RAGAS DENTAL COLLEGE (RDC) AND HOSPITAL, CHENNAI
CODE OF ETHICS

I. Do Good

II. Minimising the risk of Harm

- Physical Harm
- Psychological Harm
- Social Harm
- Financial Harm

III. Informed Consent

IV. Confidentiality

V. Avoiding deceptive practices

VI. Providing the right to withdraw

VII. Responsibility to the community, colleagues and self

RAGAS Dental College and Hospital, Chennai

[A unit of Jaya Educational Trust]

Institutional Review Board Standard Operating Procedure

Executive Summary**

This compilation is a standard, elaborate, written instruction to achieve uniformity of performance in the management of dental research & clinical studies conducted under the aegis of RAGAS Dental College and Hospital, Chennai.

The following is summary of Standard Operating Procedures are based on general Indian Good Clinical Practice and Indian Council of Medical Research's statement of ethics in research involving human participants, 2006 and as per the recent recommendation of The Tamil Nadu Dr. MGR Medical University, Chennai and is only applicable and pertains to the conduct of all human research by students of RAGAS Dental College and Hospital, Chennai, as well as external students in the campus.

Since the field of human subject protection, research participation, legislations and interpretation of the documents are constantly evolving, sections of this document may be subject to change. The Chairman of the Institutional Review Board retains the right to induct or call for a change for the above-mentioned clause.

**** All procedures in the protocol have been framed based on ICMR Ethical Guidelines, including the draft bill, 2016, available at ICMR Website

INTRODUCTION

The Institutional Review Board (IRB)at RAGAS Dental College and Hospital, Chennai Is charged with a twofold mission:
(1) To determine and certify that all projects reviewed by the IRB conform to the regulations and policies set forth by the law enforcing authorities and recommendations for an ethical conduct of research concerning the physical & mental health, welfare, safety, rights, and privileges, and privacy of human subjects in research; and
(2)To assist investigators in conducting ethical research which complies with the nationally and international recommendations and regulations in a way that permits safe accomplishment of the proposed research activity.

MEMBERSHIP OF THE IRB

Appointment and Service of Members

All the following heads of department serve as the members of first term of IRB. The appointment is for this post is for 5 years.

1. Dept. Of Microbiology
2. Dept. Of Biochemistry&Physiology
3. Dept. Of Pathology
4. Dept. Of Pharmacology
5. Dept. Of Anatomy
6. Dept. Of General Medicine
7. Dept. Of General Surgery
8. Dept. Of Community Dentistry
9. Dept. Of Oral Pathology
10. Dept. Of Orthodontia
11. Dept. Of Oral Medicine, Radiology
12. Dept. Of Prosthodontia
13. Dept. Of Pedodontia
14. Dept. Of Periodontia
15. Dept. Of Conservative Dentistry
16. Dept. Of Oral Surgery
17. One social worker
18. One advocate

- Alternate Members (representations)are allowed with the permission of the chair and shall be from the same department
    - Shall not be below the position of an associate professor (6 years of experience after post graduation)
    - Shall sign attendance and participate in the deliberation.
- The period of membership is for 5 years and is for the head of department for the first term only. For subsequent terms the chair with the consultation of board shall decide.

MANAGEMENT OF THE IRB

IRB Chair

- The IRB Chair is extra-mural and the tenure is 3 years and extension as determined by IRB. He/she is appointed unanimously by the IRB. He/she appoints a member secretary. However he /she should be respected researcher and are well informed in regulations relevant to the use of human subjects in research. Whenever the chair or member secretary is not available to conduct IRB business, the chair may designate a board member to assume his/her responsibilities during the period of his/her absence. It is essential that the chair has no conflict of interest in any form with regards to project submitted or investigators.
- The IRB chair and member secretary should have experience in dealing with research conduct on human subjects, have thorough knowledge of regulations and state statutes concerning human subjects research, and understanding of local, national and international research policies, conflict of interest policies and knowledge of ethical guidelines governing research.
- Responsibilities of the chair, or their designee, include:
    - Determining the type of review (exempt, expedited, full board),
    - Reviewing the assigning of primary reviewers by staff,
    - Running full board meetings, reviewing minutes prepared by staff,
    - Reviewing specific revisions to protocols/consent documents that are required as conditions of approval,

- And reviewing serious adverse event reports and any unanticipated problems involving risks to subjects or others.
- In addition, they shall be responsible for defining and interpreting terms such as conflict of interest.
- In addition, they serve as a resource for investigators and IRB members regarding issues related to University, state, national andinternational policies on human subject's research.

