Standard Operating Procedures

Mumbai Oncocare Centre Institutional Ethics Committee II (MOC IEC II)

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MUMBAI ONCOCARE CENTRE
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Cellcure Cancer Centre
Private Limited
CIN: U74999MH2017PTC301138

MOC IEC II SOP Approval Page

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1. Objective of SOP:

The objective of this SOP is to ensure a strict concordance with the statements of General principles on Research using Human Subjects in Biomedical Research as well as the Statement of Specific Principles on Research to the effective functioning of the Institutional Ethics Committee (IEC) under the guidelines of ICMR, New Drugs and Clinical Trials Rules, 2019 and WHO Operating Guidelines for Ethical Review Committee that Review Biomedical Research, and ICH (International Conference on Harmonization) Good Clinical Practice (GCP) and applicable regulatory requirements.

2. General principles in biomedical research involving human subjects:

The committee will contribute a quality and consistent ethical review mechanism for health and biomedical research is put in place for all proposals dealt by the committee as prescribed by the Ethical guidelines for biomedical research on human subjects of ICMR

To ensure that the research protocols that are carried out at **Cellcure Cancer Centre Private Limited (Mumbai Oncocare Centre)** ethics committee are in accordance to the guidelines laid down by Indian Council of Medical Research (ICMR), Indian GCP, ICH GCP & As per New NDCT Rules 2019, the following criteria, but not limited to these only, must be met:

- Do not compromise the safety of the subject.
- Study procedures to be conducted under the supervision of medical persons with the required expertise
- Include solely patients who have given voluntary and informed, consent to participate in the clinical study.
- The Purpose of the research should be directed towards the increase in knowledge about human beings

- Research is conducted under conditions that no person/persons becomes a mere means for the betterment of others.
- Research is subjected to a regime of Evaluation at all stages on proposal, i.e. design, experimentation, statistical validity, declaration and use of results thereafter.

General Principles:

Any research using the human beings as subjects of medical or scientific research or experimentation shall bear in mind the following principles.

i. **Principles of essentiality** whereby, the research entailing the use of human subjects is considered to be absolutely essential after a due consideration of all alternatives.
ii. **Principles of voluntariness,** whereby respect for the right of the participant to agree or not to agree to participate in research, or to withdraw from research at any time, is paramount. The informed consent process ensures that participants' rights are safeguarded.
iii. **Principle of non-exploitation**, whereby, as a general rule, research subjects are remunerated for their involvement in the research or experiment; and, irrespective of the social and economic condition or status, or literacy or educational levels attained by the research subjects kept fully apprised of all the dangers arising in and out of the research. Sufficient safeguards to protect vulnerable groups should be ensured.
iv. **Principle of social responsibility**, whereby the research is planned and conducted so as to avoid creation or deepening of social and historic divisions or in any way disturb social harmony in community relationships.
v. **Principles of ensuring privacy and confidentiality** whereby to maintain privacy of the potential participant, her/his identity and records are kept confidential and access is limited to only those authorized. However, under certain circumstances (suicidal ideation, homicidal tendency, HIV positive status, when required by court of law etc.) privacy of the information can be breached in consultation with the EC for valid scientific or legal reasons as the right to life of an individual supersedes the right to privacy of the research participant.

vi. **Principles and risk minimization** whereby due care is taken by all stakeholders (including but not limited to researchers, ECs, sponsors, regulators) at all stages of the research to ensure that the risks are minimized and appropriate care and compensation is given if any harm occurs.

vii. **Principles of professional competence** whereby the research is planned, conducted, evaluated and monitored throughout by persons who are competent and have the appropriate and relevant qualification, experience and/or training.

viii. **Principles of the maximization of benefit,** whereby due care is taken to design and conduct the research in such a way as to directly or indirectly maximize the benefits to the research participants and/or to the society.

ix. **Principle of institutional arrangements** whereby institutions where the research is being conducted, have policies for appropriate research governance and take the responsibility to facilitate research by providing required infrastructure, manpower, funds and training opportunities.

x. **Principles of accountability and transparency** whereby the research should be conducted in a fair, honest, impartial and transparent manner to guarantee accountability. Related records, data and notes should be retained for the required period for possible external scrutiny/ audit.

xi. **Principle of totality of responsibility** y whereby all stakeholders involved in research are responsible for their actions. The professional, social and moral responsibilities compliant with ethical guidelines and related regulations are binding on all stakeholders directly or indirectly.

xii. **Principle of environmental protection** whereby researchers are accountable for ensuring protection of the environment and resources at all stages of the research, in compliance with existing guidelines and regulations.

3. Role of Institutional Ethics Committee (IEC):

All the proposals submitted to the IEC shall be as per the SOP and the IEC will review and make unbiased recommendations on all types of research proposals involving human participants with a view to safeguard the dignity, rights, safety and well being of all actual and potential research

participants. The goal of research, however important will never be permitted to override the health and well being of the research subjects. The IEC will ensure that all the cardinal principles of research ethics viz. Autonomy, Beneficence, Non-malfeasance and justice are taken care of in the planning, conduct and reporting of the proposed research. For this purpose, IEC will look into the aspects of informed consent process, risk benefit ratio, distribution of burden and benefits and provision 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. The committee will also examine compliance with all applicable regulatory requirements, applicable guidelines and laws.

4. Authority under which Institutional Ethics Committee (IEC) is constituted:

The Institutional Ethics Committee is constituted by the authority vested in the Director Dr.Ashish Joshi,Cellcure Cancer Centre Private Limited (Mumbai Oncocare Centre) The Institutional Ethics Committee has been constituted under the guidelines of ICMR, NDCT Rule 2019, WHO Operating Guidelines for Ethical Review Committee that Review Biomedical Research, and ICH (International Conference on Harmonization) Good Clinical Practice (GCP).

The Institutional Ethics Committee shall review the work of the biomedical and health research Centre before initiation and oversee throughout the duration of the biomedical and health research as per National Ethical Guidelines for Biomedical and Health Research Involving Human Participants.

An institution or organization or any person shall conduct any biomedical and health research with the approval of the Ethics Committee for biomedical and health research.

Any biomedical and health research shall be conducted in accordance with the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants as may be specified by the Indian Council of Medical Research from time to time.

Institutions desirous of conducting biomedical and health research as well as clinical trials or bioavailability or bioequivalence study shall require obtaining registration from specified authorities.

Name of IEC: Mumbai Oncocare Centre Institutional Ethics Committee II

5. Composition of the IEC:

The Institutional Ethics Committee of **Cellcure Cancer Centre Private Limited (Mumbai Oncocare Centre)** shall be multidisciplinary and multi-sectorial in composition. Independence and competence are the two hallmarks of the IEC.

The Chairperson of the Committee Should be from outside the Institution. This is to maintain the independence of the Committee.

The Member Secretary is from the Institution and will be responsible for day to day activities of the IEC.

Other members are mix of medical / non-medical, scientific and non-scientific background, including lay public to reflect the differed viewpoints.

The composition may be as follows:-

1. Chairperson
2. Member-Secretary
3. Basic medical scientists
4. Clinicians
5. legal expert
6. Social scientist / representative of non-governmental voluntary agency
7. lay person from the community

The IEC shall include at least one member whose primary area of interest or specialization is nonscientific and at least one member who is independent of the institution in the committee to safeguard the interest and welfare of all sections of the community/society.

All the IEC members of the Ethics Committee shall follow the provisions of these rules, Good Clinical Practices Guidelines, New CT Rule 2019 and other regulatory requirements IEC shall have majority of its members from other institutions.

