NORTH EASTERN INDIRA GANDHI REGIONAL INSTITUTE OF HEALTH & MEDICAL SCIENCES, SHILLONG, MEGHALAYA

(An Autonomous Institute, Ministry of Health & Family welfare, Govt. of India)

Combined Format for Submitting Undergraduate (MBBS/BSc Nursing)/PG (MD, MS, MSc Nursing)/Post Doctoral (DM/PDF) Thesis/Project OR Dissertation Proposal for Consideration

By

NEIGRIHMS SCIENTIFIC ADVISORY COMMITTEE (NSAC)

INSTITUTE ETHICS COMMITTEE (IEC) (Human Studies)

Version 1.0

SECTION- 1

PART A – GENERAL INFORMATION

1. Title of the dissertation/Project
2. Name of the candidate with mobile numbers and email ID
3. Name of the course studying
4. Year of admission
5. Month and year of appearing for final examination
6. Month and year of submitting dissertation
7. Name (s), Designation (s) & Addresses of the guide and co-guide (s) with mobile numbers and email ID
8. A. State whether it is intradepartmental or interdepartmental

   B. If the study is interdepartmental

   I. State the names of collaborating departments
   II. State whether consent has been obtained from them
9. Total funds required for the study (in rupees)
10. Source of funding

PART B – TECHNICAL DETAILS

1. Title of the dissertation

2. Introduction

    A. Problem statement
    B. Rationale
    C. Novelty
    D. Expected outcome and application

3. Research question(s)

4. Research hypothesis (es), if any

5. Aim and objectives: Primary objective(s) & secondary objective(s)

6. Review of literature

7. Methodology

    A. Study design
    B. Study participants (human, animals or both)
        a. Inclusion criteria
        b. Exclusion criteria
        c. Withdrawal criteria, if any (trial-related therapy, follow-up and documentation are terminated prematurely as it is indicated to ensure safety of the participants)
        d. Rescue criteria, if applicable (starting symptomatic therapy either to control symptoms of disease or to overcome lack of adequate efficacy of the study drug or placebo) :
        e. Number of groups to be studied, identify groups with definition
    C. Sampling
        a. Sampling population
        b. Sample size calculation
        c. Sampling technique
    D. Randomization details (for interventional studies)- Intervention details with standardization techniques (drugs / devices / invasive procedures / noninvasive procedures / others)

    E. Study procedure

    F. Data collection methods including settings and periodicity

    G. If the clinical trial, whether registration with CTRI will be done

    H. Are the drugs/devices to be used approved for these indications by Drug Controller General of India (DCG-I)? (Enclose the approval letter for the drug/device from DCG-I for trial on humans or give undertaking to get the approval from DCGI; For all drugs and devices submit documents showing DCGI approval for the proposed indication of the study)

    I. List of variables and their measurement methods with standardization techniques

        a. Independent variables
        b. Outcome variables
        c. Confounding and interacting variables

    J. List variable wise statistical tests to be used for data analysis

8. List risks and benefits of the study

9. Relevant references for the project
   (Minimum 10, Maximum 20) (in Vancouver style)

10. Enclosures

    A. Brief CV of guide and co-guides

    B. Data collection proforma

    C. Questionnaires

    D. Consent form (English version)

    E. Other relevant papers

11. Undertaking for DCGI approval

12. Declarations by guide

A. Signature of the candidate
(Name & Designation)

Signature of the guide
(Name & Designation)

Signature (s) of the co-guide
(Name & Designation)

Signature of Head of the Department
of the candidate
(Name & Designation)

B. Signature(s) of the Co-guide from collaborating department (s)
(Name & Designation)

Signature(s) of Head(s) of the Collaborating department (s)
(Name and Designation)

SECTION – 2

(For Institute Ethics Committee (IEC)-Human Studies)

