INSTITUTIONAL ETHICS SUB-COMMITTEE (IESC)

DR. D. Y. PATIL MEDICAL COLLEGE, HOSPITAL AND RESEARCH CENTRE

PIMPRI, PUNE - 411018

STANDARD OPERATING PROCEDURES (HUMAN STUDIES) 2017

Version – 2.1
w.e.f. – 15th April 2017

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Standard Operating Procedures (SOP)
for
Institutional Ethics Sub-Committee (IESC)
Dr. D. Y. Patil Medical College, Hospital and Research Centre, Pimpri, Pune

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Name and Designation	Signature
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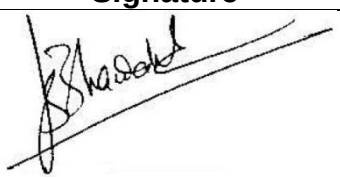
VII. SOPs accepted by:

Name and Designation	Signature
Dr. J. S. Bhawalkar Dean, DYPMC, Pune Professor Department of Community Medicine	

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1. Objective:

The objective of this SOP is to contribute to the effective functioning of the Institutional Ethics Sub-Committee (IESC) so that quality and consistent ethical review mechanism for health and biomedical research is put in place for all proposals as prescribed by the ethical guidelines for biomedical research on human subjects of ICMR.

2. Role and Scope of IESC:

IESC will review all research proposals submitted by the researchers of Dr. D. Y. Patil Medical College, Hospital and Research Centre (DYPMC), Pune involving human participants with a view to safeguard the dignity, rights, safety and well being of all actual and potential research participants. The goals of research, however important, should never be permitted to override the health and well being of the research subjects.

The IESC will take care that all the cardinal principles of research ethics viz. Autonomy, Beneficence, Non-maleficence and Justice are taken care of in research protocols. For this purpose, it will look into the aspects of informed consent process, risk benefit ratio, distribution of burden and benefit and provisions for appropriate compensations wherever required. It will review the proposals before start of the study as well as monitor the research throughout the study until and after completion of the study through appropriate well documented procedures. These may be in the form of six monthly reports, final reports (e.g. publications, financial outcomes, patents and implementation of results) and site visits etc. The committee will also examine compliance with all regulatory requirements, applicable guidelines and laws.

The role of IESC can be modified according to the requirement of the Institute from time to time.

3. Composition of IESC

IESC shall be multidisciplinary and multisectorial in composition.

The number of members in the committee shall be kept small (7- 9 members).

The Chairperson of the committee shall be from the Institution and not necessarily Dean/former Dean of DYPMC. The Member Secretary, drawn from DYPMC itself, shall conduct the business of the Committee. Other members will be a mix of medical and non-medical scientific and non-scientific persons including general public to reflect the differed viewpoints. The composition of the Committee shall be as follows:

i. Chairperson

ii. 1-2 Basic Medical Scientists

iii. 1-2Clinicians

iv. One Legal Expert

v. One Ethicist/ Bioethicist/ Philosopher/ Theologian

vi. One Lay Person

vii. Member Secretary

There shall be adequate representation of age, gender, community etc. in the committee to safeguard the interests and welfare of all sections of the society. The committee cannot consist entirely of men or entirely of women. If required subject experts will be invited to offer their views.

4. Authority under which IESC is constituted:

The Dean, Dr. D. Y. Patil Medical College, Hospital and Research Centre, Pune constitutes the Committee.

The committee will be reviewed and reconstituted every 3 years and as required.

5. Membership:

a. The Dean appoints the members based on their competency and integrity.**(Annexure 1A-C)**

b. The duration of appointment is initially for a period of 3 years.

c. There shall be no bar on members for serving more than one term, though it is desirable to have around one third fresh members.

d. At the end of 3 years, the committee shall be reviewed and reconstituted.

e. A member can be replaced in the event of death, long-term non-availability or for any action deemed unfit for a member.

f. A member can tender resignation from the committee with proper reasons to do so, which should be acceptable to Dean, DYPMC.

g. All members should maintain absolute confidentiality of all discussions during the meeting.

h. Conflict of interest should be declared by members of the IESC.

i. Members will be required to undergo training in research ethics and bioethics.

6. Quorum requirements:

The minimum of 50% + 1 member are required to compose a quorum depending on the number of members in the committee. All decisions should be taken in meetings and not by circulation of project proposals.