Every member of the Ethics Committee shall be required to undergo such training and development programs as may be specified by the Central Licensing Authority from time to time, Provide that any member, who has not successfully completed such training and developmental programs, shall be disqualified to hold the post of member of the Ethics Committee and shall cease to be a member of such committee.

If required, IEC may invite The members representing medical scientists and clinicians shall possess at least post graduate qualification in their respective area of specialization, adequate experience in the respective fields and requisite knowledge and clarity about their role and responsibility as committee members, for example for drug trials a pharmacologist; preferably a clinical pharmacologist may be included.

Similarly, based on the requirement no member of an Ethics Committee, having a conflict of interest, shall be involved in the oversight of the clinical trial or bioavailability or bioequivalence study protocol being reviewed by it and all members shall sign a declaration to the effect that there is no conflict of interest of research area, for example HIV, genetic disorders etc. specific patient groups While considering an application which involves a conflict of interest of any member of the Ethics Committee, such member may voluntarily withdraw from the Ethics Committee review meeting, by expressing the same in writing, to the Chairperson represented in the committee.

The details in respect of the conflict of interest of the member shall be duly recorded in the minutes of the meetings of the Ethics Committee

All the members will be appointed by the **Director-** Cellcure Cancer Centre Private Limited (**Mumbai Oncocare Centre)** with appropriate documentation of their appointment and acceptance. The appointment will be based on their competencies and integrity.

6. Terms of reference:

The terms of references for IEC includes description on terms of appointment of members with reference to the duration of the term, quorum requirement, the policy for removal, replacement, resignation procedure, frequency of meetings, and payment of processing fee to the IEC for review, honorarium / consultancy to the members / invited experts etc. as given in the SOP.

The SOPs will be revised periodically **(i.e. every five years)** or based on the changing requirements. The term of appointment of members could be extended for another term and a defined percentage of members (25%) could be changed after five years. It would be preferable to appoint persons trained in bioethics or persons conversant with ethical guidelines and laws of the country. Substitute member may be nominated if meetings have been continuously missed (i.e. three consecutive times) by a member due to illness or other unforeseen

6.1 Appointment, Training, Resignation and Reconstitution

Terms of Appointment:

Appointment: The Chairperson and Member Secretary will be appointed by the Director Dr.Ashish Joshi, Cellcure Cancer Centre Private Limited (Mumbai Oncocare Centre) with appropriate documentation of their appointment and acceptance. Other member's appointment will done by Chairperson of EC. The appointment will be based on their competencies and integrity.

Duration: This Committee has been constituted for a period of 5 years. Extension of membership may be considered due to non-availability of members of similar stature, qualification and intent to contribute to ethical human testing.

Renewal: Director and other hospital administrative will have authority to continue or replace the existing members after completion of their term. At the end of the term, 1/5 of the IEC members will be replaced such as to maintain the composition. Rotation (replacement) will start from 6th year of constitution of the IEC.

Replacement: During the tenure, Director in consultation with Chairperson will have the authority to replace any of the members in the event that the member has not complied with the conditions of appointment, is absent without prior information for three consecutive meetings or on an occurrence of any event which casts a serious doubt on the integrity or ethics of the member.

Training: All members must be trained prior to their involvement in IEC meetings. The Director will have the authority to conduct the training. The IEC members will be encouraged to keep abreast of all national and international developments in ethics through orientation courses on related topics by its own members or regular training organized by constituted body (ies), so that they become aware of their role and responsibilities. . Any change in the regulatory requirements will be brought to their attention. All IEC members must be aware of local, social and cultural norms as this is the most important social control mechanism. All the regulatory updates of the clinical trials shall be discussed during the ethics committee meetings. Any new member will also be trained on GCP.

Resignation: If any member wishes to discontinue from the IEC he/she would be required to inform the Director through Chairperson, in writing. Members may voluntarily resign from the committee at 2 months notice citing appropriate reasons and incase of internal members their membership would be considered withdrawn, if they resign from the Institute.

As per new CT rule 2019, any change in the membership or the constitution of the registered Ethics Committee shall be intimated in writing to the Central Licencing Authority within thirty working days.

A member may be relieved or terminated of his/her membership in case of:

i. Long term non-availability (i.e. absence of a member in three consecutive IEC meetings)
ii. For any action not commensurate with the responsibilities laid down in the guidelines deemed unfit for a member.
iii. Inability to participate in the IEC meetings on any grounds
iv. Relocation to another city or any such matter, from where member cannot participate in the IEC deliberations.

6.2 Conditions of Appointment and Conflict of Interest:

For appointment to the committee, medical scientist and clinicians should have post graduate qualification and should have sufficient years of work experience at positions of significant responsibility and aware of their role and responsibilities as committee members. Professional integrity and commitment to human welfare would be important criteria for inclusion as members.

A member should be willing to disclose his/her full name, profession, designation and affiliations.

After the initial constitution, subsequent appointment to the committee shall be guided by the quorum requirements and activity of the members involved.

Any members who have obvious undue influence on the decisions of other members by the way of their institutional association, financial liability, kinship or authority would need to voluntarily excluded themselves from the quorum. In case, this is not done voluntarily, exclusion may be suggested (if deemed necessary) by at least 2 other members.

A member should declare at the first meeting in which he/she participates, all conflicts or potential conflicts, of interest that may compromise his/her position on the IEC. It would be up to the rest of the IEC to take an appropriate decision.

A member who has direct involvement or self-affirmed conflict of interest with a proposal being considered shall not form a part of the quorum.

No member may participate in review, comment or approval of any activity in which he/she has a conflict of interest except to provide information as requested by the IEC/IRB.

All IEC members should maintain absolute confidentiality of all discussions during the meeting, including the documents circulated for review, unless required by law.

All committee members and Scientific Review Committee members have to sign a Confidentiality agreement at the time of appointment regarding meeting deliberations, applications, information on research participants and related matters, the term of which shall be binding on them even after the termination of the contract.

All IEC, including the Chairperson, are subject to the Policy on Conflicts of Interest approved by the Director, as amended by the Director, from time to time.

In the event that a matter arises in which an Ethics Committee member is implicated, the Ethics Committee shall meet without the presence of the implicated Ethics Committee member.

7. Quorum requirement:

According to NDCT 2019, minimum of 7 members are required to compose a quorum.

All decisions must be taken in meetings and not by circulation of project proposals. Minutes of Meeting along with the list of members present during the meeting must be maintained.

i. Basic Medical Scientist (preferably one pharmacologist or should be a post graduate with adequate experience in the respective field)
ii. Clinician (should be a post graduate Doctor with adequate experience in the respective field)
iii. Legal Expert
iv. Social Scientist / Representative of NGO /Philosopher/ Ethicist / Theologian.
v. Lay person from community

8. Roles and Responsibilities of IEC Members:

<u>Responsibilities</u>:

i. Attend the EC meetings
ii. Review the protocols and other study related documents
iii. Opine on the new project provided
iv. Monitoring of approved projects, with special reference to Adverse events/SAE
v. Survey of execution of the projects, as and when required
vi. Provide inputs to the Data Safety Monitoring Committee
vii. Maintain confidentiality

Roles:

a) **Chairperson:** Will manage the working of the IEC and ensure that all the members are following the SOP. Management of Member in terms of appointment, removal and replacement. Completion of quorum in every meeting. Communicating with investigator, members, licensing bodies, checking of minutes of meeting, IEC office management.
b) **Member-Secretary:** Will coordinate among the IEC and Hospital. Should prepare agenda and minutes of meetings. Organizing meetings, sending documents to members, coordinating with Administrative officer and Chairperson.

c) **Basic Medical Scientists:** Will comment on the scientific aspect and justification of the clinical study submitted.
d) **Clinicians**: Will comment on the clinical aspects of the clinical study submitted.
e) **Legal Experts**: Will comment on the legal aspects including Clinical Trial agreements, Conflict of Interest insurance policies, Informed consent and legalities of a clinical study.
f) **Social Scientist**/representation of non-governmental voluntary agency: Should comment on the social impact/social concern of the clinical study.
g) **Lay Persons:** Should comment on general feasibility of the study and the impact as a lay person to the society. Should raise concern if any that are effect rights and well-being in terms of understanding of the lay persons of the society.