Member-secretary

The chair shall appoint an excellent outstanding staff among the IRB members to act as a member-secretary who assists the chair in affairs of the board. The office of the member-secretary shall be responsible for collection of the research proposals, maintenance of records and to assist the chair in the affairs.

Administrative Designee

- Chair may designate key members of the IRB staff to serve as their designee in the following types of situations:
- Triage received applications to the chairs for exempt and expedited review;
- Make assignment of protocols, in consultation with the IRB Chair, to primary reviewers for IRB meetings;
- Review authorizations for questionnaire or similar documents or requests;
- Any other tasks as assigned by the chair(s).
- A chair determines that an IRB administrative staff member qualifies as an experienced designee by evaluating their knowledge of IRB policies, procedures, regulations, and guidance.

Consultants/Ad hoc Reviewers

- At its discretion, the IRB may invite scientists or non-scientists from within or outside the RAGAS Dental College and Hospital, Chennai, who have special expertise, to function as consultants and ad hoc reviewers of a project application. These individuals have access to all documents submitted to the IRB relevant to the specific project under review, may participate at the deliberations and make recommendations on the project, but **will not vote.**

IRB Members

- The members of the IRB (regular or alternate) are appointed by the chair to safeguard the rights and welfare of human subjects in research. All IRB members (full, shared positions, alternate) will be required to sign a confidentiality agreement.
- The length of service for an appointed IRB member is not will be definite as unlike in other Western countries the membership is reserved for the post of head of department and not an individual.

IRB Member and IRB Consultant Conflicting Interests

- No IRB member or consultant/ad hoc reviewer may participate in the IRB initial or continuing review of any project in which the member/consultant has a conflict of interest, except to provide information requested by the IRB.
- In cases where the assigned initial reviewer is a PI or has a conflict of interest, the reviewer must declare that conflict of interest and the study application will be re-assigned to another reviewer.
- When the member with a conflict has a protocol for review before the IRB (investigator-member), the member may be present at the IRB meetings, in the capacity of an investigator or PI, only to provide information requested by the IRB.
- The investigator-member or the alternate**will not vote on the study**.
- If the researcher is the PI on the project they must be absent from the room during the final discussion and vote.
- The absent member is not counted towards a quorum when the vote on the study in question is taken.

Duties of IRB Members

- Duties of members include reviewing human subject application materials in advance of meetings and being prepared to discuss issues related to human subject's protections, serving as primary reviewer when requested by the chair, and having an understanding of the specific requirements of human subject's regulations.
- Member duties include:
    - Protecting the rights and welfare of research subjects.
    - Determining that risks to subjects are minimized.
    - Update/ procure necessary IRB Certification
    - Assist the IRB in procuring registration with appropriate authorities as legally required
    - Ensuring that the investigators:
        - Use procedures that are consistent with sound research design and that do not expose subjects to risk,
        - Whenever appropriate, use procedures already being performed on the subjects for diagnostic or treatment purposes, and
        - Ensuring that the investigator follows a procedure for properly documenting informed consent
        - Determining that risks to the subjects are reasonable in relation to the anticipated benefits to subjects.
        - Determining that selection of subjects is equitable.
        - Determining if the informed consent is adequate and contains all other locally mandated elements, and if not, request clarifications and changes in the consent form in order to adequately explain the purpose of the research, the risks and benefits entailed therein.
        - Determining that the research plan makes adequate provision for ensuring the safety of the subjects.
- Before the IRB meeting, the IRB member should: -
    - Review all required documentation in the application submission package before the assigned project(s) is/are presented.
    - Discuss any questions about the assigned projects with the investigator, other IRB members, or consultants prior to the IRB meeting.
    - Decide whether the investigator should attend the meeting to discuss any problems or concerns noted with the project.
    - Determine if specific changes are needed in the application, protocol or consent form, and come to the meeting with recommended wording to be transmitted to the investigator.
    - As soon as deemed appropriate by the IRB chair, the board member will prepare and present initial submission reviews at full-board meetings, review and present continuation and review materials at full-board meetings, present serious adverse event information at full-board meetings, and recommend any changes, additions or deletions in any of the above actions.
- **Board Meetings**
    - IRB meetings are held every three – six months or once fifteen projects have been submitted or when the chair calls for.
    - The chair shall inform in writing the date, venue and topics taken up by the board at least a fortnight in advance, by **EMAIL**by the Member Secretary/ Administrative Designee.
    - Copies of all applicable regulations are available for reference at every convened meeting of the IRB.
    - Full time board members are expected to attend each scheduled board meeting. If the full board member is unable to attend, their alternate will be asked to attend.
    - If a situation arises where the board member cannot attend, and the member has been assigned as a primary reviewer for the meeting, the member should contact the IRB and request that the project be reassigned to another primary reviewer.