7. Convening and Conducting IESC meetings:

The Chairperson will conduct all meetings of the IESC. If for reasons beyond control, the Chairperson is not available, an alternate Chairperson will be elected by the members present from among themselves.

The meetings will be held quarterly, preferably and as feasible in the **2nd week** (preferably, Wednesday 2:00 pm) of:

a. **January**
b. **April**
c. **July**
d. **October**

Additional meetings may be held as and when required.

The Member Secretary will be responsible for organizing the meetings, maintaining the records and communicating with all concerned. He/She will circulate the notice of the meetings. Research protocols should be circulated to the committee members at least 2 weeks in advance. He/She will prepare the minutes of the meetings and get them approved by the Chairperson before communicating to the Principal Investigator (PI).

8. Independent Consultants:

IESC may call upon subject experts as consultants for review of selected research protocols, if need be. These experts may be specialists in ethical or legal aspects, specific diseases or methodologies or represent specific communities, patient groups or special interest groups e.g. cancer patients, HIV/AIDS positive persons or ethnic minorities. They are required to give their specialized view but will not take part in the decision making process.

They may be paid remuneration as deemed suitable by the Chairperson in consultation with the Dean.

9. Application process:

a. **10 copies** of the proposal along with the application and documents in prescribed format duly signed by the Principal Investigator (PI) and Co-investigators/ Collaborators forwarded by the Head of the Departments with copy of covering letter for information to Dean, DYPMC are to be submitted to the office of Member Secretary, IESC.

b. All proposals, including those which are included in exceptional list (refer Point No. 11), should be submitted to Member Secretary, IESC in the prescribed application form **(Annexure- 2A-B)**.

c. Interdisciplinary, inter-institutional projects and projects of investigators from other institutions for which patients, other resources or collaboration of

DYPMC is required, should also be submitted to IESC for review. Prior approval of Dean, DYPMC will be mandatory before submitting such proposal to DPU IEC for further clearance.

d. Whenever required co-investigator may be recommended, for research proposals as mentioned under Point No. 9(b), from concerned department for smooth conduction of research. Though the final decision regarding the same will remain with Principal Investigator.

e. All relevant documents should be enclosed with application (as mentioned under Point No. 10: Documentation).

f. The date of meeting will be intimated to the researcher, to be present, if necessary to offer clarifications.

g. The decision will be communicated in writing. If revision is to be made, the revised document(s) in required number as will be specified in communication letter should be submitted within a stipulated period of time as specified in the communication or before the next meeting.

h. In the revised proposal, the PI should highlight the changes in the protocol/brochures/informed consent form etc. and should also attach copy of communication letter sent by IESC.**(Annexure 5C)**

i. Prescribed fee, if any, should be remitted along with the application.

10.Documentation:

For a thorough and complete review, all research proposals should be submitted with the following documents:

1. Name of the applicant with designation and department.
2. Name of the Institute/ Hospital/ Field area where research will be conducted.
3. Approval of the Head of the Department.
4. Protocol of the proposed research.
5. Ethical issues in the study and plans to address these issues.
6. Proposal should be submitted with all relevant enclosures like proformae, case report forms, questionnaires, follow-up cards etc.
7. Informed consent process, including Patient Information Sheet (PIS) and informed consent form in local language(s).**(Annexure 3A-B)**
8. Curriculum vitae of all the investigators with relevant publications in last five years.
9. Any regulatory clearance required.
10. Source of funding and financial requirements for the project.

11. Other financial issues including those related to insurance.
12. An agreement to report only Serious Adverse Events (SAE) to IESC.
13. Statement of conflict of interest, if any.
14. Agreement to comply with the relevant national and applicable international guidelines.
15. A statement describing any compensation for study participation (including expenses and access to medical care) to be given to research participants; a description of the arrangements for indemnity, if applicable (in study related injuries); a description of the arrangements for insurance coverage for research participants, if applicable; all significant previous decisions (e.g. those leading to a negative decision or modified protocol) by other ethical committees (ECs) of regulatory authorities for the proposed study (whether in the same location or elsewhere) and an indication of the modification(s) to the protocol made on that account. The reasons for negative decisions should be provided.
16. Plans for publication of results – positive or negative – while maintaining the privacy and confidentiality of the study participants.
17. The PI should provide the details of other ongoing research projects (Title of the project, Date of starting and duration, source and amount of funding).
18. Any other information relevant to the study.