9. The work procedure of the IEC is as follows:

I. The SOP will be distributed in controlled form to all the members and other stakeholders. The SOP will be revised within every five years, but if the requirements change it can be revised intermittently. The SOP version or date will be changed only if the SOP is revised.

II. The chairperson will conduct all meetings of the IEC. If for any reasons beyond control, the chairperson is not available, an alternate Chairperson will be elected from the members by the members present, who will conduct the meeting.

III. The Member Secretary is responsible for organizing the meetings, maintaining the records and communicating with all concerned. He/she will prepare the minutes of the meetings and get it approved by Chairperson before communicating to the researchers.

IV. Ethics Committee will meet as and when required, preferably once in 2 Months

V. Applicant must submit the proposal at least **three week** in advance of the scheduled IEC meetings.

VI. All Study documents submitted for MOC IEC reviewed will be circulated to all members on Email (Soft Copy) three week before EC Meeting. Hard copies will be shared with MOC IEC members on request

VII. The IEC member (or Designee) will acknowledge the receipt of the package by signing and dating the acknowledgment copy of the application letter. If available the member (or designee) will stamp the letter with IEC stamp.

VIII. On receipt of proposal, the documents will be circulated to all the IEC members well in advance of the meeting, for detailed review. While reviewing the proposal following criteria should be considered:

- Minimize risk to the participants
- Risks must be reasonable in relation to the anticipated benefits
- Participants are selected equitably
- Informed consent is adequate, easy to understand and properly documented
- The research plan makes adequate provision for monitoring the data collected to ensure the safety of participants, where appropriate
- There are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data where appropriate
- Appropriate safeguards are included to protect vulnerable participants

IX. During each meeting limited number of protocols will be discussed (i.e. as decided and communicated by Ethics Committee) keeping in view that all parameters required for competent review are discussed and consensus drawn

X. Quorum of 7 members, as given in the SOP, is required to conduct the IEC meeting. If a member is unable to attend a meeting, his/her opinion on the project MUST be submitted in writing to the Chairperson of the committee, before the date of the meeting for a decision. The members, who are unable to attend a meeting, will not be allowed to vote. But their feedback or suggestions on the proposal may be discussed during the meeting to maintain the multi-sectorial and competent review of the proposal.

XI. For expedited review the IEC will meet earlier as is required. Requirement of quorum is similar to that explained above. Chairperson and Member Secretary will decide on scheduling expedite review meeting

XII. The final decision of the IEC will be in from of any one of the categories given below:

a. Approval
b. Disapproval
c. Modification before Approval
d. Discontinuation of previously approved project

XIII. The IEC decisions will be communicated in writing under the signature of the IEC member secretary

XIV. In case of a positive decision a statement of the responsibilities of the applicant will be communicated. The IEC expects that, the researchers keep the committee informed of, but not limiting to the following:

- All cases of protocol amendments should be submitted for IEC review and approval before implementation
- All cases of amendments to the Informed Consent Form and Patient Information Sheet must be submitted to IEC for review and approval before implementation.
- All cases of amendments to recruitment material
- Serious and unexpected adverse events related to the conduct of the study
- Protocol deviation, if any should be informed with adequate justification

- Any new information that may affect the risk/benefit ratio of the study
- **Annually study progress report** (the clock for the same starts from the date of receipt of MOC IEC approval for the study)
- Final report to be submitted at the end of the study
- Premature termination of the study should be notified with reasons along with summary of the data obtained so far
- Site close out to be notified along with the final status report including the details of subjects, IP and documentation
- All administrative changes, which has study implications must be notified to IEC

XV. In case of a conditional decision i.e. where ethics clearance is subject to condition i.e. Modification of study documents or requirement of additional documents, the IEC will communicate to the researcher or Investigator the stipulated requirement, including suggestions for revision and the procedure for re-reviewing the application. Any time limit imposed for reply will also be stated.

XVI. In case of negative decision a clear statement of the reason(s) for the negative decision will be communicated to the researcher or Investigator including whether it may be submitted as new proposal with appropriate changes. The right to appeal and procedure for re-review (if any) will also be communicated.

XVII. With regard to approval of amendments: should an amendment to a study-related document be administrative in nature and does not involve any change which may jeopardize the subject or the study, then it may be approved by EC in an expedited manner or as an amendment. But the decision to consider the amendment as minor or major lies fully with the IEC. If an amendment is considered major it will be approved during a full meeting involving the full quorum as stated in the New CT rule 2019.

XVIII. **SAE Reporting:** Reported Indian SAE's will be discussed during the IEC meetings to decide on the quantum of compensation and causality of the event.

XIX. An IEC may decide to reverse its positive decision on a study if it receives information that may adversely affect the risk/benefit ration

XX. The discontinuation of a trial may be ordered if the IEC finds that the goals of the trial have already been achieved midway or unequivocal results are obtained.

XXI. IEC allows investigators to present and defend the proposals during the IEC meetings. The Investigator may also be called to present if a clarification is sought on certain issues in the applications

XXII. IEC may seek help from the outside experts if required. 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 views but do not take part in the decision making process which will be made by members of the IEC

XXIII. Minutes of meetings will be documented and maintained for every meeting conducted by IEC

XXIV. IEC decision will be communicated within **2 weeks** of IEC Full Board meeting

XXV. One hard copy of the proposal along with a soft copy (PDF Copy only) need to be submitted to MOC IEC II for competent review

XXVI. The date of IEC meetings will be communicated to researchers or investigators. If there is any change in the schedule it will be communicated well in advance.

10. Types of clinical research projects reviewed by the committee:

I. Observational studies
II. Record reviews and historical studies
III. Surveys, Questionnaires and Interviews
IV. Epidemiological studies
V. Prospective studies either with or without any intervention
VI. Company sponsored drug trials
VII. Studies evaluating new devices and implants
VIII. Review & approval of manuscript for data publication

11. List of documents reviewed for each clinical trial project:

I. Protocol or protocol amendments
II. Investigator brochure or amendments
III. English language Informed consent form,
IV. Marathi, Hindi Informed consent form Translations and its back translations
V. Translation and back translation certificates
VI. Any recruitment or retention material or any other advertisement. Their translations and back translations along with certificates, if applicable
VII. Insurance policy and certificate
VIII. Updated CVs of the Investigators along with medical registration certificates
IX. GCP training certificates of the Investigators
X. Form FDA 1572, if applicable
XI. Undertaking from investigators
XII. Copy of Clinical Trial Agreement (CTA)
XIII. DCGI clearance/approval, if applicable. If approval is awaited mention in application letter and submit the DCGI submission letter
XIV. CTRI registration number/Document
XV. IEC approvals from other investigative site(s), if applicable
XVI. Other relevant regulatory approvals, if applicable
XVII. Financial Disclosure Form (FDF) form all investigators, if applicable
XVIII. Case Report Form (CRFs), subject diary, questionnaires, follow-up cards etc. If translations and back translations to be used then those along with certificates also need to be submitted.
XIX. Source templates provided by Sponsor. If it is site specific template printed on letter head it must only be notified to IEC for review.
XX. Any Other relevant documents required for the study

12. Serious adverse events:

Serious adverse events (SAE) will be reviewed in IEC meetings. Opinions from specialists in the particular area, who don't have any conflict of interest, may be taken, if required. In cases of

significant SAEs, Principal Investigator of the study will be asked to justify the continuation of the study.