- If the board member has reviewed the submission, they may submit their comments to the IRB Chair who may review them and present the submission to the board.
- A primary reviewer unable to attend and failing to notify the IRB will cause the study review to be delayed until the following meeting and shall be responsible for the same.
- In order to begin an **IRB** meeting, a quorum of members must be present. A quorum is defined as having more than half of the voting board members present at the meeting, including two member whose primary concerns are in a nonscientific area. "Presence" at a meeting means the person must participate by being at the meeting in person or participating by conference call. Any actions taken at a meeting without the presence of a nonscientist or more than half of the **IRB** voting members are considered invalid.
- Should the quorum fail during a meeting, the **IRB** may not take further action or vote unless the quorum is restored.

Compensation of IRB Members

For IRB members, who are also employees of RAGAS DENTAL COLLEGE AND HOSPITAL, CHENNAI no monetary benefits are set aside.

Those members not affiliated with RAGAS DENTAL COLLEGE AND HOSPITAL, CHENNAI are compensated for serving on the IRB. They are provided with a payment for their work on the IRB which may be used at the discretion of the member. The amount and mode of payment shall be set by the chair.

Administrative Support

- The IRB Administrative Staff (IRB AS), are units within the RAGAS DENTAL COLLEGE AND HOSPITAL, CHENNAI and report directly to the member secretary. The IRB Administrative Staffof RAGAS DENTAL COLLEGE AND HOSPITAL, CHENNAI consists of one teaching staff member of RAGAS DENTAL COLLEGE AND HOSPITAL, CHENNAI who has working knowledge of the IRB and scientific research assisted by the office personnel. Together they
  - Assists in preparing the agenda for and monitoring IRB meetings;
  - Maintains files on all human subjects research (including copies of relevant correspondence between the IRB and investigators) that takes place at RAGAS DENTAL COLLEGE AND HOSPITAL, CHENNAI;
  - Maintains databases for tracking studies;
  - Notes down the deliberation (without participation), prepare and maintain meeting minutes;
  - Screens research applications for completeness prior to initiating the IRB review process;
  - Acts as a resource for investigators on general regulatory information, guidance with forms, and assistance in preparing an application for IRB review;
  - Maintains the institution's IRB membership rosters;
  - Provides staff support to the IRBs for all written correspondence;
  - Sends notices of approval, study closure (other than closure of the study by the investigator), and termination;
  - Generates and sends reminder notices to investigators of upcoming continuing reviews;
  - Maintains information on regulations relating to human subjects research;
  - Provides education regarding the IRB process and regulations to the RAGAS DENTAL COLLEGE AND HOSPITAL, CHENNAI research community;
  - Provides education opportunities to IRB members;
  - Maintains records of IRB membership including training;
  - Coordinating the quality assurance and quality improvement programs for the IRB's;
  - All IRB administrative staff will be required to complete a confidentiality agreement.
  - Periodically coordinate with the Government regulatory bodies to ensure that IRB complies with rules and guidelines laid down.

Submission of research protocols

- Submission of the research proposal should be in the prescribed format.
- Application shall be submitted year around at the member-secretary office.
- All application should be in triplicate in hard copy as well as by e-Mail
- All application shall be filled completely.
- Incomplete submissions shall be summarily rejected without notice. However the office of IRB AS shall be helpful in this regard.

Notification of Meetings and Distribution of Materials

- The agenda and application materials are distributed to IRB members sufficiently in advance of the meeting date to allow time for review, generally a fortnight to a week in advance.
- The agenda indicates the date, time, and place of the meeting. For both new protocol and protocols reviewed for modifications or continuing review at full board meetings the IRB members receive the protocol, informed consent and/or assent document(s), and other materials as determined by the chair, member secretary or member designee.
- Complete file documentation is available to all IRB members upon request.

