NATIONAL INSTITUTE OF MENTAL HEALTH AND NEURO SCIENCES
(INSTIUTTE OF NATIONAL IMPORTANCE), BANGALORE – 560 029

Date:

From:
Name and
Address of the Investigator (from NIMHANS)

To:

Chairperson/Member Secretary,

NIMHANS Ethics Committee

National Institute of Mental Health and Neurosciences

Bangalore-560029

"Through Proper Channel"

Sir,

Sub: Ethical clearance for the Clinical Trial protocol entitled "……"

I am herewith submitting 1 original + 3 hard copies and 14 CDs of Clinical Trial protocol entitled "……..……...…….." for consideration by the Institute Ethics Committee.

The Clinical Trial study awaits funding from M/s ……

Thanking you,

Yours sincerely,

Name &
Signature of the Principal Investigator

Encl. As above

Remarks of the HoD with Name, Signature & Seal:

Check List of Documents
(Required to be submitted to Ethics Committee)

Documents (1+3 Hard Copies + 14 CDs including all the duly filled in IEC forms including covering letter)	**Remarks (Tick the appropriate)**
1. Covering letter for the project proposal ("Through Proper Channel"……..	Yes/No
2. Summary Sheet of the research project ……..	Yes/No
3. (Clinical/Drug Trial proposal submitted for Ethical Clearance as per the NIMHANS Ethics Committee guidelines). ……	Yes/No
i. Consent form duly signed by the investigators/ collaborators. (Duly signed Attestation & Declaration Form)	Yes/No
ii. Consent of the concerned Head of the department ….. (Duly signed Attestation & Declaration Form)	Yes/No
iii. Consent of Head of the institute of which IEC clearance is sought.(Duly signed Attestation & Declaration Form)	Yes/No
iv. Authorization/ sanctioning letter (finance sanction) from sponsoring agency …….	Yes/No
v. Consent form as per the guidelines of NIMHANS IEC ….. (Informed Consent Form)	Yes/No
vi. Consent form for carrying out the required investigations from the concerned Heads of Department(s), if applicable……	Yes/No
vii. Undertaking by the investigator(s) …..	Yes/No
viii. **Other information:**	
1. Brief summary of the clinical trial.	Yes/No
2. A copy of the DCGI Clearance/Approval Letter (Regulatory Clearance)	Yes/No
3. A copy of the DGFT Clearance/Approval Letter (Regulatory Clearance) if the Human samples are lifted outside India).	Yes/No
<u>Compensation to research subjects from accidental injury:</u>	
4. A copy of the agreement/letter agreeing for the payment of immediate monitory relief to the patients/subjects for the study related injuries (temporary/permanent disability. In case of death, their dependents are entitled to material compensation)	Yes/No
OR	
5. A copy of the Insurance Policy for having covered the patients/subjects under Insurance for providing compensation for the study related injuries (temporary/permanent disability. In case of death, their dependents are entitled to material compensation)	Yes/No
6. Brief CV of the investigator (s) (one to two pages only) giving the professional experience; and title of 5 relevant publications)	Yes/No

Date: **Name and Signature of the Principal Investigator**

SUMMARY SHEET OF THE REAESRCH PROJECT SUBMITTED TO THE

HUMAN ETHICS COMMITTEE OF NIMHANS

IEC Meeting No: **Dt.:**
Protocol No.

1	**Title of the project**	
2	**Investigators and their Department(s)**	
3	**Funded or Non funded project? If yes, name of the funding agency (Govt, Private, Foreign)** **Is the project being submitted for funding?**	
4	**Are human subjects involved in the study?**	
5	**Does the study involve healthy volunteers / vulnerable population (Children, Pregnant women, mentally challenged etc.)?**	
6	**Type of study – Prospective/Retrospective**	
7	**Is the submission in NIMHANS – IEC format? (not the format of the funding agency)**	
8	**Does the study involve any invasive procedures? If yes, list the procedures and the possible risk** a) **Greater than minimal** b) **Not more than minimal risk** c) **No risk** d) **Only part of the diagnostic test (Refer to: ICMR Website)**	
9	**Detail the measures taken for reducing the risk**	
10	**Does the study involve biological specimens? If yes, list the specimens**	
11	**Does the research / study involve:** • **Human exposure to radioactive agents?** • **Human exposure to infectious agents?** • **Investigational new drug?** • **Investigational new device?** • **New treatment regime?** • **Use of new vaccines?** • **Observation of public behavior?** • **Fetal tissue or abortus?** • **Pathological or diagnostic clinical specimen only? (Mention source……)** • **Existing data available via public archives source? (specify……)**	

	• **Existing data available from co-investigator?**	
12	**Is informed consent form attached? If not, is there a justification?**	
13	**Does the informed consent form address the following :**	
	a) **Provide adequate information in a layman's language to the patient/surrogate?** b) **Is the method of selection of subjects' inclucing random selection, if applicable is explained?** c) **Are invasive procedures and possible risks adequately explained?** d) **Are financial implications explained to the patient/surrogate?** e) **Are there separate ICF's for patients and volunteers?** f) **If subject is a minor, is there an appropriate assent form?** g) **Is the course of action, in case, any abnormalities are detected during the investigation, clearly spelt out?** h) **Is provision for the subject to opt out of the study made explicitly** i) **Is confidentiality of the subject's data assured** j) **If major risks are involved, is mechanism of compensation for any injury suffered (e.g., Insurance) clearly spelt out?** k) **Are the contact details of the PI and investigators provided?** l) **If the study involves a biological specimen, is the consent obtained only for the current study or for future research also** m) **Are translations of the ICF in local languages provided?**	
14	**In case of Clinical Trials**	
	a) **Name of the drug (device) being**	

	investigated?	
	b) **Is the product currently in clinical use in India?**	
	c) **Does the trial involve an investigational new drug**	
	d) **Name and address of the manufacturer?**	
	e) **Is there a DCGI approval for the trial?**	
	f) **Is it a multi-centric trial? If yes, how many Indian and how many foreign centres are involved?**	
	g) **Does the drug have statutory approval for clinical use in the country of origin?**	
	h) **Does the study have a placebo arm? If does, what risk does it entail for the subjects? justify the use of the placebo**	
	i) **Is any standard treatment withheld in any subject as a part of the study? If yes, provide justification for the same and assurance of patient safety**	
	j) **Are the possible risks documented in the literature adequately explained in the ICF**	
	k) **Is the trial covered by an insurance scheme? (If yes, details)**	
	l) **Are there any conflicts of interest for the investigators: e.g., remuneration paid to the investigator by the company, investigator's financial involvement in the company**	
	m) **Implications of costs to the patient** n) **Does the trial cover the patient's treatment cost,** o) **Does the trial pay for the additional costs to the patient on account of his participation in the trial,** p) **Is the patient / volunteer provided remuneration for participating in the trial?**	
15	**In case of chart review / retrospective**	

	studies, please mention as to how the identify of the patient is de linked and how confidentiality is maintained?	
16	a. **Does the research deal with sensitive aspects of the subject's behavior such as sexual behavior, alcohol use or illegal conduct such as drug use?** b. **"Are there any elements in the protocol that are likely to induce anxiety or distress to the subject (e.g., intrusive questionnaire, presentation of material that is unpleasant to the participant etc.)**	
17	**Are there any other Ethical Issues involved in the investigation? If yes, please give a brief description?**	

18	**Indicate the biological samples collected for the proposed study (blood/CSF/tissue/muscle biopsy/cerebrospinal fluid etc.)** **If yes, how often?** **Will the samples stored for future research? Yes/No**	
19	**Whether the patient/participants are paid for incidental charges? Yes/No** **If yes, the same should be included in the informed consent form.**	
20	**Whether the proposed study is a collaborative study? Yes/No** **If yes, does the other institution have IERB? Yes/No** **If yes, have you received that IERB approval? Yes/No**	
21	**Is there a Bio-safety Department in the collaborative institute for disposing of biological samples in a scientific manner after carrying out investigation? Yes/No**	
22	**Whether the sample size allows enough power to detect the difference/results expected from the investigation? Yes/No**	

DECLARATION AND ATTESTATION FORM
(This form is applicable only for research projects/clinical trials)

I. I/We have read the terms and conditions for…….(insert name of the funding agency/sponsoring agency) Research Grant. Necessary Institutional facilities will be provided, if the research project is approved for financial assistance.

II. I/We agree to submit within one month from the date of termination of the project, the final report and a list of articles, both expendable and non-expendable, left on the closure of the project.