Any SAE, including laboratory test abnormalities, clinical trial related injury or death, regardless of causal relationship, must be immediately reported to the Institutional Ethics Committee Chairman, Sponsor and RA (DCGI) within **24 hours**.

Reporting of fatal SAEs

Investigator to report fatal SAE within **24 hours** of becoming aware [as per as per Table 5 of the Third Schedule and in compliance with the procedures as specified in Chapter VI] to

- Sponsor/Contract Research Organization (CRO),
- Chairperson of Ethics Committee
- Drugs Controller General of India (DCGI)

Investigator to submit the analysis report (causality assessment) within **14 Calendar days** of becoming aware of the event to [as per as per Table 5 of the Third Schedule and in compliance with the procedures as specified in Chapter VI]

- Sponsor/CRO (if applicable)
- Chairman of Ethics Committee
- Head of Institute
- DCGI

In case of serious adverse event of death occurring to the clinical trial subject, the IEC shall forward it's report on the serious adverse event of death, after due analysis along with its opinion on the financial compensation, if any, to be paid by the Sponsor or his representative, whosoever had permission from the Licensing Authority as defined under rule 21(b) for conducting the clinical trial, to the:

- Licensing Authority (DCGI)

The report need to be submitted within 30 calendar days of the occurrence of the SAE. The Ethics Committee will foresee that subjects receive the benefits as decided by the LA/Expert Committee.

Reporting of Non-Fatal SAEs

Investigator to report non-fatal SAE within **24 hours** of becoming aware [as per as per Table 5 of the Third Schedule and in compliance with the procedures as specified in Chapter VI] to

- Sponsor/CRO
- Chairman of Ethics Committee
- DCGI

Investigator/Sponsor to submit the analysis report (causality assessment) within **14 Calendar days** of becoming aware of the event to [as per as per Table 5 of the Third Schedule and in compliance with the procedures as specified in Chapter VI]:

- Chairman of Ethics Committee,
- Head of Institute
- DCGI

In case of serious adverse event other than death occurring to the clinical trial subject, the IEC shall forward it's report on the serious adverse event of death, after due analysis along with its opinion on the financial compensation, if any, to be paid by the Sponsor or his representative, whosoever had permission from the Licensing Authority as defined under rule 21(b) for conducting the clinical trial, to:

- Licensing Authority (DCGI)

The report needs to be submitted within 30 calendar days of the occurrence of the SAE. The Ethics Committee will foresee that subjects receive the benefits as decided by the LA.

Causality Assessment table :

Causality Term	Assessment Criteria
Certain	•Event or laboratory test abnormality, with plausible time relationship to drug intake • Cannot be explained by disease or other drugs • Response to withdrawal plausible (pharmacologically, pathologically) • Event definitive pharmacologically or phenomenologically (i.e. an objective and specific medical disorder or a recognised pharmacological phenomenon) • Rechallenge satisfactory, if necessary
Probable / Likely	•Event or laboratory test abnormality, with reasonable time relationship to drug intake • Unlikely to be attributed to disease or other drugs • Response to withdrawal clinically reasonable • Rechallenge not required
Possible	• Event or laboratory test abnormality, with reasonable time relationship to drug intake • Could also be explained by disease or other drugs • Information on drug withdrawal may be lacking or unclear
Unlikely	• Event or laboratory test abnormality, with a time to drug intake that makes a relationship improbable (but not impossible) • Disease or other drugs provide plausible explanations
Conditional / Unclassified	• Event or laboratory test abnormality • More data for proper assessment needed, or • Additional data under examination
Unassessable/ Unclassifiable	• Report suggesting an adverse reaction • Cannot be judged because information is insufficient or contradictory • Data cannot be supplemented or verified

>**Compensation:** Compensation is something, typically money, awarded to research participants in a clinical trial in recognition of Clinical trial related injury or death OR participants receive monetary or other benefits for their participation in the clinical trial.

As per New Drugs and Clinical Trials Rules, 2019, in case of clinical trial related injury or death, the trial subject is entitled to pay financial compensation. The sponsor or his representative is required to pay the financial compensation as per the rule 42 of the New Drugs and Clinical Trials Rules, 2019. As per the rule financial compensation will be over and above the expenses incurred on the medical management of the trial subject.

> SEVENTH SCHEDULE (rules 39, 40, and 42):

-Formulae to determine the Quantum of compensation in the cases of Clinical Trial related injury or Death

1. Formula in case of clinical trial related death:

Compensation = (B x F x R) / 99.37

Where,

B = Base amount (i.e. 8 lacs)

F = Factor depending on the age of the trial subject as per Annexure 1 (based on Workmen Compensation Act)

R = Risk Factor depending on the seriousness and severity of the disease, presence of co-morbidity and duration of disease of the trial subject at the time of enrolment in the clinical trial between a scale of 0.5 to 4 as under:

(1) 0.5 terminally ill patient (expected survival not more than (NMT) 6 months)
(2) 1.0 Patient with high risk (expected survival between 6 to 24months)
(3) 2.0 Patient with moderate risk
(4) 3.0 Patient with mild risk
(5) 4.0 Healthy Volunteers or trial subject of no risk.

However, in case of patients whose expected mortality is 90% or more within 30 days, a fixed amount of Rs. 2 lacs should be given.

2. Formula in case of clinical trial related injury (other than death):

For calculation of quantum of compensation related to injury (other than death), the compensation shall be linked to the criteria considered for calculation of compensation in cases of death of the trial subject as referred to in section of this Schedule. The quantum of compensation in case of Clinical Trial related SAE should not exceed the quantum of compensation which would have been due for payment in Case of death of the trial subject since the loss of life is the maximum injury possible.As per the definition of SAE, the following sequelae other than death are possible in a clinical trial subject, in which the trial subject shall be entitled for compensation in case the SAE is related to clinical trial.

(i) A permanent disability:

In case of SAE causing permanent disability to the trial subject, the quantum of compensation in case of 100% disability shall be 90% of the compensation which would have been due for payment to the nominee (s) in case of death of the trial subject.

The quantum for less than 100% disability will be proportional to the actual percentage disability the trial subject has suffered.

Accordingly, following formula shall be applicable for determination of compensation:

Compensation = (C x D x 90) / (100 x 100)

Where:

D = Percentage disability the trial subject has suffered.

C = Quantum of Compensation which would have been due for payment to the trial subject's nominees) in case of death of the trial subject.

(ii) Congenital anomaly or birth defect: The congenital anomaly or birth defect in a baby may occur due to participation of anyone or both the parent in clinical trial. Following situations may arise due to congenital anomaly or birth defect.

(a) Still birth;
(b) Early death due to anomaly;
(c) No death but deformity which can be fully corrected through appropriate intervention; (

d) Permanent disability (mental or physical).