Meeting Procedures

- The IRB meeting is called to order by the chair or member-secretary or the designee, when a decided quorum of members is in attendance.
- The meeting ends when business is finished or is suspended whenever a quorum of members is no longer present for deliberations. A quorum consists of more than half of the full board voting members.
- IRB meetings are conducted by the IRB chair, member secretary or a designee member of the board.
- Information on full board protocols and grants, expedited and exempt reviews, continuing reviews, modifications and adverse event reviews are discussed by the assigned primary reviewer(s).
- Scientific reviewers are requested to contact the investigator, if necessary, to resolve questions prior to presentation. If the scientific reviewer believes that the issues related to the protocol cannot be resolved in a reasonable amount of time, the reviewer may recommend that the protocol be tabled and the reviewer will continue to work directly with the investigator to resolve any outstanding issues. In addition, each new full board protocol is assigned a non-scientist reviewer- who is asked to present their review input at the full board meeting.
- The IRB vote count follows the presentations by the reviewers and adequate discussion.
- At the discretion of the chair and/or the reviewers, the investigator(s) may be invited to attend the meeting for the purpose of additional clarification or discussion.
- The principal investigator is required to leave the meeting for subsequent discussion and voting.
- At the discretion of the chair, voting may be by written ballot, a show of hands, or voice vote.
- The official meeting minutes record, without individual identification, the number of votes to approve, approve with minor modification, withhold approval pending major modifications, table or reject.
- The names of those members who abstain or who are absent from the room are included with the vote count for each protocol.
- A majority vote of the members present at the meeting is required for approval.
- Proxy votes, written, electronic, or telephone, are not allowed.

- Investigators are notified in writing of the decision of the IRB and any changes, if required.
- If approved with minor modifications, the changes may be reviewed and approved by the chair, member secretary or member designee, once returned to the IRB. These protocols do not need to return to the full board for review.

Study File Documentation

IRB records are defined as the physical research files created and maintained at the IRB, which reflect selected data elements in the IRB physical files, and the IRB minutes.

Meeting Minutes

Members and alternates of the IRB receive minutes of full board meetings. Minutes include written notification of all new projects approved (full board and expedited), projects determined to be exempt, continuing reviews (full board and expedited), modifications (full board and expedited), and reportable adverse experience.

LEVELS OF REVIEW

By protocol all research project protocols of RAGAS DENTAL COLLEGE AND HOSPITAL, CHENNAI should be submitted to the member-secretary and approval of the IRB obtained before commencement of the study

- The IRB staff may make determinations regarding those projects that do not involve human subjects either by not "engaging" the RAGAS DENTAL COLLEGE AND HOSPITAL, CHENNAI in Human Subject Research or by those projects which involve Coded Research.
- All human subject research applications are assigned to full board review unless they meet the criteria for exemption or being expedited.
- All projects involving the use of investigational drugs, devices, or biologics is required receive full board review.
- The IRB is obligated to review all such activities, whether funded or not, and certify that the research meets the state, local and IRB requirements for exemption.
- The IRB has determined that the review and determination of exemption status will be performed by the chair, member secretary or chair's designee of the IRB.
- Research will be determined to be exempt only when the sole involvement of human subjects.
- The chair, member secretary or member designee will not consider any research exempt that involves prisoners, sensitive aspects of subject's behavior, sensitive surveys, or that takes place in settings where subjects have a reasonable expectation of privacy.
- Not consider any research exempt that involves survey or interview procedures or observation of public behavior of children except for research involving observation of public behavior when the investigator(s) does not participate in the activities being observed.
- Not consider any research exempt that involves a test article not approved by drug controller of India
- The proposal shall be classified as exempt, expedited or a full board review and appropriately proceeded as decided by IRB.
- Subjects have the right to:
    - Be protected against invasion of their privacy,
    - Expect that their personal dignity will be maintained, and
    - Expect that the confidentiality of private information will be preserved.

