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# KNH-UoN ERC APPLICATION FORM

| ETHICS RESEARCH COMMITTEE<br><br>**Application Number** |
|---|

Submit one copy of this form with original inked signatures. **Handwritten and /or incomplete forms** will not be accepted. All relevant appendices e.g. consent forms, questionnaires, instruments, drug information summary, data collection forms, debriefing statements, advertisements, etc.) must be included at the back of the proposal.

## I. PRINCIPAL INVESTIGATOR: Provide the information requested below:

Last Name First name Academic degrees

Professional titles and/or work position within your home institution

_____

Home institution(s) and/or department (s) approving this research project.

_____

Mailing address, telephone and fax numbers, and email address

All correspondence shall be addressed to the Principal Investigator. Research Administrators may have delegated signatory authority only when listed as Co-investigators.

## II PROJECT TITLE

_____
_____
_____
_____

As the Principal Investigator in this research I declare that:

1) Any change to this protocol and/or procedure shall be notified to and effected only after approval by the KNH-UoN ERC.
2) I shall notify the KNH-UoN ERC of intended publication, or any other form of dissemination of results of this study and provide the draft contents.
3) Other members of the research team are bound by 1) and 2) above.

_____ Date_____

Principal Investigator's Signature

**III RESEARCH PERSONNEL**. Please provide the information requested below for research administrators, co-investigators and collaborators in this research project.

_____

Last name First name Academic Degrees

_____

Professional titles and/or work position within your home institution

_____

Home institution(s) and department (s) approving this research project

_____

Mailing address, telephone and fax numbers, e-mail address

_____ Date_____

Research Administrators' Signature

_____ Date_____

Co-Investigators' Signature

_____ Date_____

Collaborator's Signatures

REQUIRED ATTACHMENTS

1. Letters of Study Approval from the Principal Investigator's Home Institution (Department).
2. One copy of the Curriculum Vitae of each member in the research team describing their research qualifications and experience.
3. Research Personnel Information (Roles and responsibilities in the research project).

## IV FUNDING INFORMATION

Briefly describe current and pending grant and contract information

## V. DESCRIPTION OF RESEARCH PROJECT

Please provide an executive summary of this research project including, in non-technical language, the following information:

**1) Background and Purpose of Research**

a) A clear justification for the study, its significance in meeting the needs of the country and/or participant population.
b) Summarize information on previous studies and on published research on this topic, including nature, extent and relevance of animal studies and other preclinical and clinical studies.
c) Explain what hypotheses or research question(s) this activity is designed to answer, its assumptions and its variables. Please state specific objectives and/or aims.

2) **Research Ethics**
Provide a definition of the ethical issues and considerations that you believe are implicit to this research project, and when appropriate, explain how you will deal with them.

3) **Research Methodology and Procedures**
   a) Study design.
   b) Research procedures (please use non-technical language).
   c) Source, amount or dose of the products/materials.
   d) Provide information (about the type of specimen, amount, use and destination) if shipment is required.

4) **Human participants in the project** (number and type of participants, inclusion/ exclusion criteria and the recruitment strategy).

5) **Study location:** Include a statement about the sites (s) where the study will take place. Attach letters of cooperation.

6) **Risks and benefits of the study**

7) **Potential adverse events and proposed interventions**
Please provide the information requested below in an attachment formatted as shown by the requested information.

   a) **Nature and Degree of Risk**: Describe any possible injury, stress, discomfort, invasion of privacy and other side effects from all study procedures, drugs and devices (both standard and experimental), interviews and questionnaires. Include psycho-social risks as well as physiological risks. Include risks arising from the withholding of standard procedures (Do not refer to the consent form).

   b) **Minimization of Risk**: Specify what steps you will take to protect the participant's rights and welfare. Please describe specific measures applicable to minors, foetuses-in-utero, prisoners, and pregnant women, decisional impaired or economically or educationally disadvantaged subjects.

   c) **Unknown Conditions**: Explain how you will handle the unanticipated discovery of a participant's unknown condition (disease, suicidal intention, genetic predisposition, etc.) as a result of study procedures.

   d) **Benefits:** Describe concisely and realistically the benefits of the proposed study for participant and for society (if none, please state accordingly).

   e) **Adverse Events Treatment**: Explain how you will handle adverse events that might result both immediately, and in the future, from study procedures. Please specify under what conditions an adverse event will be referred for treatment by someone outside the research team.

f) **Adverse Events Facilities**: Please state whether or not you have access to adequate facilities and equipment to handle possible adverse events. If not, please outline what measures you will take to handle the occurrence of an adverse event.

g) **Financial Responsibilities**: Please explain who will be responsible for the treatment of physical injuries resulting from participation in study procedures.

8) **Confidentiality of research data** (how to deal with direct identifiers, data storage, access and use).

9) **Ethical consideration**: Summarize the ethical issues arising from the study and how they will be dealt with.

10) **Additional information** (where applicable e.g. radiation exposure, access and use of private records, audio- visual recordings, etc.)

11) **Consent /assent forms and waiver** (Justify what applies):

- ☐ Written
- ☐ Oral
- ☐ Waiver