The compensation in such cases would be a lump sum amount such that if that amount is kept by way of fixed deposit or alike, it shall bring a monthly interest amount which is approximately equivalent to half of minimum wage of the unskilled worker (in Delhi). The quantum of compensation in such cases of SAE shall be half of the base amount as per formula for determining the compensation for SAE resulting into death.

In case of birth defect leading to sub-clause (c) and (d) of this clause to any child, the medical management as long as required shall be provided by the Sponsor or his representative which will be over and above the financial compensation.

(iii) Chronic life-threatening disease; and
(iv) Reversible SAE in case it is resolved.

In case of clinical trial related SAE causing life-threatening disease and reversible SAE in case it is resolved, the quantum of compensation would be linked to the number of days of hospitalisation of the trial subject. The compensation per day of hospitalization shall be equal to the wage loss. The wage loss per day shall be calculated based upon the minimum wage of the unskilled worker (in Delhi).

Since, in case of hospitalisation of any patient not only the patient loses his/her wage, there will be direct or indirect losses of various kind including inconvenience, wage loss of attendant, etc. The compensation per day of hospitalisation in such case shall be double the minimum wage.

Accordingly, following formula shall be applicable for determination of compensation:

Compensation = 2 X W X N.

Where,

W = Minimum wage per day of the unskilled worker (in Delhi)
N = Number of days of hospitalization

Annexure 1

Factor (F) for calculating the amount of compensation

Age	Factor
Not more than...	
16	228.54
17	227.49
18	226.38
19	225.22
20	224.00
21	222.71
22	221.37
23	219.95
24	218.47
25	216.91
26	215.28
27	213.57
28	211.79
29	209.92
30	207.98
31	205.95
32	203.85
33	201.66
34	199.40
35	197.06

36	194.64
37	192.14
38	189.56
39	186.90
40	184.17
41	181.37
42	178.49
43	175.54
44	172.52
45	169.44
46	166.29
47	163.07
48	159.80
49	156.47
50	153.09
51	149.67
52	146.20
53	142.68
54	139.13
55	135.56
56	131.95
57	128.33
58	124.70
59	121.05
60	117.41
61	113.77
62	110.14
63	106.52
64	102.93
65 or more	99.37

13. Informed Consent:

Definition: A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate.

(a) In all trials, a freely given, informed, written consent is required to be obtained from each study subject. The Investigator must provide information about the study verbally as well as using a

patient information sheet, in a language that is nontechnical and understandable by the study subject.

(b) The subject's consent must be obtained in writing using an “Informed Consent Form”. Both the patient information sheet as well as the informed consent form should have been approved by the ethics committee and furnished to the Central Licensing Authority. Any changes in the informed consent documents should be approved by the ethics committee and submitted to the Central Licensing Authority before such changes are implemented.

(c) Where a subject is not able to give informed consent (e.g. an unconscious person or a minor or those suffering from severe mental illness or disability), the same may be obtained from a legally acceptable representative a legally acceptable representative is a person who is able to give consent for or authorize and intervention in the patient as provided by the law of India).

(d) If the trial subject his or her legally acceptable representative is unable to read or write an impartial witness should be present during the entire informed consent process who must append his or her signature to the consent form.

(e) In case of clinical trials on pediatrics, the subjects are legally unable to provide written informed consent and are dependent on their parent or legal guardian to assume responsibility for their participation in clinical studies. In such case,-
(i) Written informed consent should be obtained from the parent or legal guardian. However, all pediatric participants should be informed to the fullest extent possible about the study in a language and in terms that they are able to understand.
(ii) Where appropriate, pediatric participants should additionally assent to enroll in the study. Mature minors and adolescents should personally sign and date a separately designed written assent form.
(iii)Although a participant's wish to withdraw from a study must be respected, there may be circumstances in therapeutic studies for serious or life-threatening diseases in which, in the opinion of the Investigator and parent or legal guardian, the welfare of a pediatric patient would be jeopardized by his or her failing to participate in the study. In this situation, continued parental or legal guardian consent should be sufficient to allow participation in the study.

(f) A checklist of essential elements to be included in the study subject's informed consent document as well as a format for the informed consent form for trial subject is given in Table 3of this Schedule.

(g) An audio-video recording of the informed consent process in case of vulnerable subjects in clinical trials of New Chemical Entity or New Molecular Entity including procedure of providing information to the subject and his understanding on such consent, shall be maintained by the investigator for record: Provided that in case of clinical trial of anti-HIV and anti-leprosy drugs, only audio recording of the informed consent process of individual subject including the procedure of providing information to the subject and his understanding on such consent shall be maintained by the investigator for record.

Review of Informed consent documents:

- Informed Consent Documents- Participant Information Sheet & Informed Consent Forms (ICFs) for adults. For studies involving children, parent information sheet and consent form and child information sheet and assent form are mandated in case of children between age 7-18.
- English, Hindi and Marathi ICDs are to be mandatorily submitted to IEC. ICDs in other languages may be submitted if required by the study Back translations of participant information sheet & informed consent forms is mandatory for vernacular languages other than Hindi and Marathi and may be requested on a case to case basis for Hindi and Marathi.
- Application for waiver of consent (if applicable)
- Audio video informed consent (if applicable)
- Participant recruitment and enrollment procedures/advertisement (if any)
- Projects Eligible for Waiver of the Written Informed Consent Process

The EC will consider waiving the requirement of obtaining written informed consent from a subject of research, if the nature of the research meets one of the following definitions:

a. Does not violate and is not invasive, and
b. Does not involve risks to the subjects that are more than minimal.

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research is not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests, i.e. the nature of the research meets one of the following definitions:

i. Research involving collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if the investigator records the information in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects, or if the sources of the information are publicly available.

ii. Research involving normal educational practices.
iii. Research involving use of educational tests, survey procedures, interview procedures or observation of public behavior without revealing subjects' identity, placing them at risk of criminal or civil liability, or damaging their financial standing, employability or reputation.

iv. Research that anticipates but lacks definite plans for involvement of human subjects, such as institutional-type center or training grants; any study involving human subjects under the umbrella of such grants will have to be reviewed subsequently by the EC, prior to its initiation.

v. Research that cannot practicably be carried out, if informed consent were to be obtained in advance, provided that the rights and welfare of the subjects will not be adversely affected; in this instance, arrangements shall be made to provide pertinent information to the subjects after their participation.

- In emergency situations, the EC has right to make exceptions to informed consent requirements after appropriately reviewing such protocols.

- Projects Eligible for Waiver of the Requirement for Documentation of the Informed Consent.

The EC may waive the requirement for documentation of the informed consent (a signed Subject Consent Form), but not that of obtaining informed consent, under one of the following circumstances:

a. The principal research risk is potential harm resulting from a breach of confidentiality, and the only record linking the subject and the research is the consent document.

b. The research presents no more than minimal risk of harm to subjects, and does not include any procedure, for which written consent would be required, if it were to be performed for clinical management. Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests.
In cases where the EC will waive the requirement for documentation of informed consent, the investigators shall still provide the subject with the written Subject Information Sheet shall be reviewed and approved by the EC. Based on this information, the investigator shall obtain oral consent to participate, but the granting of the consent will not be documented in writing.