11.Review procedures:

a. IESC will review all research proposals submitted by the researchers of Dr. D. Y. Patil Medical College, Hospital and Research Centre, Pimpri, Pune involving human participants.

b. The Committee will approve all the proposals submitted to it, except:
    - Clinical trials of drugs and devices,
    - Ph.D. research projects and
    - Funded research projects other than ICMR-STS projects.

c. The projects listed above as exception and other projects as deemed suitable by IESC to be reviewed and approved by DPU IEC shall be forwarded to main committee (DPU IEC) with remarks from IESC.

d. The meeting of the IESC shall be held quarterly as mentioned under Point No. 7. The date of next meeting will be decided at the end of previous meeting. Additional meetings may be held as and when required.

e. The proposals will be sent to members at least 2 weeks in advance.

f. Decisions will be taken by consensus after discussions, and whenever needed voting will be done. Decision of majority of members will be final.

g. Researchers will be invited to offer clarifications if need be.

h. Independent consultants/Experts will be invited to offer their opinion on specific research proposals if needed.

i. The decisions will be minuted and Chairperson's approval taken in writing.

12.Element of review:

a. Assessment of predictable risks/ harms.

b. Examination of potential benefits.

c. Procedure for selection of subjects in methodology including inclusions/ exclusion, withdrawal criteria and other issues like advertisement details.

d. Management of research related injuries, adverse events.

e. Compensation provisions.

f. Justification for placebo in control arm, if any.

g. Availability of products after the study, if applicable.

h. Patient information sheet (PIS) and informed consent form in English/Hindi and local language.

i. Protection of privacy and confidentiality of research participants.

j. Involvement of the community, wherever necessary.

k. Plans for data analysis and reporting.

l. Adherence to all regulatory requirements and applicable guidelines.

m. Competence of investigators, research and supporting staff.

n. Facilities and infrastructure of study sites.

o. Criteria for withdrawal of patients, suspending or terminating the study.

13.Expedited review:

All revised proposals, unless specifically required to go to the main Committee (DPU IEC) and as decided by the Committee in the meeting, will be examined in a meeting of identified members convened by the Chairperson to expedite decision making. The approvals will be reported in the next IESC meeting by Member Secretary. Expedited review may also be taken up in cases of nationally relevant proposals requiring urgent review.

14.Decision making:

a. Members will discuss the various issues before arriving at a consensus decision, whenever needed voting will be done. Decision of majority of members will be final.

b. A member should withdraw from the meeting during the decision procedure concerning an application where a conflict of interest arises and this should be indicated to the Chairperson prior to the review of the application and recorded in the minutes.

c. Decisions will be made only in meeting where quorum is complete.

d. Only members can make the decision. The expert consultants will only offer their opinions.

e. Decision may be to approve, reject or revise the proposal; or to forward the proposal to main Committee (DPU IEC) for review. Specific suggestions for modification and reasons for rejection should be given.

f. In cases of conditional decisions, clear suggestions for revision and the procedure for having the application re-review would be specified.

g. Revised/modified proposals will be reviewed by an expedited review or full review as decided by the Committee in the meeting.

h. All approved proposals will subject to the following standard conditions. Additional conditions may be added by the IESC.

   i. PI should submit six monthly reports of the ongoing project in format prescribed by the Institute, to the IESC.**(Annexure 5B)**

   ii. The final report of the completed study should be submitted by PI.

   iii. The PI should highlight the changes in the protocols/brochures/informed consent form etc. being amended from the previous documents while submitting amended documents to IESC.**(Annexure 5C)**

15. Communicating the Decision:

a. Decision will be communicated by the Member Secretary in writing.

b. Suggestions for modifications, if any and reasons for rejection shall be informed to the PI.

c. The schedule/ plan of ongoing review by the IESC would be communicated to the PI.

d. Applicants not satisfied with the decision of IESC may be advised to submit their proposals to be reviewed by DPU IEC.

e. IESC clearance certificate shall be issued to PI/CI only after presentation of CSC clearance certificate.

