



## IJN Research Ethics Committee

# NOTIFICATION OF CLOSURE FORM

### Details of Research Project

Project Registration Number	
Project Title/Study Project	
Sponsor	
Investigator	
Expiry Date	

### Reason for Closure

- Study Completed
- Cancelled prior to Initiation
- Discontinued due to insufficient enrollment
- Study closed due to safety
- Terminated by sponsor
- Other. Explain :

\_\_\_\_\_

Summary of results :

\_\_\_\_\_

Publications (*please give citation(s) and attach a copy of publications or manuscripts resulting from this protocol*):

\_\_\_\_\_

If industry sponsored, has the Sponsor conducted a close-out visit?

Yes       No       Pending       N/A

Date : \_\_\_\_\_ (DD/MMM/YYYY)

Summary of Study Participant Enrollment

- Retrospective Study Data
- Prospective Study Data :

a) Target Number of Subjects approved : \_\_\_\_\_

b) Actual Number of Subjects recruited : \_\_\_\_\_



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- i. Number of subjects screened : \_\_\_\_\_
- ii. Number of subjects enrolled : \_\_\_\_\_
- iii. Number of subjects completed the study : \_\_\_\_\_
- iv. Number of subjects who withdrawn/discontinued research : \_\_\_\_\_

**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 : \_\_\_\_\_

**Dissemination of Results :**

Have the results already been shared with participants?

- Yes       NO       Pending       N/A

**Data Security and Storage :**

Have data storage and security arrangements changed in any way?

- Yes       No

If yes, please clarify :

\_\_\_\_\_  
\_\_\_\_\_

How long will data be retained?

\_\_\_\_\_  
\_\_\_\_\_



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By signing below, the Investigator assures the information contained on this form is true and accurate.

Investigator's signature : \_\_\_\_\_

Date : \_\_\_\_\_

(DD/MMM/YYYY)

Name :

**FOR OFFICE USE ONLY**

Date Received :

Signed :

Date :