Format of informed consent form for Subjects participating in a clinical trial :

- Informed Consent form to participate in a clinical trial
- Study Title:
- Study Number:
- Study introduction and details of sponsor, Investigator and Ethics Committee
- Subject's Initials: _____ Subject's Name: _____
- Date of Birth/Age: _____
- Address of the Subject _____
- Qualification _____
- Occupation: Student or Self-Employed or Service or Housewife or Others (Please click as appropriate) .
- Annual Income of the subject:
- Name and address of the nominees and his relation to the subject (for the purpose of compensation in case of
  trial related death).

Patient Initials/Thumb impression

(i) I confirm that I have read and understood the information Sheet dated _____ for the above study and have had the opportunity to ask questions. [ ]

(ii) 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 my medical care or legal rights being affected [ ]

(iii) I understand that the Sponsor of the clinical trial, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial.I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published. [ ]

(iv)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 purposes. [ ]

(v) I agree to take part in the above study. [ ]

Date: _____/ ____ /

Signatory's Name: _____

Signature of the Investigator: _____ Date: ____ / ____ /

Study Investigator's Name: ___ _____

Signature of the Witness _____ Date: ____ / ____ /

Name of the Witness:_____

Copy of the Patient Information Sheet and duly filled Informed Consent Form shall be handed over to the subject his or her attendant.

14. Vulnerable groups:

Effort may be made to ensure that individuals or communities invited for research be selected in such a way that the burdens and benefits of the research are equally distributed.

- Research on genetics should not lead to racial inequalities.
- Persons who are economically or socially disadvantaged should not be used to benefit those who are better off than them.
- Rights and welfare of mentally challenged and mentally differently abled persons who are incapable of giving informed consent or those with behavioral disorders must be protected.
- Appropriate proxy consent from the legal guardian should be taken after the person is well informed about the study, need for participation, risks and benefits involved and the privacy and confidentiality procedures. The entire consent process should be properly documented
- Adequate justification is required for the involvement of participants such as prisoners, students, subordinates, employees, Children, service personnel etc. who have reduced autonomy as research participants, since the consent provided may be under duress or various other compelling reasons.

15.Waiver of consent:

A researcher can't decide that his /her proposal falls in the exempted, expedited or full review category. All research proposals must be submitted to the EC. The decision on the type of review required rests with the EC and will be decided on a case-to-case basis.

The EC may grant consent waiver in the following situations.

- Research can't practically be carried out without the waiver and the waiver is scientifically justified.
- Retrospective studies where the participants are-de-identified or cannot be contacted.
- Research on anonymized biological samples/data.

- Certain type of public health studies and surveillance programmers' evaluation studies.
- Research on data available in the public domain.

16.Record keeping:

(1) The Ethics Committee will maintain data, record, registers and other documents related to the functioning and review of clinical trial or bioavailability study or bioequivalence study, as the case may be, for a period of five years after completion of such clinical trial.

(2) In particular and without prejudice to the generality of the sub-rule (1), the Ethics Committee will maintain the following records for a period of five years after completion of every clinical trial or bioavailability study or bioequivalence study, namely: -

(i) The constitution and composition of the Ethics Committee.

(ii) The curriculum vitae of all members of the Ethics Committee.

(iii) Standard operating procedures followed by the Ethics Committee.

(iv) National and international guidelines followed by the Ethics Committee.

(v) Copies of the protocol, data collection formats, case report forms, investigators brochures, etc., submitted for review.

(vi) All correspondence with committee members and investigators regarding application, decision and follow up.

(vii) Agenda of all Ethics Committee meetings and minutes of all Ethics Committee meetings with signature of the Chairperson.

(viii) Copies of decisions communicated to applicants.

(ix)Records relating to any order issued for premature termination of study with a summary of the reasons thereof.

(x) Final report of the study including microfilms, compact disks or video recordings

(xi) Recommendation given by Ethics Committee for determination of compensation.

(xii) Records relating to the serious adverse event, medical management of trial subjects and compensation paid.

(3) The Ethics Committee will furnish the information maintained under sub-rule-1 and sub-rule - 2, as and when required by the Central Licensing Authority or any other officer authorized on its behalf.

17.Site Monitoring and Post monitoring activities:

Routine monitoring for site may be decided at the time of approval of the project by the full board. This is recorded in the IEC minutes

I. Before the visit:

- Irrespective of the cause of conducting monitoring the following procedures will be followed.
- The IEC will identify and select one or more IEC members (henceforth referred to as monitors) to conduct monitoring at site.
- The selected members will be given a letter in this regard.
- The agenda of the monitoring will be decided by the identified monitors in consultation with the member secretary and chairperson.
- The member secretary will decide the date of the monitoring in consultation with monitors and the PI.
- The final date will be communicated with PI and monitors.
- Monitor will carry with them site monitoring visit report forms.

II- During the visit:

- Monitor will follow the checklist and oversee the progress of the study will ensure that the study conduct, and data handling comply with the protocol, GCP and applicable ethical and regulatory requirements.

III- After the visit:

- The monitor will submit the completed site monitoring visit report to the IEC within 7 working days of conducting a site monitoring visit or at the time full board meeting.
- The report should describe following the finding of the monitoring visit.

- The member secretary will present the monitoring report at the next full board IEC meeting and the concerned monitor will provide additional details/clarification to members, as required.
- The IEC will discuss the findings of the monitoring process and take appropriate action.
- The IEC will convey the decision to the PI in writing within 14 working days of the meeting.

18.Management of regulatory inspection:

The regulatory inspection of the IEC can be conducted with or without prior notification by the regulatory agency. Foreseeing the regulatory inspection, the IEC will take all the measures required to ensure that the trials are conducted strictly in accordance with the clinical trial regulations and guidelines.

Ethics committee shall remain open for inspection by the inspectors or officials of the Central Drugs Standard Control Organization (CDSCO). The IEC shall allow inspectors or officials of the CDSCO to enter its premises to inspect any record, data, or document related to clinical trials approved by the IEC and shall provide adequate replies to queries/observations (if any) raised by such inspectors or officials of the CDSCO in relation to the conduct of the clinical trial.

Preparation for the Regulatory Inspection:

i. IEC will be registered under the Licensing Authority. The renewal of registration will be done three months prior to the expiry of registration. For this, IEC will keep a track of the registration approval date
ii. IEC will be constituted as per the ICMR Guidelines & New CT Rule
iii. IEC will ensure that the right, safety and well being of the subjects participating in the biomedical research is always protected
iv. IEC will review all study protocols considering the following criteria:

- Minimize risk to the participant
- Risks must be reasonable in relation to anticipated benefits
- Participants are selected equitably
- Informed consent is adequate, easy to understand and properly documented
- The research plan makes adequate provisions for monitoring the data collected to ensure the safety of participants, where appropriate
- There are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data, where appropriate
- Appropriate safeguard are included to protect vulnerable population

v. IEC will maintain all appropriate records to substantiate proper functioning of the Ethics Committee deliverables

vi. If the Inspection is conducted with prior notice, all the members of the IEC will be made aware of the Inspection

During Inspection:

- During the Inspection the delegated personnel from IEC will be present to face the Inspection
- He/she will provide the inspectors with requested records/documents
- If any questions are raised by the Inspectors, the delegated personnel will answer all the questions to the point and with facts/evidence.