16.Follow up procedures:

a. Six monthly reports should be submitted by the PI on prescribed format along with comments. **(Annexure 5B)**

b. Final report should be submitted at the end of study on prescribed format including a copy of the report sent to sponsoring agency.

c. All serious adverse effects (SAEs) and the interventions undertaken should be intimated immediately to IESC. The PI should submit the SAEs reported by other centers from time to time to the Member Secretary for information to IESC along with comments if any action is required in the current study.

d. Protocol deviation, if any, should be informed with adequate justifications.

e. Any amendment to the protocol should be resubmitted for renewed approval.

f. Any new information related to the study should be communicated to IESC.

g. Premature termination of study should be notified with reasons along with summary of the data obtained so far.

h. Change of investigators/ sites should be done with the approval of IESC.

i. If PI fails to submit the follow up reports within stipulated time or is unavailable for whatsoever reason, IESC may ask to change the PI or ethical clearance may be revoked.

17.Record keeping and Archiving:

a. Curriculum Vitae (CV) of all members of IESC.

b. Copy of all existing relevant National and International guidelines on research ethics and laws along with amendments.

c. Copy of all study protocols with enclosed documents, progress reports and SAEs.

d. Minutes of all meetings duly signed by the Member Secretary and Chairperson.

e. Copy of all correspondence with members, researchers and other regulatory bodies.

f. Final report of the approved projects.

g. All documents should be archived for minimum of ten years after the completion of study. A copy of filled Case Report Form (CRF) shall remain with the PI for minimum of fifteen years.

18. Updating IESC Members:

a. All relevant new guidelines should be shared by the members of IESC and brought to the attention of other members.

b. Members will be encouraged to attend National and International training programs/conferences/seminars in the field of research ethics for maintaining and improving the quality in ethical review and be aware of the latest developments in this area.

19. Review of SOPs:

a. IESC SOPs will be reviewed and revised every 3 years and as required, based on changes in guidelines of National and International research regulatory authorities.

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

रुग्णाचे संमती पत्र

अभ्यास क्रमांक:

अभ्यासातील रुग्णाचा ओळख क्रमांक:

अभ्यासाचे नाव:

प्रमुख संशोधांकर्त्याचे नाव:

दूरध्वनी क्रमांक:

अभ्यासाच्या माहितीपत्रकात, दिनांक: ___/___/___ ह्या दिवशी नमूद केलेल्या गोष्टी मी वाचलेल्या आहेत/मला समजणाऱ्या भाषेत समजावल्या गेलेल्या आहेत. मला अभ्यासाची संपूर्ण माहिती समजली आहे. मला प्रश्न विचारण्याची संधी दिली गेली आहे.

संशोधनाचा प्रकार आणि उद्देश व त्यातील संभाव्य धोके आणि फायदे, तसेच संशोधनासाठी लागणारा वेळ आणि त्याच्याशी संलग्न माहिती मला सविस्तर समजण्यात आलेली आहे.

मला हे समजते की ह्या संशोधनात माझी भागेदारी स्वेच्छेने आहे. मला कुठल्याही वेळी ह्या मधून काहीही कारण न देता, तसेच माझी वैद्यकीय शुश्रूषा व कायदेशीर अधिकार प्रभावित न होता बाहेर पडता येईल.

मी असे समजतो/ समजते की ह्या संशोधनामध्ये माझ्याबद्दल गोळा केलेली माहिती, डॉ. डी. वाय. पाटील मेडिकल कॉलेज, पिंपरी, पुणे; येथे काम करणाऱ्या जबाबदार व्यक्तींकडूनच अभ्यासली जाईल. मी याद्वारे संशोधांकर्त्यांना, ह्या माहितीचा संशोधनाकरिता वापर करण्यास संमती देतो/ देते. मला हे समजते की ह्या संशोधनादरम्यान कोठेही माझे नाव प्रकाशित होणार नाही व माझी ओळख गुप्त ठेवण्यात येईल.

मी ह्या संशोधनातून निर्माण होणारा कुठल्याही माहितीचा किंवा निष्कर्षाचा वापर फक्त वैज्ञानिक कारणांसाठी प्रकाशित करण्यास परवानगी देत आहे.

मी वरील संशोधनात सहभागी होण्यास संमती देत आहे.

(स्वाक्षरी/डाव्या हाताचा अंगठा): दिनांक:

ठिकाण:

सहभागकर्त्याचे नाव:

संपूर्ण पत्ता:

वरील संमतीपत्र माझ्या उपस्थितीत मिळवले गेले आहे.

(प्रमुख संशोधांकर्त्यांची स्वाक्षरी)

१) साक्षीदार-१		२)साक्षीदार-२
स्वाक्षरी:	स्वाक्षरी	:
नाव:	नाव	:
पत्ता:	पत्ता	:

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