Proforma to be submitted to the Institute Ethics Committee (IEC) (Human Studies) for Undergraduate (MBBS/BSc Nursing) /PG (MD, MS, MSc Nursing) /Post Doctoral (DM/PDF) Thesis/Project OR Dissertation

1. Title of the project:
2. Name and department/address of the investigator:
3. Name of Faculty (Guide/Co-guide) with designation & department:
4. Date of approval by PG research monitoring committee:
5. Ethical issues involved in the study:

   Less than minimal risk/ minimal risk/ more than minimal risk to the study subjects (for guidance please consult ICMR guidelines) [Along with the level of risk, the risks should be discussed in detail]
6. Benefit of the study:
7. Details of Informed Consent Process:

a) Who will take the informed consent?

b) When will the informed consent be taken?

c) How will the informed consent be taken?

d) Where will the informed consent be taken?

8. Do you need exemption from obtaining Informed Consent from study subjects - if so give justifications.
9. Whether Consent forms in English and in local language are enclosed?

(if the consent form in local language is not applicable, appropriate explanations must be provided)

10. Documents attached
    a. Review Exemption Application Form (if applicable)
    b. Brief CV of all faculty investigators (guide/co-guide) (including no. of projects with him/her) - Needed for all Investigators for each project separately
    c. For student projects, the guide should give a signed statement on a separate sheet with details of the project proposal that "I take full responsibility and accountability for planning, execution and adverse events occurring during the study. The data collected and records will be retained by me for a period of three years".
    d. Others

11. Conflict of interest for any other investigator(s) (if yes, please explain in brief)

12. We, the undersigned, have read and understood this protocol and hereby agree to conduct the study in accordance with this protocol and to comply with all requirements of the ICMR guidelines (2006)

Signature of the Investigator: Date:

Signature of the Guide: Date:

Signature of the Head of the Department Date:

Signature of the Co- Guides: Date:

Signature of the Heads of the Department of Co- Guides: Date:

(Note: The performa must be accompanied by Informed Consent Document (ICD) in Khasi, English, Hindi . Informed Consent Document should comprise Patient Information Sheet and the consent form. The investigator must provide information to the subjects in a simple language, and it should address the subjects, in a dialogue format. Studies involving children below 7 years should include parent / LAR consent form while studies involving children above 7 years and below 18 years of age should include assent form in addition to parent / LAR consent form)

INFORMED CONSENT DOCUMENT (ICD)

Patient / Participant information sheet

INFORMATION FOR PARTICIPANTS OF THE STUDY

Instructions - This is the patient information sheet. It should address the participant of this study. Depending upon the nature of the individual project, the details provided to the participant may vary. A separate consent form for the patient/test group and control (drug/procedure or placebo) should be provided as applicable. While formulating this sheet, the investigator must provide the following information as applicable in a simple language in Khasi,English and Hindi which can be understood by the participant. (Do not copy & paste from the study protocol submitted to NSAC).

- Title of the project
- Name of the investigator/guide
- Purpose of this project/study
- Procedure/methods of the study including withdrawal criteria
- Expected duration of the subject participation
- The benefits to be expected from the research to the participant or to others and the post trial responsibilities of the investigator
- Any risks expected from the study to the participant
- Maintenance of confidentiality of records
- Provision of free treatment for research related injury
- Reimbursement for participating in the study
- Compensation to the participants for foreseeable risks and unforeseeable risks related to research study leading to disability or death.
- Freedom to withdraw from the study at any time during the study period without the loss of benefits that the participant would otherwise be entitled
- Possible current and future uses of the biological material to be generated from the research and if the material is likely to be used for secondary purposes or would be shared with others, this should be mentioned
- Possible current and future uses of the data to be generated from the research and if the data is likely to be used for secondary purposes or would be shared with others, this should be mentioned
- Address and mobile number of the Principal investigator (PI) and Co- PI, if any:

Signature of the investigator:

Signature of the participant:

Place:
Date :

CONSENT FORM

Title of the project:

Participant's name: Address:

The details of the study have been provided to me in writing and explained to me in my own language. I confirm that I have understood the above study and had the opportunity to ask questions. I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without the medical care that will normally be provided by the hospital being affected. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s). I have been given an information sheet giving details of the study. **Risk and benefit of this project has been explained to me.** I fully consent to participate in the above study.

