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

Date:

From:
(Name, address, and contact details of the student)

To:
Chairperson/Member Secretary, Departmental Ethics Sub-committee
Department of (Mention name of Department here)
National Institute of Mental Health and Neuro Sciences
Bangalore-560029

"Through Proper Channel"

Sir / Madam,

Sub: Ethical clearance for the M.Sc/M.Phil/PDF/Ph.D/MD/DM Thesis Protocol **(Tick the appropriate)** titled "……"

I am herewith submitting 1 + 1 (Hard Copy) of the M.Phil/PDF/Ph.D/MD/DM/MSc Thesis/ dissertation Protocol **(Tick the appropriate)** titled "……
……..." for consideration by the Departmental Ethics Sub-committee. The protocol has to undergo scientific review and approval at Departmental level/ PhD Committee (tick the appropriate).

Thanking you,

Yours sincerely,

Name & Signature of the student

Encl. As above

Remarks of the Guide with name, signature and seal

Remarks of HoD with Name, Signature & Seal:

Check List of Documents for dissertation / thesis
(Required to be submitted to Ethics Sub-committee)

Documents (1+1 Hard Copy + PDF e-version by e-mail with all the duly filled in IEC formats including covering letter)	**Remarks (Tick the appropriate)**
1. Covering letter for the project proposal ("Through Proper Channel" ……..	Yes/No
2. Summary Sheet of the **Thesis / dissertation Protocol**	Yes/No
3. (Research Project proposal submitted for Ethical Clearance as per the NIMHANS Ethics Committee guidelines). ……	Yes/No
i. Consent form duly signed by the **student /** collaborators. (Duly signed Attestation & Declaration Form)	Yes/No
ii. Consent of the concerned Head of the department …..	Yes/No
iii. Authorization/ sanctioning letter (finance sanction) from sponsoring agency …….	Yes/No
iv. Informed Consent form as per the guidelines of NIMHANS IEC	Yes/No
v. Consent form for carrying out the required investigations from the concerned Heads of Department(s), if applicable……	Yes/No
vi. Undertaking by the student …..	Yes/No

Date: **Name and Signature of the Student**

SUMMARY SHEET OF THE THESIS PROTOCOL SUBMITTED TO THE DEPARTMENTAL ETHICS SUB-COMMITTEE, NIMHANS

Submitted on…….

1	**Title and duration of the project**		
2	**Student and Department**		
3	**Funded or Non funded project? If yes, name of the funding agency (Govt, Private, Foreign) OR Is the project being submitted for funding?**		
4	**Are human subjects involved in the study? IF yes, mention type of participants (patients, relatives, professionals etc.**		
5	**Does the study involve healthy volunteers?**		
6	**Does the study involve vulnerable population (Children, Pregnant women, personas with disabilities, persons with mental illness etc.)?**		
7	**Study Design (Describe briefly)**		
8	**Is the submission in NIMHANS – IEC format? (should not be in the format of the funding agency)**		
9	**Procedures and risks: list the procedures carried out and the possible risk (classified as less than minimal, minimal, low or high)**	Procedures 1) 2)	Risk
10	**Detail the measures taken for reducing the risk**		
11	**Does the study involve biological specimens? If yes, list the type specimens and the amount**		
12	**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?**	Yes/No Yes/No Yes/No Yes/No Yes/No Yes/No Yes/No Yes/No Yes/No Yes/No Yes/No
13	**Is informed consent form attached? If not, mention justification**	
14	**Does the informed consent form address the following :**	
	a) Provide adequate information about title, purpose, procedures, & details of participation in a layperson's language to the participant? **b) Is the method of selection of subjects including random selection, if applicable is explained?** **c) Are procedures including invasive procedures and possible risks adequately explained?** **d) Are financial implications explained to the patient/legal guardian?** **e) Are there separate ICF's for participants, legally acceptable representatives (LAR'S) and volunteers? If so, list** **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 treatment / 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 the details of payments included?**	
15	**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?**	
16	**In case of chart review / records-based studies, mention as to how the identity of the patient is de linked and how confidentiality is maintained**	
17	**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.)**	
18	**Mention specific Ethical Issues involved in the proposed research (List & briefly describe)**	
19	**Is there payment to participants? If yes, details**	
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 / Not applicable
22	**Mention whether the sample size allows enough power to detect the difference/results expected from the investigation**	
23	**Is there any conflict of interest?**	
24	**Is there Financial interest of (i) investigators or (ii) sponsors? If yes, provide details**	

GUIDELINES FOR PREPARATION OF INFORMED CONSENT DOCUMENT

- The Informed consent document (ICD) has three sections:
    - Participant Information Sheet (to share information about the research)
    - Undertaking by the investigator
    - Certificate of Consent (for signatures by participants **OR** their Legally acceptable representatives (LAR's) on agreeing to take part)
- **ICD should be continuous document without page breaks, titled as "Informed consent document" and divided into 3 sections as mentioned above. Pages of ICD should be numbered in the format XX of YY starting from PIS and ending in certificate of consent.**
- The informed consent form should mention the type of **participant to whom it is meant** (Mention clearly as to which group this particular consent form is intended for, for e.g., controls or patients) and have the **full title of the study** in the **Heading**
- It should be prepared as per the Section 5 of the National Ethical Guidelines for Biomedical and health Research for Human Participants (https://icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf)
- ICD should be of an 8th standard reading level, with simple language, short sentences, with as few technical words as possible
- A copy of the ICD should be handed over to the participant.