III. I/We agree to submit audited statement of accounts duly signed by the auditors of the Institute.

Signature of the:-

a) Principal Investigator (with date) **----------**

Name in Capital Letters:

Seal:

b) Co-Investigator(s) (with date) **----------**

Name in Capital Letters:

Seal:

c) **Head of the department with remarks (with date)** **----------**

Name in Capital Letters:

Seal:

d) Head of the Institution with remarks: **----------**

Name in Capital Letters:

Seal:

Date:

Annexure - IV

SPECIMEN CONSENT FORM

Title of the Study:

Information to participants:

This section should contain the information about the diagnosis made, if any, and also about the various modes of treatments available. Subject needs to be given the free choice of selection of the treatments that are available, including the one which is being considered for the research study purpose. Even if there is scope for slightest risk involved in the proposed mode of treatment/procedure, the same needs to be clearly informed to the participant and/or guardian of the person participating in the study. Participant in the proposed study be clearly informed about his/her right to withdraw from the study without any reason, if he/she desire so, and that would not affect in any way his/her treatment or of his/her ward/relative who is undergoing the treatment. Details regarding the scope of treatment in terms of duration, medications/procedures to be used and the clinical materials such as blood etc. that needs to be collected in terms of volume and periodicity be clearly stated in the information to be provided to the participant and/or the guardian **(investigator need to mention in the informed consent form that the blood (in terms of ml.)/specimen/sample to be drawn/collected will be specifically used for the study being undertaken and not for any other purpose).** This information be made available to the participant **in a language understandable to him/her**, it needs to be followed by with the request and assurance, as enumerated below, from the investigator. i.e.,

Undertaking by the investigator:

Your consent to participate in the above study is sought. You have the right to refuse consent or withdraw the same during any part of the study without giving ant reason. In such an event, you will still receive best possible alternative treatment, without any prejudice. If you have any doubts about the study, please feel free to clarify the same. Even during the study, you are free to contact any of the investigators for clarification if you so desire (investigator Name, Department and contact Telephone No. need to be furnished). Investigator has to declare that all the information/data collected from you (participant) will be kept in strict confidence.

Consent:

I have been informed about the procedures of the study. The possible risks too have been explained to me as stated in the information. I have understood that I have the right to refuse my consent or withdraw it any time during the study without adversely affecting my/my ward's treatment. I am aware that by subjecting to this investigation, I will have to give more time for assessments by the investigating team and that these assessments do not interfere with the benefits.

I, ……, the undersigned, give my consent to be a participant of this

investigation/study program/clinical trial.

Signature of the patient/guardian — Signature of the witness

(Name and address) — (Name and address)

Signature of the Doctor/investigator:

Name and Designation

Date : — Place:

Please Note :

1. The above format - is only a guideline, which may need to be altered according to the situation as to whether the participant is a patient, or patient's guardian or a volunteer who may take part in studies involving the study of normal subjects.

2. Informed consent form be made available to the patients/subjects/participants in a language which is understandable to him/her.

3. In the case of illiterates, Investigator has to explain/readout the contents of the informed consent form in a language which is understandable to him/her. After that, a certificate as given below be recorded.

"I have been explained the contents of the informed consent form in a language understandable to me and I am signing this document on my own".

Name of the Patient/Subject/Participant:

Signature/Thumb Impression:

Address:

4. The translated version of the informed consent form need to be certified by the translator (whoever translates) for its correctness/trueness with respect to English version (original version). *Also see certificate of translation which required to be furnished at the end of each informed consent form.

5. In case, the study involves only English speaking patients/subjects/participants, an undertaking stating that the "study involves only English speaking patients/subjects/participants" be furnished.

***CERTIFICATE OF TRANSLATION**

This informed consent form in …….version (mention language) is

translated by …….(indicate name of the translator)

and it is true/correct with respect to English (original) version.

Translator Signature with date:

Translator Name:

Address:

Annexure - I

From:
Name and
Address of the Investigator (from NIMHANS)

To:
Chairperson/Member Secretary,
NIMHANS Ethics Committee
National Institute of Mental Health and Neurosciences
Bangalore-560029

Sub: Ethical clearance for Research Project/Clinical Trial/Ph. D Thesis Protocol/MD Thesis Protocol entitled "……."

UNDERTAKING

With respect to the above said Research Project/Clinical Trial/Ph. D Thesis Protocol/MD Thesis Protocol (**strike off whichever is not relevant**) involving human subjects for which the ethical clearance being sought, I am to state that I have gone through the "NIMHANS Ethical Guidelines…….Human Subjects" and am aware of the rules governing the studies involving the human subjects. I am also aware that these guidelines are strictly to be followed while carrying out the above said research project involving human subjects.

Further, I also affirm that I will be responsible to keep inform the IEC of,

i. Any serious and unexpected adverse events and remedial steps taken to tackle them.
ii. Any new information that may influence the conduct of the study.
iii. Any changes made in the consent form.
iv. In the event of need to amend the original protocol approved by the EC, the proposed amendment shall be brought to the notice of EC for its consideration and approval. Under no circumstances I/we deviate from the original approved protocol without prior consent to that effect from the IEC.

Name and Signature of the Principal Investigator

Date: