INSTITUTIONAL RESEARCH ETHICS BOARD

ETHICS SUBMISSION FORM

INSTITUTE OF NEUROSCIENCES, KOLKATA

SECTION 1 PROJECT REGISTRATION

1.1a	**Project Title**

1.2	*When will recruitment of research participants start?* **Start Date**	
	When will all contact and follow up with study subjects and/or data collection be concluded? **End Date**	

1.3	**Principal or Lead Investigator at this site (I-NK).**			
	Name			
	Title & Position			
	Degrees			
	Departmental Affiliation			
Mailing Address	Building & Street Address			
	City, Province			
	Postal Code			
	Telephone		Fax	
	Email			

1.4	---------- Date: **Signature of Local Principal Investigator attesting following points:**

a) all co-investigators have reviewed the protocol contents and are in agreement with the protocol as submitted;
b) the investigator(s) will adhere to the Protocol and Consent Form as approved by the ICMR
c) the Principal Investigator will notify the DCGI/ICMR of any changes or adverse events/experiences in a timely manner;
d) the study will not start until the contract/ agreement has been approved by the appropriate university, hospital or research institute official;
e) if the study is funded by the Industry andif external regulatory approval is required, the investigators will not start the study until all approvals are in place.

1.5	List all co-investigators and collaborators. Include research personnel only if they have a significant role in the conduct of the study.Expand chart as required.		
Name	Title/Position	Degrees	Role

1.6a	Is this a multi-centered study?	YES	
		NO	
1.6b	If YES, who is the Principal Investigator or Project Leader for the entire study? Provide name and complete contact information.		

1.7a	What is the status of the funding or support for this project?	Funding not required	
		Funded by the Institution	
		Funded by Industry	
		Funded by any other Organisation	
1.7b	Name of funding agency(s) or sponsor(s) (In the case of grant funding also provide the grant or proposal number if known.)		
1.7c	Name of investigator receiving/applying for funding		

SECTION 2 PROJECT DESCRIPTION

2.1	**Provide a brief overview of the proposed research describing the population, intervention and outcome.**

2.2a	Is this a sequel to previously approved research?	YES	
		NO	
2.2b	If YES, indicate the previous ethics review number(s):		
2.2c	If YES, describe differences from the previously approved protocol(s):		
2.3	Background & Justification – Briefly summarize knowledge base and past human and/or animal research which has led to this project. When describing previous human studies or trials indicate the number of participants. (1 page maximum– adhere to page limitations)		

2.4	Study Design: Indicate which of the following best describes the type of investigation proposed. (select all that apply)		
Interventional Study		Pilot Study	
Placebo Control		Qualitative Study	
Randomized		Epidemiological Study	
Observational		Device Assessment/Development	
Case controlled		Open-Label Extension Study	
Cross sectional		Other-Specify	
Cohort			

2.5	Objectives and Hypotheses: Provide a clear statement of the purpose and objectives of the project. (i.e. Why are you doing the study?) State hypotheses and/or research question(s).

2.6	Methodology - Describe the study design and what will be done to the participants at each stage of the research. Investigators are encouraged to use flow charts or diagrams in their descriptions For clinical trials (if applicable) include a description of "stopping rules" or "discontinuation criteria". (2 page maximum – adhere to page limitations)

2.7	References – If possible please restrict the list to ten (10) of the most relevant references. References must be properly cited and contain the author, title of article, journal and page number(s).

Sample Size:		
2.8a	Number of subjects at this centre	
2.8b	Number of subjects in entire study	
2.8c	Number of centers participating	

For <u>all</u> study types (including pilot studies), justify the sample size on scientific grounds.

2.9	If a formal sample size calculation **was not performed**, justify why a formal sample size calculation is not required or possible; and give a rationale for the proposed number of subjects.

OR

2.10a	If a formal sample size calculation **was performed**, complete the following:	
2.10b	Alpha error and indicate if one- or two-sided	
2.10c	Statistical power	
2.10d	Estimated value of outcome measure in the ***CONTROL GROUP***	
2.10e	Difference which can be detected with specified sample size	

2.10f	Primary outcome measure	

2.10g	In lieu of the actual sample size calculation, provide a comprehensive reason or rationale for the choice of sample size, including reflections on the power of the study and when appropriate, clinical justification.

All other research studies in which a sample size calculation was done must complete Sections 2.11a and 2.11b

2.11a	Sample Size Calculation – give the actual calculation

2.11b	Sample Size Reference: Give a reference for the formula or method used. If a table in a published source was used instead of a calculation, provide the reference(s) and table reference numbers. If a sample size calculator was used, provide a description of the software package used and/or the URL for internet-based calculators.

2.12	Analysis - State how the data will be analyzed to fulfil each objective or to test each hypothesis. Please state specific primary and secondary end points if appropriate. (1 page maximum– adhere to page limitations)

SECTION 3: RESEARCH PARTICIPANTS

3.1a	Will the study involve males AND females?	YES	
		NO	
3.1b	If NO, explain why only one gender is being selected. (e.g. condition under study is gender specific)		

3.2a	What is the age range of the participants?	LOWER AGE LIMIT	
		UPPER AGE LIMIT	

3.3	Participant Inclusion and Exclusion Criteria: List all inclusion/exclusion criteria and indicate with an asterisk (*) those criteria which will be included in the Letter of Information.
3.3a	Inclusion Criteria
3.3b	Exclusion Criteria

SECTION 4: RESEARCH PROCEDURES AND PATIENT CARE

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4.1	Indicate which of the following interventions, testing or procedures are to be performed on the human participants ***as part of this research study***.			
	Drugs or Natural Products		Analysis of existing data	
	Devices		Analysis of existing biological specimens	
	Radiation		Cognitive or perceptual experiment	
	Magnetic Resonance Imaging		Chart or document review	
	PET Scans		Evaluation of program or services	
	Surgery		Observation of behavior	
	Non-surgical manipulation (e.g. physiotherapy)		Interview/survey/questionnaire/diaries	
	Collection of blood		Audio or video taping	
	Non-invasive physical measurements (e.g. BP, weight)		Gene therapy - *If the study uses a gene transfer vector, the vector is considered to be a drug and must be reported in drug section*.	
	Collection of other bodily materials or tissues		Other	

SECTION 5: BIOLOGICAL SPECIMENS TO BE COLLECTED FROM SUBJECTS

5.1	Are biological specimens (e.g. blood, tissue, muscle biopsies or tumor samples) to be taken or analyzed for the purposes of **this** research protocol?	YES	
		NO	

SECTION 6: QUESTIONNAIRES, FORMS & OTHER DATA TO BE USED IN STUDY

6.1	In the chart below list all questionnaires and forms etc. that will be used in the study and indicate who will be completing or administering the form. (e.g. subject , interviewer, nurse, spouse, caregiver, physician etc).**Expand chart as required.** Attach a copy of the data collection forms. E.g. Chart abstraction sheets, questionnaires, surveys, interview outlines etc. Do not insert copies of instruments in this chart; append them at the end of the protocol submission form. If there are no actual forms, you must append a comprehensive list of data to be collected or topics to be covered.

TITLE OF QUESTIONNAIRE, SURVEY, SCALE, DATA COLLECTION FORM ETC. (do not insert the questions or actual instrument here, append to the end of the submission**)**	**STATUS** Standard New Adapted	**WHO WILL COMPLETE OR ADMINISTER THE FORM?**

SECTION 7: PARTICIPANT RECRUITMENT & CONSENT PROCESS

7.1	Describe the method of recruiting and sampling participants.

7.2	Identify **who** will be contacting the potential participants to recruit them. In the case of patients, initial contact must be made by a member of the patient's health care team, circle of care or someone the patient would expect to have relevant information about them.

7.3	Indicate where the research will be conducted.