Participant Information Sheet (PIS)

The following aspects need to be covered in a question/ answer format in the PIS:

1. Introduction – names, designations and affiliations of investigators, invitation to participate, and the liberty of the participant to ask questions take his or time to decide, and **the reason why the participant is being invited / selected**
2. Purpose of the research – Include scientific background to the study and the aims / hypotheses being tested or explored in as simple terms as possible. Unjustifiable statements, claims, and assurances should be avoided.
3. Type of Research Intervention and the procedures adopted - include step-by-step details what the participants have to undergo if they agree to participate; details should include commitments of the participants - number of visits, types of samples taken or assessments / tests / data collection or treatments that are done, duration of assessments and so on.
1. Benefits to individual, community, society etc.
2. Any foreseeable risks, injuries, discomfort or inconvenience to the participant resulting from participation in the study and how they are dealt with, including the issue of compensation / insurance coverage
3. Voluntary nature of the participation
4. Payments and Reimbursements – covering for travel, refreshments, lost wages and alike

5. Privacy and Confidentiality of participation and records, and steps taken to maintain confidentiality
6. Sharing of the results – with the participant, with scientific community, and assurance about keeping the identity confidential.
7. Right to Refuse or Withdraw at any stage without affecting routine treatment to which the person is entitled
8. Alternatives to Participation

Template for Participant information sheet is given below:

Participant information sheet

(Note: Modify as per requirement of study)

Name of the study

Type of participant

- Introduction
- What is purpose of this study?
- Why I am being invited?
- Do I have to take part?
- What will happen to me if I take part in this study?
- What investigations or treatments will be conducted in this study?
- Will I benefit from this study?
- Risks – What are the risks that I am likely to face if I participate in this study? What if something goes wrong?
- How will my confidentiality be protected?
- What if I don't want to participate in this study, or I want to withdraw later?
- What happens with the data collected / results / my samples?
- Who is organising the study?
- Who has reviewed this study?
- Whom should I contact for more information?

Undertaking

Should have the following elements:

a) Consent is being sought for participation
b) Right to refuse consent or withdraw at any time without assigning any reason
c) If the person is undergoing treatment, an assurance that best possible treatment will continue despite refusal to participate
d) Freedom to clarify any doubts about the study and contact investigators at any time during the study
e) Assurance of confidentiality

An example of undertaking for **participants who are receiving treatment is as follows**:
"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 any 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). All the information/data collected from you (participant) will be kept in strict confidence."

Certificate of Consent

Should have the following elements:

a) Participant's statement that he/she has read or understood
b) voluntariness in consenting,
c) possible choices, including withdrawal from study,
d) understanding of the participants about risks and benefits and consequences of consenting to participate
e) In the case of an illiterate participant, oral consent should be taken with the thumbprint taken along with a literate witness's signature
f) IT SHOULD BE CAREFULLY DESIGNED SPECIFICALLY TO SUIT THE ETHICAL REQUIREMENTS FOR A GIVEN STUDY

A specimen certificate of consent by the participant who is receiving treatment is given below:

I have read the participant information sheet / participant information sheet has been read out to me. I have been informed about the procedures of the study. The possible risks too have been explained to me as stated in the Participant Information Sheet. **I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction** I am aware that I have the right to refuse my consent or withdraw it any time during the study without adversely affecting my treatment. I am aware that by subjecting to this

research, 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, voluntarily give my consent to be a participant of this research study.

Name and Signature of participant
Date

Name and signature of investigator
Date

Name and signature of witness (if required, as in case illiterate participants and consent by LAR)
Date

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Consent of the guide, co-guide/joint guide and Head of the Department

Title of the Thesis / dissertaion:

x	x	x
Signature of the student	**Signature of the Guide**	**Signature of the Co-guide/Joint Guide**
( )	**( )**	**( )**
Name in capital letters	**Name in capital letters**	**Name in capital letters**
Department	**Department**	**Department**

Signature of the HoD

( )
Name in capital letters

Department

From:

(Name, address, and contact details of the student)

To:

Chairperson/Member Secretary, Departmental Ethics Sub-committee
Department of (Mention name of Department here)
National Institute of Mental Health and Neuro Sciences
Bangalore-560029

Sub: Ethical clearance for M.Sc/M.Phil/PDF/Ph.D/MD/DM Thesis Protocol **(Tick the appropriate)** titled "……"

UNDERTAKING

With respect to the above said M.Sc/M.Phil/PDF/Ph.D/MD/DM Thesis/ dissertation Protocol, 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 Student

Date: