Annexure- 1A

Letter Ref. No: Date:

From:
Dean
DYPMC
Pimpri, Pune – 18

To:

_____

_____

_____

Sub: <u>Constitution of Institutional Ethics Sub-Committee (Human studies)</u>

Dear Sir / Madam,

On behalf of Dr. D. Y. Patil Medical College, Hospital and Research Centre, Pimpri, Pune, I request your concurrence for appointment as a member of Institutional Ethics Sub-Committee of this institute. Kindly send your written acceptance in the enclosed format and provide the necessary information requested.

On receipt of your acceptance, I shall send you the formal appointment letter.

Yours sincerely,

Signature:

Name:

Annexure- 1B

From:

_____

_____

_____

To:
The Dean
DYPMC
Pimpri, Pune – 18

Sub: <u>Consent to be a member of Institutional Ethics Sub-Committee (Human Studies).</u>

Ref: Your Letter No: Dated:

Dear Sir/Madam,

In response to your letter stated above, I give my consent to become a member of IESC of DYPMC. I shall regularly participate in the IESC meetings to review and give my unbiased opinion regarding the ethical issues.

I shall be willing for my name, profession and affiliation to be published.

I shall not keep any literature or study related document with me after the discussion and final review.

I shall maintain all the research project related information confidential and shall not reveal the same to anyone other than project related personnel.

I herewith enclose my CV.

Thanking you.

Yours sincerely,

Signature _____

Name of the Member _____ Date:

Address:

Telephone No: (Off) (Res. /Mob.)

Email:

Annexure 1C

APPOINTMENT ORDER

Dr/ Mr. / Mrs.: _____Date:_____

I am pleased to appoint you as_____ of the Institutional Ethics Sub-Committee (IESC) (Human research) at Dr. D. Y. Patil Medical College, Hospital and Research Centre, Pimpri, Pune w.e.f. _____ for a term of _____ year(s), provided following conditions of appointment are met.

The renewal of your appointment will be by consensus & 1 month notice on either side will be necessary prior to resignation/ termination of appointment.

I sincerely hope your association with IESC, DYPMC will be fruitful to the Institute &the Community we serve.

Dean

(Name)

DYPMC,
Pimpri, Pune – 18

Signature of Appointee

(Name)

(Date)

Annexure- 2A

Proforma to be submitted to the Institutional Ethics Sub-Committee
(Human Studies)

(For projects other than those mentioned in Annexure 2B)

Kindly submit 10 copies of proforma and consent forms in 2 parts (in English, Hindi and Marathi) to the Member Secretary, Institutional Ethics Sub-Committee, DYPMC, Pune.

PART – A

1. Title of the project:
2. Name of the investigators/co-investigators with designation & department:
3. Number of projects already with the investigators/co-investigators:
4. Date of approval by College Scientific Committee:
5. Sources of funding:
6. Objectives of the study:
7. Justification for the conduct of the study:
8. Permission from Drug Controller General of India (DCGI), if applicable.
9. Costs involved (Approx. in Rs.)
    a) Investigations
    b) Disposables
    c) Implants
    d) Drugs/Contrast Media

Who will bear the costs of the requirements? 1. Patient. 2. Investigator(s). 3. Exempted. 4. Other Agencies (Name)

10. 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 at ICMR website)

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?

13. Documents attached

    (a) Brief CV of investigators (including no. of projects with him/her).

    (b) Investigator's Brochure

    (c) Others

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

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 Investigators: Date:

Signature of the Head of the Department Date:

(Note: The proforma must be accompanied by Consent forms 1 & 2 in English, Hindi and Marathi. Consent form 1 is 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.)

PART – B (Synopsis of the Proposal)

It should include:

Title, aim, objectives, review of literature, methodology in details (type of study, study design, sample size, inclusion criteria, exclusion criteria, methods in detail including principles of instruments, procedures, dosages of drug, duration of treatment, investigations to be done, data analysis method, statistical analysis, proforma), implication(s) of the study, references and budget.

Annexure- 2B

Proforma to be submitted to the Institutional Ethics Sub-Committee (Human Studies) for MD/MS/DM/M.Ch/Ph.D Students (for Thesis or Dissertation)/MBBS student projects

Kindly submit 10 copies of proforma and consent forms in 2 parts (in English, Hindi and Marathi) to the Member Secretary, Institutional Ethics Sub-Committee, DYPMC, Pune.

PART – A

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 College Scientific Committee/ Departmental PG committee:
5. Sources of funding:
6. Objectives of the study:
7. Justification for the conduct of the study:
8. Permission from Drug Controller General of India (DCGI), if applicable.
9. 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 - at ICMR website)

10. Do you need exemption from obtaining Informed Consent from study subjects – if so, give justifications.
11. Whether Consent forms part 1 and 2 in English and in local language are enclosed?
12. Conflict of interest for any other investigator(s) (if yes, please explain in brief).

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 Investigators: Date:

Signature of the Head of the Department: Date:

(Note: The proforma must be accompanied by Consent forms I & II in English and Tamil. Consent form I 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.)

PART – B (Synopsis of the Proposal)

It should include:

Title, aim, objectives, review of literature, methodology in details (type of study, study design, sample size, inclusion criteria, exclusion criteria, methods in detail including principles of instruments, procedures, dosages of drug, duration of treatment, investigations to be done, data analysis method, statistical analysis, proforma), implication(s) of the study, references.

Annexure- 3A

Consent Form (Part 1)
PARTICIPANT INFORMATION SHEET (PIS)

The project must be accompanied by the Participant information sheet addressed to the patient or participant or parent/ guardian, in case of minor. While formulating the participant information sheet, the investigator must provide the subjects with the following information in **English, Hindi and Marathi in a simple layman's language which can be understood by them, in a narrative form, directed to the participant/ LAR, covering all the points**:

1. Study Title.

2. Aim and methods of the research study.

3. Expected duration of participation.

4. The benefits to be expected from the research to the participant or to others.

5. Any risk or discomfort to the participant associated with the study.

6. Maintenance of confidentiality of records.

7. Provision of free treatment for research related injury.

8. Compensation of subjects for disability or death resulting from such injury.

9. Freedom of individual to participate and to withdraw from research at any time without penalty or loss of benefits to which the subject would be entitled otherwise.

10. Amount of blood sample (quantity in tea spoon full) to be taken.

11. Costs and source of investigations, disposables, implants and drugs/ contrast media.

12. Telephone number/ contact number of Principle investigator and Co-Investigator at the top of each page.

13. In case of a drug trial:

    a. The chemical name of the drug, date of its manufacturing and batch number must be mentioned.

    b. Initial bioequivalence study of the drug/ references should be provided.

14. Self-certification should be given that the translation to vernacular language is correct.

Annexure- 3B

Consent Form (Part 2)
PARTICPANT INFORMED CONSENT FORM (PICF)

Protocol Study number: _____

Patient identification number for this study: _____

Title of the project: _____

_____

Name of Principal investigator: _____Tel. No(s)_____

The contents of the information sheet dated_____ that was provided have been read carefully by me / explained in detail to me, in a language that I comprehend, and I have fully understood the contents. I confirm that I have had the opportunity to ask questions.

The nature and purpose of the study and its potential risks / benefits and expected duration of the study, and other relevant details of the study have been explained to me in detail. I understand that my participation is voluntary and that I am free to withdraw from the study at any time, without giving any reason, without my medical care or legal right being affected.

I understand that the information collected about me from my participation in this research and sections of any of my medical notes may be looked at by responsible individuals from Dr. D. Y. Patil Medical College, Pimpri, Pune. I give permission for these individuals to have access to my records. I also give my consent to publish my data for academic purposes provided my identity is kept confidential.

I agree to take part in the above study.

---------- Date:
(Signatures / Left Thumb Impression) Place:

Name of Participant: _____Son/Daughter/spouse of: _____

Complete postal address:_____

This is to certify that the above consent has been obtained in my presence.

---------- Date:
Signatures of the Principal Investigator Place:

1) Witness – 1

Signature
Name:
Address:

2) Witness – 2

Signature
Name:
Address:

NB: Three copies should be made, one each for (1) Patient (2) Researcher (3) Institution (Investigators are advised to prepare the translation in simple understandable Hindi on their own).

Annexure- 3C

□□णाचे संमती प□

अ□यास □ मांक:

अ□यासातील □□णाचा ओळख □ मांक:

अ□यासाचे नाव:

□मुख संशोधांक□याचे नाव:

दू□वनी □ मांक:

अ□यासा□या माहितीप□कात, दिनांक: ___/___/___ □या दिवशी नमूद केले□या गो□टी मी वाचले□या आहेत/मला समजणा□या भाषेत समजाव□या गेले□या आहेत. मला अ□यासाची संपूण□माहिती समजली आहे. मला □□न विचार□याची संधी दिली गेली आहे.

संशोधनाचा □कार आणि उ□देश व □यातील संभा□य धोके आणि फायदे, तसेच संशोधनासाठी लागणारा वेळ आणि □या□याशी संल□न माहिती मला सवि□तर समज□यात आलेली आहे.

मला हे समजते की □या संशोधनात माझी भागेदारी □वे□छेने आहे. मला कु□ठ□याही वेळी □या मधू□न काहीही कारण न देता, तसेच माझी वै□यकीय शु□ूषा व कायदेशीर अधिकार □भावित न होता बाहेर पडता येईल.

मी असे समजतो/ समजते की □या संशोधनाम□ये मा□याब□दल गोळा केलेली माहिती, डॉ. डी. वाय. पाटील मेडिकल कॉलेज, पिंपरी, पु□ो; येथे काम करणा□या जबाबदार □य□तींकडूनच अ□यासली जाईल. मी या□वारे संशोधांक□याला, □या माहितीचा संशोधनाकरिता वापर कर□यास संमती देतो/ देते. मला हे समजते की □या संशोधनादर□यान कोठेही माझे नाव □काशित होणार नाही व माझी ओळख गु□त ठेव□यात येईल.

मी □या संशोधनातू□न निमा□ा होणारा कु□ठ□याही माहितीचा किंवा नि□कषा□ा वापर फ□त वै□ ानिक कारणांसाठी □काशित कर□यास परवानगी देत आहे.

मी वरील संशोधनात सहभागी हो□यास संमती देत आहे.

(□वा□ री/डा□या हाताचा अंगठा): दिनांक:

ठिकाण:

सहभागक□याचे नाव:

संपू□ण□प□ा:

वरील संमतीप□ मा□ या उप□थितीत मिळवले गेले आहे.

(□मुख संशोधांक□याची □वा□ री)

१) सा□ीदार-१ २)सा□ीदार-२

□वा□ री: □वा□ री:

नाव: नाव:

प□ा: प□ा:

Annexure- 4

Checklist for attached Documents

1. Covering letter, through proper channel
2. Project proposal – **10 Copies**
3. Curriculum Vitae of Investigators
4. Brief description of proposal
5. Patient information sheet
6. Informed Consent form
7. Copy of advertisements/Information brochures.
8. Copy of clinical trial protocol and/or questionnaire.
9. HMSC/DCGI/DBT/BARC clearance if required.
10. Undertaking that the study shall be done in accordance with ICMR and GCP guidelines.
11. In case of multi-centric study, IEC clearance of other centres must be provided.
12. Definite undertaking as to who will bear the expenditure of injury related to the project.
13. If an insurance cover is intended, Insurance certificate must be provided (as per ICMR guidelines).
14. Permission to use copyrighted Questionnaire/proforma.
15. Investigator should provide undertaking what they will do with the leftover sample tissue.
16. Others

Annexure- 5A

Ongoing Approved Research Review Submission Form

1. Reference number.
2. Month / Year of approval.
3. Number of ongoing review.
4. Title of the research proposal.
5. Name of the Principal Investigator (PI) with qualification and designation.
6. Name of the Co-investigator(s) (Co-PI) with qualification and designation.
7. Duration of the Project.
8. Source of funding & financial allocation for the project / trial.
9. Has subject recruitment begun?
10. If subject recruitment has not begin, give reasons and proceed to No: 20.
11. How many subjects have been screened?
12. How many subjects have been recruited?
13. How many more to be recruited?
14. Is subject recruitment continuing?
15. Are there any 'drop outs'?
16. Are subjects still receiving active intervention?
17. Have there been any adverse events? If yes, give details.
18. Have there been any Serious Adverse Events adverse events? If yes, give details.
19. Have there been any unanticipated study-related problems?
20. Is there any new risk or benefit information? If yes, give details.
21. Are there any interim changes to the protocol or consent form? If yes, give details including submission of revised protocol and consent form for approval.
22. Does the scientific literature indicate changes in knowledge relevant to the conduct of the study?
23. List of attachments for review, if any.
24. Remarks, if any.
25. Signature of the Principal Investigator with date.

Note: The above information and enclosures should be furnished wherever necessary depending upon the nature of study proposal.

Annexure-5B

Six monthly progress of Project

Institutional Ethics Sub-Committee Proposal No._____

Study title:_____

_____

Name of the Principal Investigator: _____

Designation / Department: _____

_____

Duration of Study: _____

Date of Starting of the Study: _____

Period of Six monthly progress report: from_____to_____

Progress:

Side Effect if any:

Amendments if any:

Discontinuation reasons:

Progress:

Signature of Principal Investigator

Date:

Annexure- 5C

Institutional Ethics Sub-Committee

Format for submission of revised/additional documents, protocols and information regarding already approved projects to be submitted by the Principal Investigator

(Two copies of this form along with the revised documents to be submitted)

1. IESC Reference No:

2. Approval Date and Number:

3. Title:

4. Principal Investigator:

5. Purpose of this submission:

6. **New documents being submitted:** Please list the documents being submitted along with the differences from the previously approved documents in a tabular form as below:

S. No.	List of Documents being submitted	List the modifications/revisions made from previously approved proposal, wherever applicable

Place: Signature PI/Collaborator_____

Date: Name: _____

Annexure- 6

Ref. No.: I.E.S.C./ / **Date:**

CERTIFICATE

The study titled _____ to be conducted by **(Name/Designation)** from the Department of _____ is ethically approved in its presented form.

The above mentioned study was approved in the Institutional Ethics Sub-Committee meeting held on _____ at _____. The following members were present for the meeting:

1)
2)
3)
4)
5)

Name, Designation, Department, Institute being the principal investigator and any of the proposed study team members did not participate in the decision making process of the Ethics Committee and voting pertaining to this study.

The IESC expects to be informed about the progress of the study, any SAE occurring in the course of the study, any changes in the protocol and patient information/ informed consent/ assent and asks to provide a copy of the final report.

Name
Member Secretary
Institutional Ethics Sub-Committee

Name
Chairman
Institutional Ethics Sub-Committee

Protocol for submission of research proposal

Projects to be forwarded by Dean **(10 hard copies)**

Submit to

SECRETRIAT (Dept of FMT: **10 hard copies**; and soft copies to below mentioned email ids)

IESC CSC

To be presented in the combined meeting by PI/CI 5-10 minutes PPT

Corrections to be made and resubmitted final version in **2 copies** within **10 days** of meeting

CSC & IESC Certificate issued

Forwarded to DPU, if required

- Proposals can be submitted any time or before the date of submission as mentioned in circular.
- Combined meeting schedule:
  - January
  - April
  - July
  - October
- Submission latest by last week of previous month.
- Meeting: Second week (Preferably Wednesday 2:00 pm).
- Rectified proposals to be submitted in **2 copies** within 10 days of meeting.
- Email: iesc.medical@dpu.edu.in
  csc.medical@dpu.edu.in
- Standard Operating Procedures **(SOPs)** of IESC (pdf) along with **annexure** (word file) are available at medical college website at medical.dpu.edu.in