clinical Trial**

☐ **Student – Postgraduate Research**

☐ **Student – Postgraduate Coursework**

☐ **Principal Investigator Driven Clinical Trial**

2. Is this project a continuation of a current or previous project with ethics approval? ☐ **Yes** ☐ **No**

If YES, please provide HREC file reference number: …….

3. Has this project been submitted to any other ethics committees? ☐ **Yes** ☐ **No**

If YES, please provide the following details:

Ethics Committee (incl. Human, Animal and Biosafety Committees)	**Status** (To be Submitted, Submitted, Approved, Not Approved)	**Date**	**Copy of Ethics Approval Attached?**

***Please note that ethics approval cannot be granted retrospectively.**

4. Proposed commencement date of project: ……..

5. Proposed completion date of project: ……

6. Background to the project:

- Briefly describe the history of the topic you intend to address.

7. Aims of the project:

- Briefly describe your primary research question and what outcomes you hope this project will achieve in 100 words or less.

8. Participant level of involvement and selection criteria:

- Please list the **study sites** including where data will be collected from and where it will be analysed.
- Briefly describe on what basis participants will be included in, or excluded from, the project, the recruitment process that will be used, and the participants' level of involvement.
- What are the inclusion criteria and the exclusion criteria?

9. Design & methodology:

- Briefly outline the methods you propose using to achieve the aims of the project including data analysis methodology

10. Will written informed consent be sought? ☐ **Yes** ☐ **No**

- **If YES**, please attach copies of the proposed Participant Consent Form.
- *The consent of patients is the Hospital responsibility not the responsibility of the Ethical Committee of Sinai University.*

11. Possible Investigator Conflicts of Interest:

(a) Do any potential 'dependent or unequal relationship' issues arise between any of the named investigators and the conduct of this research? (e.g. relationships between researchers and participants that may compromise the voluntary nature of participants' decisions).

Yes ☐ **No** ☐

(**If YES**, please provide details of the conflict of interest and mechanisms in place to address these issues)

(b) Do any of the named investigators have access to personal or other sensitive information required for the conduct of this research as a condition of employment, rather than as a researcher?

Yes ☐ **No** ☐

(**If YES**, please provide details)

(c) Do any of the named investigators have any current or previous affiliation with, or financial involvement in, any organisation or entity with direct or indirect interests in the subject matter or materials of this research?

Yes ☐ **No** ☐

(**If YES**, please provide details regarding the nature of the affiliation(s) and matters that may need consideration)

(d) Do any of the named investigators have any other potential conflict of interest issues not covered above?

☐ **Yes** ☐ **No**

(**If YES**, please provide details regarding the nature of the conflict(s) and matters that may need consideration)

Part C. THE RESOURCES

1. Funding:

- Name all sources of funding, sponsorship and interested parties)

Has this project been submitted for funding? ☐ **Yes** ☐ **No**

If YES,
Name of Funding Body :

Title of Application :

Investigators Named on Application :

Duration of Support :

Status (*i*.e. Submitted, Funded) **:**

2. Basis of funding agreement:

- Provide details about any agreements regarding payment to researchers for enrolment of participants.

Part D.

فى حال انطبقت المادة ٤ او المادة ٢٣ فى قانون تنظيم البحوث الطبية الاكلينيكية المصري رقم ٢١٤ لعام ٢٠٢٠ولائحتة التنفيذية. علي الباحث/ راعي البحث/ منظمة البحوث التعاقدية استكمال اي موافقات لازمة من هيئة الدواء المصرية والمجلس الاعلى لمراجعة اخلاقيات البحوث الطبية الاكلينيكية طبقا لما نص عليه القانون المصري ولائحته التنفيذية.

مع ارفاق ما ينطبق من الاسباب التالية:

- بحث طبى إكلينيكي يشمل استخدام مركبات دوائية مستحدثة أو بيولوجية أو دواعى استعمال جديدة أو أشكالاً أو مستلزمات أو أجهزة طبية لم تستخدم فى جسم الإنسان من قبل ولم تحصل على اعتماد الجهات الدولية (المادة ٤)
- بحث يجرى مع جهات أجنبية أو دراسة عالمية مشتركة (المادة ٤) (لإستطلاع رأى جهاز المخابرات العامة
- تخزين او تسفير عينات بشرية) (المادة ٢٣ (

Part E. SIGNATURES AND DECLARATIONS

TITLE OF PROJECT:

- I certify that the information given is correct to the best of my knowledge.
- I acknowledge that I must notify the Committee in advance of any ethically-relevant variation to the project.

Principal Investigator:

Name Signature Date

2nd Investigator:

Name Signature Date

3rd Investigator:

Name Signature Date

4th Investigator:

Name Signature Date

If necessary, please copy and paste to include all researcher signatures.