

Chairman Dr.	SRI NARAYANI HOSPITAL & RESEARCH CENTRE	
Member Secretary Dr.	SRIPURAM, THIRUMALAIKODI, VELLORE – 632 055 Vellore District, Tamil Nadu, India	

Letter for Submission of Application for Initial Review/Resubmission

Date: [DD/MM/YYYY]

Place:

From
Name [Principal Investigator]
Designation, Department & Affiliation

To,
The Member Secretary
SNHRCEC
Sri Narayani Hospital and Research Centre, Thirumalaikodi, Vellore
Sub: Protocol submission for IEC review

Dear Sir/Madam

We are interested in carrying out research on a project entitled
“ _____ ” in SNHRC. We are
submitting the duly filled application herewith as hard copy document along with a
softcopy. We request you take up this proposal for a discussion in the next IEC meeting.

Sincerely,

(Signature)

Name of the Principal Investigator

Chairman Dr.	SRI NARAYANI HOSPITAL & RESEARCH CENTRE	
Member Secretary Dr.		SRIPURAM, THIRUMALAIKODI, VELLORE – 632 055 Vellore District, Tamil Nadu, India

Enclosures:

Sl. No	Description	Particulars
1	Title of the Research Proposal	
2	Protocol Number	
3	Name of the PI, Designation, Department	
4	Name of Co-PI, Designation, Department	
5	Funding Source	
6	Duration of the Proposed Study	
	Will the research proposal be submitted to Health Ministry Screening Committee (HMSC) for International Collaboration	<input type="checkbox"/> Yes <input type="checkbox"/> No
	Does the research proposal require ICMR central ethics committee approval	<input type="checkbox"/> Yes <input type="checkbox"/> No
7	Information about the study for Volunteers	
	English	<input type="checkbox"/> Yes <input type="checkbox"/> No
	Tamil	<input type="checkbox"/> Yes <input type="checkbox"/> No
	Hindi	<input type="checkbox"/> Yes <input type="checkbox"/> No
	Bengali	<input type="checkbox"/> Yes <input type="checkbox"/> No

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8	Informed Consent from Study Volunteers	
	English	<input type="checkbox"/> Yes <input type="checkbox"/> No
	Tamil	<input type="checkbox"/> Yes <input type="checkbox"/> No
	Hindi	<input type="checkbox"/> Yes <input type="checkbox"/> No
	Bengali	<input type="checkbox"/> Yes <input type="checkbox"/> No
9	Translation of Informed Consent	
	Tamil	<input type="checkbox"/> Yes <input type="checkbox"/> No
	Hindi	<input type="checkbox"/> Yes <input type="checkbox"/> No
	Bengali	<input type="checkbox"/> Yes <input type="checkbox"/> No
10	Back Translation of Informed Consent	
	Tamil to English	<input type="checkbox"/> Yes <input type="checkbox"/> No
	Hindi to English	<input type="checkbox"/> Yes <input type="checkbox"/> No
	Bengali to English	<input type="checkbox"/> Yes <input type="checkbox"/> No
11	Translation Certificate	<input type="checkbox"/> Yes <input type="checkbox"/> No
12	Back Translation Certificate	<input type="checkbox"/> Yes <input type="checkbox"/> No
13	Details on Anticipated Risks and Mitigation Strategy	
14	Will the study participants receive compensation for travel, accommodation, and incidental expenses? If yes, give details	<input type="checkbox"/> Yes <input type="checkbox"/> No
15	Indemnity Insurance	<input type="checkbox"/> Yes <input type="checkbox"/> No
16	Clinical Trial Insurance	<input type="checkbox"/> Yes <input type="checkbox"/> No
17	Clinical Trial Agreement	<input type="checkbox"/> Yes <input type="checkbox"/> No
18	Any Other Relevant Information	<input type="checkbox"/> Yes <input type="checkbox"/> No
19	DCGI Approval/Submission Letter	<input type="checkbox"/> Yes <input type="checkbox"/> No
20	CV of Principal Investigator	<input type="checkbox"/> Yes <input type="checkbox"/> No
21	Soft Copy Submission	<input type="checkbox"/> Yes <input type="checkbox"/> No
22	Signature of Principal Investigator	

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DETAILS OF ONGOING / COMPLETED / TERMINATED STUDY

Sl. No	Description	Particulars
1	SNHRCEC Protocol Number	
2	Title of the Research Proposal	
3	Name of PI, Designation, Department	
4	Name of Co-PI, Designation, Department	
5	Funding Source	
6	Duration of the proposed study	
7	Date of Study Approval	
8	Name of Study Sponsor	
9	Name of CRO	
10	Study Initiation Date	
11	Study End Date	
12	DCGI approval Date	
13	Central Trial Registry of India Date	
14	Number of Volunteers/Patients from SNHRC	
	Screened	
	Recruited	
	Dropout	
15	Any Serious Adverse Events, if Yes, Provide Details	
16	Were there deviations from protocol, if yes, provide details of submission of revised protocol/amendment and approval date	
17	Publications if any, provide details	
18	Does the study require Extension, if Yes provide justification	
19	Signature of Principal Investigator	