COVERING LETTER

From

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To

The Chairman/Member secretary,
Human Institute Ethical Committee,
Thanjavur Medical College and Hospital, Thanjavur

Respected Sir,

Sub: Requisition – approval of research protocol – Institutional Ethical Committee meeting - Thanjavur Medical College - Regarding

I, _____ working as _____ in the department of _____, Thanjavur Medical College, Thanjavur, herewith enclosing the research protocol entitled _____ _____ for the approval of IEC, Thanjavur Medical College.

Thanking you

Yours truly

Enclosed:

1. Proforma of research protocol
2. Informed consent (information to the patients)
3. Self-declaration
4. Questionnaire (if applicable)
5. Copy of important references.

For Office Use only

S. No	Signature of the members	Comments	Approved/Rejected/ Approved with modification

CHECK LIST

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

Title:

Name of the Investigator:

Designation & Department:

S.No	Items	Yes/No
1	Protocol discussed internally in the concerned department and obtained HOD's permission?	
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)	
6	Permission from DCGI (**if applicable)**.	
7	Has the Sample size calculated and mentioned?	
8	Consent form part **1 and 2 in both English and Tamil** attached?	
9	Consent form part **1 (information to the participant/ parent/guardian)** in layman (simple) language.	
10	Validated questionnaire both in Tamil and English 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 ICMR guidelines in consent form part 1	
13	Confidentiality mentioned as per ICMR guidelines in consent form part 1	
16	Ethical issues explained in detail with **level of risk**	
17	**No discrepancy** between tamil and English consent form	
18	*****Head of institute (Dean) and concerned TMCH department HOD consent obtained (applicable only for projects submitted from other institutes)**	

*** This is only for other institute projects -if they are taking patients/records/samples from our Thanjavur Medical College hospital. Without the consent of DEAN and HOD of concerned department, projects will not be accepted for them.

Date: Signature of principal investigator

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

PROFORMA OF RESEARCH PROTOCOL

1. **TITLE OF THE STUDY**

   The title of the study should be short and framed in such a way that it should try to explain the type of study, Population, Intervention, comparison group and outcome of the study – whichever is applicable. For example: RCT (type of study) to compare effectiveness of ceftriaxone with azithromycin (comparison group) in patient with typhoid (population) in clinical cure (outcome).

2. **Name and designation of the principal investigator:**

3. **Name and designation of the guide:**

4. **Name and designation of the co-guide (If-applicable):**

5. **Sources of funding :**

   If applicable, the principal investigator should provide the details about the funding body (Example: Name of extra-mural funding source in India or foreign country, name of the pharmaceuticals with address).

6. **Objectives of the study:**

   The principal investigator should address the objective as primary and secondary (if applicable)

   Primary objective example:

   To compare the efficacy of ceftriaxone and azithromycin by measuring the number of days spent with fever after initiating drug in typhoid patients

   Secondary objective example:

   To compare the safety of ceftriaxone and azithromycin by measuring the number of ADR occurred in patients.

7. **Justification for the conduct of the study:**

   The principal investigator should provide the details (mentioned below with reference) regarding the

   1. Background information regarding the study
   2. Information regarding the previous/similar work conducted in the area of present study
   3. Lacuna present in the previous works and in the area of research
   4. Justification of the current study

   The principal investigator should cite the reference at appropriate place.

8. **Methodology:**

   The principal investigator should include details of the following

   A. **Study design**: (please state whether the study is RCT, cross-sectional, analytical, case-control, or cohort.
   B. **Study setting**: (Example: The study will be conducted in the in-patient department of internal medicine, Thanjavur medical college)

C. **Study subjects**: (Example: The patients who are attending the OPD of internal medicine with fever will be approached as study subjects)

D. **Inclusion criteria**: (age and sex should be mentioned always and first, followed by other inclusion criteria appropriate to the study)

E. **Exclusion criteria**: (Please do not mirror the inclusion criteria here. For example, it is redundant to mention as 'patient less than 14 years' here if 'patients >14 years of age' have been mentioned in inclusion criteria already)

F. **Sample size:**

The principal investigator should provide the sample size with appropriate justification. The sample size is calculated for RCT and other analytical studies. For observational studies, the sample size is justified (justified is different from calculated). The sample size can be obtained from 'www.openepi.com'. The principal investigator should know about the details of mean difference and SD, prevalence, Confidence interval and power of the study. With these details, the principal investigator can calculate the sample size.