IRB REQUIRED SUBMISSIONS

Please refer Annexures

CLOSING STUDIES

- PI have the responsibility of informing the IRB when a study has been completed.
- A study is considered to be open and active until the investigator has submitted a Closure Form or a letter to the IRB.
- Investigators will be notified by the IRB at least annually following the initial approval of the research or as asked by the IRB. At these notification intervals, investigators are to submit either a continuation request or a Closure Form.
- Faculty advisors for student research have the obligation to ensure that the Closure Form is filed with the IRB in a timely fashion.
- When a PI terminates employment or other association with RAGAS DENTAL COLLEGE AND HOSPITAL, CHENNAI S/he is obligated to submit a Closure Form to the IRB or formally transfer the protocol to another principal investigator via a modification which is reviewed and approved by the IRB. In very rare cases, the IRB may grant special permission for the departing individual to remain as principal investigator on the project. Cases are reviewed on a case by case basis.

INFORMED CONSENT

RESEARCH EXEMPT FROM INFORMED CONSENT

If the IRB determines that the research is exempt from IRB review, the research may not require a consent form.

ELEMENTS OF CONSENT FORM

- A statement that the study involves research.
- Purpose of the research.
- Procedures.
- Risks or discomforts
- Benefits of the research
- Treatment Alternatives.
- Costs of Participation.
- Confidentiality.
- Voluntary Participation.
- Right to Withdraw.
- Termination of Participation.
- Compensation for Subject Injury.
- Significant New Findings.
- Conflict of Interest.
- Questions.
- Continuing Contact
- Signatures
- Version Date/Page Numbering.

Translation Requirements:

The IRB will accept documents translated by an individual fluent (i.e., can speak, read and write) in a given language. While making translations, care should be exercised to make sure that an independent reverse translation should imply the same meaning of the original text.

The IRB may come to one of five determinations regarding an application:

- **APPROVED:**The PI will be given the original signed IRB Approval Form, the original stamped approved consent form. The approval date is the date the protocol was reviewed and approved by the board. At the time the study is initially approved the IRB will determine the frequency with which this review is to be done. This is normally done at least once a year, but may be required more frequently if the study involves a very new procedure or involves a considerable risk to the subject. A copy of all these documents shall be with RAGAS DENTAL COLLEGE AND HOSPITAL, CHENNAI IRB AS.
- **APPROVED PENDING MINOR MODIFICATIONS:**The PI will receive an approval form stating conditions which need to be met in order to be able to enroll subjects in the study. These conditions include minor changes to the consent and/or protocol and/or approvals from other committee. After the changes are made the investigator would then submit one copy of the protocol signed by the PIand two copies of the consent form. The changes should be tracked on the protocol and on one copy of the consent form. Once these documents are submitted the study does NOT need to go before the full board again. The modifications would be handled as an expedited event. The PI will be given an original of the approval for the modification- noting that the study status has changed to open to enrollment, the original stamped approved consent form and the original training certificate. At the time the study is initially approved the IRB will determine the frequency with which this review is to be done. This is normally done at least once a year, but may be required more frequently if the study involves a very new procedure or involves a considerable risk to the subject or the study is approved with dissenting vote. A copy of all these documents shall be with RAGAS DENTAL COLLEGE AND HOSPITAL, CHENNAI IRB AS.
- **WITHHELD APPROVAL PENDING MAJOR MODIFICATIONS**: A letter will be written to the PI outlining the general concerns. The investigator needs to address these concerns and re-submit copies of the revised protocol and consent form per full board requirements. The study will be reviewed again at a future full board meeting. In addition, the investigator may be asked to attend a future IRB meeting to answer questions. The investigator has 3 months to respond to the revisions requested. If the investigator does not respond in 3 months, the application is deactivated and returned. If the investigator wishes to conduct a study that has been deactivated, the investigator must submit a new application, incorporating comments from the prior IRB review.
- **REJECTED:** The board may also decide to reject a protocol if it feels the study has major problems involving risk to participants or other significant concerns. The investigator may attend a future IRB meeting to defend the protocol if he/she wishes to pursue the study.
- **TABLED:** A letter will be written to the PI outlining the general concerns. The investigator needs to address these concerns in written documentation or by attending a future IRB meeting. The investigator does not need to resubmit a revised protocol and consent. The study will be reviewed again at a future full board meeting.