After Inspection:

- On receipt of the query letter, if applicable, the IEC will ensure that all queries are addressed within the stipulated timelines
- If required the corrective actions will be implemented

19. Expedited review

Proposals that involve no more than minimal risk and those that do not satisfy the criteria for exemption will be eligible to apply for expedited review. Proposals cannot be considered for expedited review if identification of the subjects and or their responses would reasonably place

them at risk of criminal or civil liability or be damaging to the subjects financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal. Research involving vulnerable persons may be considered for expedited review. The Member-Secretary and the Chairperson of the IEC or designated member of the committee may do expedited review only if the protocol involves:

- Minor deviations from originally approved research during the period of approval (usually of one year duration)
- Revised proposal previously approved through full review by the IEC or continuing review of approved proposals where there is no additional risk or activity is limited to data analysis
- Research activities that involve only procedures listed in one or more of the following categories :

  Clinical studies of drugs and medical devices only when -

  - Research is on already approved drugs except when studying drug interaction or conducting trial on vulnerable population

    or
  - Adverse Event (AE) or unexpected Adverse Drug Reaction (ADR) of minor nature is reported.
- Research involving clinical materials (data, documents, records, or specimens) that have been collected for non-research (clinical) purposes.

a) **Research on interventions in emergency situation**

In case of emergency situation, research can only be approved as a pilot study or preliminary work to study the safety and efficacy of the intervention.

When proven prophylactic, diagnostic, and therapeutic methods do not exist or have been ineffective, physicians may use new intervention as investigational drug (IND) / devices/ vaccine to provide emergency medical care to their patients in life threatening conditions. Research in such instance of medical care could be allowed in patients –

i. When consent of person/ patient/ responsible relative or custodian/ team of designated doctors for such an event is not possible. However, information about the intervention should be given to the relative/ legal guardian when available later;

ii. When the intervention has undergone testing for safety prior to its use in emergency situations and sponsor has obtained prior approval of DCGI;

iii. Only if the local IEC reviews the protocol since institutional responsibility is of paramount importance in such instances.

iv. If Data Safety Monitoring Board (DSMB) is constituted to review the data;

b) **Research on disaster management**

Any sudden occurrence of a calamitous event at any time resulting in substantial material damage, affecting persons, society, community or state(s) is a disaster. Disasters create vulnerable persons and groups in society, particularly so in disadvantaged communities, and therefore, the following points need to be considered when reviewing such research:

i. Special attention to safety, and extra care must be taken to protect the privacy and confidentiality of participants and communities.

ii. Research planned to be conducted after a disaster should be essential culturally sensitive and specific in nature with possible application in future disaster situations and usefulness to community must be considered.

iii. The research undertaken should provide direct or indirect benefits to the participants, the disaster-affected community or future disaster- affected population and a prior agreement should be reached on this, whenever possible, between the community and the researcher.

iv. All international collaborative research in the disaster-affected area should be done with a local partner on equal partnership basis.

v. Transfer of biological material, if any, should be as per Government rules taking care of intellectual property rights issues.

20. IEC Fee:

Review of New Research Project:	• **Indian Trials** -Rs 1,00,000/- + Applicable GST • **Global Trials** -Rs 1,00,000/- + Applicable GST
Amendment Review Fees :	• Major Protocol Amendments (Any changes in Scientific information of study protocol)- Rs.35,000/- + Applicable GST • Minor Protocol Amendments (Administrative Changes)- No Fee
Expedited Review Fees:	Rs 1,10,000/- + Applicable GST
Continuing Review Application/Study Status Reports Review	Quarter 1 to Quarter 4- Nil
Archival Fees:	(for 05 years after completion of the trial at site)- Rs.90000/- + Applicable GST
Mode of IEC Payment	Cheque /Online Transactions

Name	Partiuclars
Company Name	CELLCURE CANCER CENTRE PVT LTD NASHIK
Bank Account No.	50200047126517
Bank Name	HDFC BANK LTD
Branch Address	Sana Building , Linking Road, Santacruz west,
Ifsc code	HDFC0000079
Company Pan No.	AAHCC2532P
GST	EXEMPTED

The fees have to be remitted as a Cheque /Online Transaction in favor of "CELLCURE CANCER CENTRE PVT LTD"

Appendix-I

List of Member Effective date: 14.Apr.2022

List of members of 'EC'

Table 1: IEC membership list with name, qualification, designation & role in IEC, specialty, contact details, gender and affiliation (Attached separately along with this SOP)

Sr No	Name	Qualification	Affiliation/Name of Organizations	Designation on IEC	Gender	External/ Internal
1	Dr.Ashok Jaykumar Vankudre	MBBS, MD with specialization in Community Medicine	Professor at Dr.Vasantrao Pawar Medical College,Hospital & Research Centre, Nashik	Chairperson	Male	External
2	Dr. Prajakta Nilesh Ahire	MBBS, D.Anesthetist	Intensivist at Cellcure Cancer Centre Nashik	Member Secretary	Female	Internal
3	Dr. Asmita Chandrashekhar Pethe	MBBS,MD Pathology	Chief Pathologist at H2G Diagnostics, Cellcure Cancer Centre Nashik	Basic Medical Scientist	Female	Internal
4	Dr Surekha Tushar Nemade	MD,DNB (Biochemistry)	Professor at Dr Vasantrao Pawar medical college,Hospital & Research Centre, Nashik	Basic Medical Scientist	Female	External
5	Dr. Manish Navinchandra	MBBS, D.Ortho.	Consultant Orthopaedic Surgeon at Narayani	Clinician	Male	External

	Choksi		Hospital, Nashik			
6	Dr Tushar Nemade	MD,DNB(Anaesthesiology)	Intensivist at Cellcure Cancer Centre Nashik	Clinician	Male	Internal
7	Dr Pankaj Rane	MD,DNB (Internal Medicine)	Consultant Physician & Intensivist at Shreeyash hospital , Nashik	Clinician	Male	External
8	Dhanlaxmi Patwardhan	Masters in Commerce,Masters in Business Administration with HR specialization	Principal Consultant at THE LINK' a Nashik based Training & Development organization	Lay Person	Female	External
9	Mrs.Manjiri Joglekar	M.Com	Accounts Manager at Jai Hospital Pvt Ltd	Lay person/	Female	External
10	Adv Sonal Gaikar	B.A. , LL.B.	Advocate at Nashik District Court	Legal expert	Female	External
11	Yogesh P. Nerpagar	MSW, B.Sc. CS, B.A.in English	Centre of Youth Development activities,Sinner,Nashik	Social Scientist	Male	External
12	Dr. Vinayak Jibhau Shenage	D.N.B. (GENERAL SURGERY) , M.B.B.S	Consultant surgical oncologist at NAMCO CHARITABLE TRUSTS SGS CANCER HOSITAL ,NASHIK	Clinician	Male	External

Appendix-II

IEC APPOINTMENT LETTER

Date:

From

Director

Cellcure Cancer Centre Private Limited

Plot No 4 and 5, S No 277/1/3,
Near Indrayani Lawns,
Aurangabad Road, Nashik 422003

To

_____

_____

Subject: Constitution of Institute Ethics Committee

Dear Sir/Madam,

On behalf of Institutional Ethics Committee, Site Name, I request your concurrence for possible appointment as a member of Mumbai Oncocare Centre, Institutional Ethics Committee. Kindly send your written acceptance in the enclosed format and provide the necessary information requested.

Thanking you,
Signature & Date:

Name & Stamp

Appendix-III

IEC ACCEPTANCE LETTER

From **Date:**

_____

To

Director

Cellcure Cancer Centre Private Limited

Plot No 4 and 5, S No 277/1/3,
Near Indrayani Lawns,
Aurangabad Road, Nashik 422003

Subject: Consent to be a member of Institute Ethics Committee.