(I also consent / do not consent to use my stored biological samples for future scientific purposes: Yes/ No – if applicable)

Signature/thumb impression of the participant: _____ Date: _____

Signature of the witness: _____ Date: _____

Name and address of the witness:

Signature of the investigator: _____ Date: _____

CONSENT FORM (for participants less than18 years of age)

Parent/Legally acceptable representative (LAR)

Title of the project:

Participant's name: Address:

Parent/LAR' s name:

The details of the study have been provided to me in writing and explained to me in my own language. I confirm that I have understood the above study and had the opportunity to ask questions. I understand that my child/ward's participation in the study is voluntary and that I am free to withdraw my child/ward at any time, without giving any reason, without the medical care that will normally be provided by the hospital being affected. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s). I have been given an information sheet giving details of the study. **Risk and benefit of this project has been explained to me.** I fully consent for the participation of my child/ward in the above study.

Assent of child/ward obtained (for participants 7 to 18 years of age)

(I also consent / do not consent to use my child/ward's stored biological samples for future scientific purposes: Yes/No – if applicable)

Signature/ thumb impression of the parent/ LAR: _____ Date: _____

Signature of the witness: _____ Date: _____

Name and address of the witness:

Signature of the investigator: _____ Date: _____

ASSENT FORM

(for children above 7 years and below 18 years of age)

Assent form to participate in a clinical research

Child Participant's name: Date of birth/Age:

Parent/LAR' s name: Address:

Title of the project:

The details of the study have been provided to me in writing and explained to me in my own language. I confirm that I have understood the above study and had the opportunity to ask questions. I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without the medical care that will normally be provided by the hospital being affected. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s). I understand that following completion of study as well as during publication of the results, confidentiality of my identity will be maintained. I have been given an information sheet giving details of the study. **Risk and benefit of this project has been explained to me.** I fully assent to participate in the above study.

(I also assent / do not assent to use my stored biological samples for future scientific purposes: Yes/No – if applicable)

Signature of the child participant : Date:
(If child knows to sign/Thumb impression)

Signature of the parent or guardian : Date:

Name and address of the witness :

Signature of the witness : Date:

Signature of the Investigator : Date:

(Assent form should be accompanied by patient / participant information sheet for children in a simple language comprehensible to a child of 7-18 years; Language used should be simpler for children in the age group 7-12 years compared to children in the age group >12-18 years)

CHECK LIST

(To be filled and duly signed by the principal investigator)

Title of the study:

Name of the Investigator:

Designation & Department:

S.No	Items	Yes/No
1	Exact title as approved by NSAC	
2	Date of NSAC approval mentioned in proper format (dd/mm/yyyy)	
2	Source of funding mentioned	
3	Adequate literature review with justification for the study mentioned	
4	Detailed description about methodology (Study design, number of groups, sample size etc)	
5	No mirror statement in Inclusion/Exclusion criteria (Ex: Age <18 in inclusion & Age >18 in exclusion)	
6a	Permission from DCGI (**if applicable)**.	
6b	DCGI approval for the mentioned indication in the study (for drugs, devices, cosmetics etc)	
7	Adequate justification for exemption from obtaining informed consent given **(if applicable).**	
8	Informed Consent Document **in Khasi, English and Hindi** attached as per NEIGRIHMS SOP format	
9	**Information to the participant/ parent/guardian** in layman (simple) language.	
10	Validated questionnaire both in **Khasi, English and Hindi** attached **(if study involves interview/ questioning)**	
11	Signature of all investigators (Principal & Co-investigator) and Head of corresponding department obtained with date	
12	Compensation mentioned as per NEIGRIHMS guidelines in consent form part 1	
13	Confidentiality mentioned as per NEIGRIHMS guidelines in consent form part 1	
14a	Separate consent form for subjects < 7 yrs attached **(if applicable)**	
14b	Separate assent form for subjects > 7 yrs < 18 yrs attached **(if applicable)**	
15	Separate consent form for cases and controls attached **(if applicable)**	
16	Ethical issues explained in detail with **level of risk**	
17	**No discrepancy** between **Khasi, English and Hindi** consent form	
18a	Declaration form from Guide (for all UG/PG/PhD/DM,MCh projects) regarding overall responsibility for the research	
18b	Declaration form from principal investigators / Guide stating that all procedures used in the study are standard and professionally acceptable (for faculty projects/ for all UG/PG/PhD/DM,MCh)	