Rebuttal or Appeal of IRB Decisions

- In RAGAS DENTAL COLLEGE AND HOSPITAL, CHENNAI no such an event is encouraged. However the chair may provide this as a special case, for which the PI may appeal an IRB decision. A PI may appeal the decision by writing a letter to the IRB chair requesting reconsideration. At the

discretion of the chair, the investigator may make such an appeal in person and/or in writing to the IRB.

- An appeal of a disapproved research project must be reviewed at a full board meeting. However, IRB retains the final authority to decide the approval.

Modifications (Amendments/ Revisions) to Currently Approved Research

All modifications to currently approved research are required to have IRB review and approval prior to implementation except when necessary to eliminate apparent immediate hazards to the subject.

If approved research is changed to eliminate an apparent immediate hazard(s) to the subject, the investigator is required to notify the IRB of the change(s) promptly (within five (5) business days). The IRB will review at the next convened meeting to determine if the change(s) instituted were consistent with the subject's continued welfare.

Suspension or Termination of IRB Approval

- The IRB has the authority to suspend or terminate approval of human subject's research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected, related and serious harm to subjects. Any suspension or termination of approval includes a statement of the reasons for the IRB's action and is reported promptly to the investigator, the investigator's department chair and to concerned authorities, The IRB may require remedial action or education as deemed necessary for the investigator or any other key personnel.
- Suspension is the temporary closing of a human research project or discontinuing an investigator's privilege to conduct human subject research. The suspension may be partial in that certain activities may continue while others may stop or it may be complete in that no activity related to the research may proceed. The IRB will make this determination.
- Termination is the ending of all activities related to a human research project or an investigator's privilege of conducting human subject research at the RAGAS DENTAL COLLEGE AND HOSPITAL, CHENNAIexcept for the continuation of follow-up activities necessary to protect subject safety.

Protocol Closure

Principal investigators have the responsibility of informing the IRB when a protocol has been completed.

A protocol is considered to be open and active until the investigator has submitted a Closure Form to the IRB.

Investigators will be notified by the IRB at least annually following the initial approval of the protocol. At these notification intervals, investigators are to submit either a continuation request or a Closure Form.

Faculty advisors for student research have the obligation to ensure that the Closure Form is filed with the IRB in a timely fashion.

When a principal investigator terminates employment or other association with RAGAS DENTAL COLLEGE AND HOSPITAL, CHENNAI, s/he is obligated to submit a Closure Form to the IRB or formally transfer the protocol to another principal investigator via a modification which is reviewed and approved by the IRB. In very rare cases, the IRB may grant special permission for the departing individual to remain as principal investigator on the project. Cases are reviewed on a case by case basis.

POST APPROVAL MONITORING ACTIVITIES

The Post Approval Monitoring and Education program has three goals:

- Enhance protection of research subjects
- Enhance quality of research data
- Enhancement of the education program

Post-approval monitoring is done by staff within the RAGAS DENTAL COLLEGE AND HOSPITAL, CHENNAI as instructed by the chair or member-secretary or specially appointed committee. The nature and extent will be instructed by them on case by case manner.

The reason(s) for on-site review may include:

- Random selections,
- Complex projects involving unusual levels or types of risks to subjects,
- Projects conducted by an investigator who previously failed to comply with IRB determinations, or
- Projects where continuing review or reports from other sources have indicated that changes without IRB approval may have occurred or subjects were consented inappropriately,
- Non-compliance or non-adherence to protocol;
- Subject or whistleblower complaints, or
- A request by an IRB member and with approval by the IRB.

APPROVAL SIGNATURES

- This document has been reviewed and approved by thePrincipal and Chair of the Institutional Review Boardafter Due consultation with the IRB

File No. ECR/1813/Ragas/Inst/TN

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Ethics Committee Registration Division)

FDA Bhawan, Kotla Road,
New Delhi – 110 002, India
Dated: 17/12/2018

To

The Chairman
Institutional Ethics Committee
Ragas Dental College & Hospital
2/102, East Coast Road, Uthandi
Chennai- 600119, Tamil Nadu
India

Sub: - Ethics Committee Registration No. **ECR/1163/Inst/TN/2018** issued under Rule 122DD of the Drugs & Cosmetics Rules,1945.

Sir/Madam,

Please refer to your application submitted to this Directorate for the Registration of Ethics Committee.