Example: From the previous study, the mean difference of number of days with fever between azithromycin and ceftriaxone was 1.3. Keeping the CI ad 95% and power of study as 80%, the sample size calculated was 15/group. Allowing 20% drop out, the final sample size calculated was 18/group.

G. **METHODS**:

describe the steps involved in the study process step by step wise. Flow chart can be provided if applicable. Without detailed methods, protocol will not be accepted.

H. **Parameter analyzed:** The principal investigator should mention the parameter analyzed with appropriate units. (Example: Hemoglobin in g/dl, Duration spent with fever in days etc.,)

I. **Statistical analysis**: The principal investigator should mention the appropriate statistical test to be done for comparing the parameters measured between the groups.

   a. Unpaired 't' test – to compare the continuous parametric data between two independent groups
   b. Mann Whitney 'U' test – to compare the scores/non-parametric data between two independent groups
   c. Paired 't' test – to compare the continuous parametric data between two paired samples
   d. Wilcoxan test – to compare the scores/non-parametric data between two paired samples
   e. Fisher's exact test – to compare the proportions/frequency between the groups with sample less than 30
   f. Chi-square test – to compare the frequency/proportions between the groups with sample >30
   g. ANOVA with post hoc tests – to compare the continuous parametric data with more than two independent groups
   h. Repeated measures ANOVA with post hoc test – to compare the parametric continuous data between more than two samples obtained from same subject.

i. Kruskal-Wallis test – Compare the scores/non-parametric data between more than two independent groups.
j. Pearson and spearman's correlation test – to find the strength of association between two parameters of parametric and non parametric distribution, respectively.

J. Dosages of drug and duration of treatment: If applicable.

9. **Permission from Drug Controller General of India (DCGI):** if applicable

10. **Ethical issues involved in the study:**
    Please mention the category: less than minimal risk/ minimal risk/ more than minimal risk to the study subjects (for guidance please refer ICMR guidelines)

11. **Do you need exemption from obtaining Informed Consent from study subjects – if so give justifications**

12. **Whether Consent forms part 1 and 2 in English and in local language are enclosed?**
    (If the consent form in local language is not applicable, appropriate explanations must be provided)

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

14. **Are the questionnaire attached has been validated?** If validated please provide the reference. If not validated please provide the adequate justification for including it in the study.

15. **References**: Attach only relevant and important references. Need not to attach all the articles quoted/referenced in the text.

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 (recent amendment)

Signature of the Investigators with name: **Date:**

Signature of the Guide and Coguide with name: **Date:**

Signature of the Head of the Department with seal: **Date:**

(Note: The proforma must be accompanied by Consent forms I & II in English and Tamil. Consent form part 1 is equivalent to Patient Information Sheet. The investigator must provide information to the subjects in a simple language, and it should address the subjects, in a dialogue format)

CONSENT FORM

PART 1 of 2

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 English and Tamil which can be understood by the participant (Do not copy & paste from the study protocol)*

A. Title of the project:
B. Name of the investigator/guide with mobile number:
C. Purpose of this project/study:
D. Procedure/methods of the study:
E. Expected duration of the subject participation:
F. The benefits to be expected from the research to the participant
G. Any risks expected from the study to the participant
H. Maintenance of confidentiality of records
I. Provision of free treatment for research related injury
J. Compensation for participating in the study
K. Compensation to the participants for foreseeable risks and unforeseeable risks related to research study leading to disability or death.
L. 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
M. Possible current and future uses of the biological material and of the data 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
N. Address and telephone number of the investigator and co-investigator/guide
O. The patient information sheet must be duly signed by the investigator

CONSENT FORM

PART 2 of 2- Participant consent form

Participant'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 have been given an information sheet giving details of the study. 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) – if applicable

Signature of the participant: _____ Date: _____

Signature of the witness: _____ Date: _____

Signature of the investigator: _____ Date: _____