Ref.: Your Letter No.: **_____Dated:**

Dear Sir,

In response to your letter stated above, I give my consent to become a member of Mumbai Oncocare Centre, Institutional Ethics Committee I shall regularly participate in the IEC meeting 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: _____

Appendix-IV

IEC CONFIDENTIALITY AGREEMENT FORM

In recognition of the fact, that I_____

_____

(Member's name, and his/her affiliation) herein referred to as the "undersigned", have been appointed as a member of the IEC, and- have been asked to assess research studies involving human subjects in order to ensure that they are conducted in a humane and ethical manner, adhering to the highest standards of care as per the national, and local regulations and institutional policies and guidelines and international and national guidelines;

Whereas, the appointment of the undersigned as a member of the IEC is based on individual merits and not as an advocate or representative of a home province, territory or community nor as a delegate of any organization or private interest;

Whereas, the fundamental duty of an IEC member is to independently review both scientific and ethical aspects of research protocols involving human subjects and make a determination and the best possible objective recommendations, based on the merits of the submissions under review;

Whereas, the IEC must meet the highest ethical standards in order to merit the trust and confidence of the communities in the protection of the rights and well-being of Human subjects;

The undersigned, as a member of the IEC, is expected to meet the same high standards of ethical behavior to carry out its mandate.

This Agreement thus encompasses any information deemed Confidential or Proprietary provided to the Undersigned in conjunction with the duties as a member of the IEC. Any written information provided to the undersigned that is of a Confidential, Proprietary, or Privileged nature shall be identified accordingly.

As such, the undersigned agrees to hold all Confidential or Proprietary trade secrets ("information") in trust or confidence and agrees that it shall be used only for contemplated purposes and shall not be used for any other purpose or disclosed to any third party. Written

Confidential information provided for review shall not be copied or retained. All Confidential information (and any copies and notes thereof) shall remain the sole property of the IEC.

The Undersigned agrees not to disclose or utilize, directly or indirectly, any Confidential or Proprietary information belonging to a third party in fulfilling this agreement. Furthermore, the Undersigned confirms that his/her performance of this agreement is consistent with the institute's policies and any contractual obligations they may have to third parties.

Agreement on Confidentiality

Please sign and date this Agreement, if the Undersigned agrees with the terms and the conditions set forth above. The original (signed and dated Agreement) will be kept on file in custody of the IEC. A copy will be given to you for your records. In the course of my activities as a member of the IEC, I may be provided with confidential information and documentation (which we will refer to as the Confidential Information; subject to applicable legislation, including the Access to "Confidential Information"). I agree to take reasonable measures to protect the information Act, not to disclose the confidential information to any person; not to use the Confidential Information for any purpose outside the Committee's mandate, and in particular, in a manner which would result in a benefit to myself or any third party; and to destroy all confidential information (including any minutes or notes I have made as part of my duties) to the Chairperson upon termination of my functions as a Committee member.

I, _____ (name of the member) have read and accept the aforementioned terms and conditions as explained in this Agreement.

_____ _____

Signature **Date**

_____ _____

Chairperson Signature **Date**

I acknowledge that I have received a copy of this agreement signed by the EC Chairperson and me.

_____ _____

Signature **Date**

Appendix-V

IEC CONFLICT OF INTEREST FORM

It is recognized that the potential for conflict of interest will always exist but has faith in the IEC and its Chairperson to manage the conflict issues so that the ultimate outcome is the Protection of human subjects.

It is the policy of the IEC that no member may participate in the review, comment or approval of any activity in which he/she has a conflict of interest except to provide information as requested by the IEC.

The Undersigned will immediately disclose to the Chairperson of the IEC any actual or potential conflict of interest that he/she may have in relation to any particular proposal submitted for review by the Committee, and to abstain from any participation in discussions or recommendations or decision making in respect of such proposals.

If an applicant submitting a protocol believes that an IEC member has a potential conflict, the investigator may request that the member be excluded from the review of the protocol.

The request must be in writing and addressed to the Chairperson. The request must contain evidence that substantiates the claim that a conflict exists with the IEC member(s) in question. The Committee may elect to investigate the applicant's claim of the potential conflict.

When a member has a conflict of interest, the member should notify the Chairperson and should not participate in the IEC meeting or voting procedure.

Examples of conflict-of-interest cases may be any of the following:

- A member is involved in a potentially competing research program.
- Access to funding or intellectual information may provide an unfair competitive advantage.
- A member's personal biases may interfere with his or her impartial judgment.

Agreement on Conflict of Interest

Please sign and date this Agreement, if the Undersigned agrees with the terms and conditions set forth above. The original (signed and dated Agreement) will be kept on file in the custody of the IEC. A copy will be given to you for your records.

Whenever I have a conflict of interest, I shall immediately inform the Chairperson not to count me for discussion or decision making in respect of such proposal.

I, _____ name of the member) have read and accept the aforementioned terms and conditions as explained in this Agreement.

_____ _____

Signature **Date**

_____ _____

Chairperson Signature **Date**

I acknowledge that I have received a copy of this agreement signed by the IEC Chairperson and me.

_____ _____

Signature **Date**

Appendix-VI

ETHICS COMMITTEE APPROVAL LETTER TEMPLATE (TO BE PRINTED ON EC LETTER HEAD, IF EC LETTERHEAD NOT AVAILABLE, SEAL CONSISTING OF EC ADDRESS REQUIRED ON THE LAST PAGE)

Date: dd/mmm/yyyy

Reference no.: <Delete if NA>

To
Dr.

Dear Dr._____

The Mumbai Oncocare Centre Institutional Ethics Committee II (MOC IEC II) reviewed and discussed your application to conduct the clinical trial entitled "…….. "on…….(date).

The following documents were reviewed:

(a)Trial protocol (including protocol amendments), dated…….version No.(s) ……

(b)Patient information sheet and informed consent form (including updates, if any) in English or vernacular language.

(c) Investigator's brochure, dated ....., Version no…… Proposed methods for patient accrual including advertisements etc. proposed to be used for the purpose.

(d) Principal investigator's current Curriculum Vitae.

(e) Insurance policy or compensation for participation and for serious adverse events occurring during the study participation.

(f) Investigator's agreement with the sponsor.

(g) Investigator's undertaking (Table 4 of NDCT rule 2019).

Mumbai Oncocare Centre Institutional Ethics Committee II

The following members of the ethics committee were present at the meeting held on (date, time, place).
……Chairperson of the ethics committee;
……. Member-Secretary of the ethics committee;

…….Name of each member with designation;

This is to confirm that only members who are independent of the Investigator and the Sponsor of the trial have voted/ provided opinion on the trial.

We approve the documents and the conduct of the trial in the presented form for entire study duration.

Mumbai Oncocare Centre Institutional Ethics Committee II (MOC IEC II) must be informed about the progress of the study, any changes in the protocol and patient information/informed consent and requests to be provided a copy of the final report. Please notify all Serious Adverse Events occurred in study to MOC IEC II within 24 hours and detailed SAE analysis reports within 14 days from its occurrence.

You are requested to submit study status report annually from date of approval till study closeout.

Mumbai Oncocare Centre Institutional Ethics Committee (MOC IEC II**)** follows procedures that are in compliance with the requirements of ICH (international Conference on Harmonization) guidance related to GCP (Good Clinical Practice) and applicable Indian regulations- The New drugs and Clinical trials rules 2019.

Yours sincerely,
……
Member Secretary,
Mumbai Oncocare Centre-Institutional Ethics Committee II,

Date of MOC IEC II Approval:

(Seal of the MOC IEC II)