Date: Signature of principal investigator

(It is mandatory to submit this form along with proforma)

REVIEW EXEMPTION APPLICATION FORM

1 Principal Investigator's Name:

_____

2 Department:

_____

3 Title of Project:

_____

4 Names of other participating staff and students:

_____

5 Brief description of the project:

Please give a brief summary (approx. 300 words) of the nature of the proposal, including the aims/objectives/hypotheses of the project, rationale, participants' description, and procedures/methods to be used in the project:-

6 State reasons why exemption from ethics review is requested?

- ✓ Audits of educational practices
- ✓ Research on microbes cultured in the laboratory
- ✓ Research on immortalized cell lines
- ✓ Research on cadavers or death certificates provided such research reveals no identifying personal data
- ✓ Analysis of data freely available in public domain
- ✓ Any other

(This should include justification for exemption e.g. study does not involve human participants. If exemption is being requested on the basis of low risk involved in the study please refer to the backside of this annexure.)

Principal Investigator's signature: _____

Date _____

Forwarded by the Head of the department:

Name: _____ Signature: _____

Date_____

Recommendations by the IEC Member Secretary:

Exemption

Cannot be exempted

Reasons_____

Discussion at full board

Signature of the Member Secretary: _____

Date _____

Final Decision:

Exemption

Cannot be exempted

Reasons_____

Discussion at full board

Signature of the Chairperson: _____

Date _____

Final Decision at Full Board meeting held on

_____

Signature of the Chairperson: _____

Date _____

No research can be counted as low risk if it involves:

(i) Invasive physical procedures or potential for physical harm

(ii) Procedures which might cause mental/emotional stress or distress, moral or cultural offence

(iii) Personal or sensitive issues

(iv) Vulnerable groups

(v) Cross cultural research

(vi) Investigation of illegal behavior (s)

(vii) Invasion of privacy

(viii) Collection of information that might be disadvantageous to the participant

(ix) Use of information already collected that is not in the public arena which might be disadvantageous to the participant

(x) Use of information already collected which was collected under agreement of confidentiality

(xi) Participants who are unable to give informed consent

(xii) Conflict of interest e.g. the researcher is also the lecturer, teacher, treatment-provider, colleague or employer of the research participants, or there is any other power relationship between the researcher and the research participants.

(xiii) Deception

(xiv) Audio or visual recording without consent

(xv) Withholding benefits from "control" groups

(xvi) Inducements

(xvii) Risks to the researcher

This list is not definitive but is intended to sensitize the researcher to the types of issues to be considered. Low risk research would involve the same risk as might be encountered in normal daily life.

Please check that your application / summary has discussed:

- Procedures for voluntary, informed consent
- Privacy & confidentiality
- Risk to participants
- Needs of dependent persons
- Conflict of interest
- Permission for access to participants from other institutions or bodies
- Inducements

In some circumstances research which appears to meet low risk criteria may need to be reviewed by the IEC. This might be because of requirements of:

- The publisher of the research
- An organization which is providing funding resources, existing data, access to participants etc.