



IJN Research Ethics Committee

APPLICATION FOR RENEWAL FORM

For ethical clearance or approval approaching the one-year expiry date and requiring a renewal or extension, it is advisable to submit this form 30 days prior to expiry date.

Details of Research Project

Project Registration Number	
Project Title/Study Project	
Sponsor	
Investigator	

Date of initial approval : _____ Date of last annual renewal : _____

Status of the Research :

- Data Analysis Only
- Research on Hold. Reasons :

- Research has not Begun. Reasons :

- Recruiting Subjects. Version No. & Date of Consent Form :

- Following up on subjects.

Start Date (If not started, please give estimated date) : _____

Completion Date (If ongoing, please give estimated date): _____

Have there been any changes to characteristics of subject population (include selection criteria and any age, sex, physical, mental and health restrictions) since the last review?

- No
- Yes. Explain changes:

Have any amendments (protocol revisions, advertisements, informed consent form, etc.) to the study been submitted since the last review?

- No
- Yes. Please list them.

Have any Co-Investigator/Site been added or removed since the last review?

- No
 Yes. Please list them.

Report on Human Participants (if applicable)

Target Number of Subjects approved : _____

Actual Number Subjects recruited : _____

Number of subject screened : _____

Number of subjects still involved in the research : _____

Number of subjects who discontinued research : _____

Number of subjects who completed research : _____

Have any subjects withdrawn from this research since last approval?

- No
 Yes. Explain : _____

Report of Serious Adverse Events (SAE) (if applicable)

Total No. of SAEs notified to IJNREC : _____

No. of subjects involved : _____

Nature of SAEs (provide the numbers as per category below)

Results in death : _____

Is life threatening : _____

Required hospital admission or prolongation of hospitalization : _____

Persistent disability or significant incapacity : _____

Congenital anomaly / birth defect : _____

Required intervention to prevent permanent impairment : _____

How do SAEs affect the risk of the study and are any changes to the protocol being contemplated based on the SAEs?

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Provide a brief summary of any preliminary results obtained to date.

Has the study resulted in any publications?

Yes.

Titles : _____

No

Has there been any complaints about the study?

Yes.

Please explain : _____

No

Signature : _____ Date : _____

(DD/MMM/YYYY)

Investigator :

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RE-APPROVAL PERIOD : FROM : _____ TO : _____

Have there been any changes to the protocol which would impact approval as per IJNREC guidelines?

Yes

No

Other vulnerable populations include in the study : _____

Full Board Review Date: _____

Expedited Review Date: _____