Based on the documents submitted by you, this office hereby registers the **INSTITUTIONAL ETHICS COMMITTEE** situated at **RAGAS DENTAL COLLEGE & HOSPITAL, 2/102, EAST COAST ROAD, UTHANDI, CHENNAI- 600119, TAMIL NADU, INDIA** with Registration number **ECR/1163/Inst/TN/2018** as per the provisions of Rule 122DD of the Drugs and Cosmetics Rules, 1945 subject to the following conditions:

1. This Registration is subject to the conditions specified under Rule 122DD and Appendix VIII of Schedule-Y of Drugs and Cosmetics Act, 1940 and Rules 1945.
2. The Ethics Committee shall review and accord its approval to a clinical trial and also carry ongoing review of the trial at appropriate intervals as specified in Schedule Y and the Good Clinical Practice Guidelines for Clinical Trials in India and other applicable regulatory requirements for safeguarding the rights, safety and well-being of the trial subjects.
3. In the case of any serious adverse event occurring to the clinical trial subjects during the clinical trial, the Ethics Committee shall analyze and forward its opinion as per procedures specified under APPENDIX XII of Schedule Y.
4. The Ethics Committee shall allow inspectors or officials authorized by the Central Drugs Standard Control Organization to enter its premises to inspect any record, data or any document related to clinical trial and provide adequate replies to any query raised by such inspectors or officials, as the case may be, in relation to the conduct of clinical trial.
5. The licensing authority shall be informed in writing in case of any change in the membership or the constitution of the ethics committee takes place.

6. All the records of the ethics committee shall be safely maintained after the completion or termination of the study for not less than five years from the date of completion or termination of the trial (Both in hard and soft copies).
7. If the Ethics Committee fails to comply with any of the conditions of registration, the Licensing Authority may, after giving an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons therefor, suspend or cancel the registration of the Ethics Committee for such period as considered necessary.
8. This registration shall be in force for a period of three years from the date of issue, unless it is sooner suspended or cancelled. Provided that if the application for re-registration is received by the Licensing Authority within three months before the expiry, the registration shall continue to be in force until orders are passed by the said authority.
    a. The Licensing Authority shall be informed in writing in case of any change in the membership or the constitution of the Ethics Committee takes place.
9. Ethics Committee shall consist of not less than seven members and is subject to a maximum of 15. One among its members, who is from outside the institute, shall be appointed as chairman, one member as a Member Secretary and rest of the members shall be from Medical, Scientific, Non-Medical and Non-scientific fields including lay public.
10. The committee shall include at least one member whose primary area of interest or specialization is Non-scientific and at least one member who is independent of the institution, Besides; there should be appropriate gender representation on the Ethics Committee.
11. The Ethics committee can have as its members, individuals from other Institutions or Communities, if required.
12. Members should be conversant with the provisions of clinical trials under this Schedule, Good Clinical Practice Guidelines for clinical trials in India and other regulatory requirements to safeguard the rights, safety and well-being of the trial subjects.
13. For review of each protocol the quorum of Ethics Committee shall be at least five members with the following representations:
    I. Basic medical scientist (preferably one pharmacologist)
    II. Clinician
    III. Legal expert
    IV. Social scientist or representative of non-governmental voluntary agency or philosopher or ethicist or theologian or a similar person.
    V. Lay person from community
14. The members representing medical scientist and clinicians should have Post graduate qualification and adequate experience in their respective fields and aware of their role and responsibilities as committee members.
15. As far as possible, based on the requirement of research area such as HIV, Genetic disorder, etc., specific patient group may also be represented in the Ethics Committee.

16. There should be no conflict of interest. The members shall voluntarily withdraw from the Ethics Committee meeting while making a decision on an application which evokes a conflict of interest which may be indicated in writing to the Chairman prior to the review and be recorded so in the minutes. All members shall sign a declaration on conflict of interest.
17. Subject experts or other experts may be invited to the meetings for their advice. But no such expert shall have voting rights.
18. This certificate is issued to you on the basis of declaration/submission by you that yours is an Institution and registration is sought for Institutional Ethics Committee.
19. Funding mechanisms for the Ethics Committee to support their operations should be designed to ensure that the committees and their members have no financial incentive to approve or reject particular studies.
20. SOP's for funding of the Ethics committee in order to support their operations must be maintained. The records of income & expenditure of Ethics Committee shall be maintained for review and inspection.
21. The Chairman of Ethics Committee shall enter into MOU with head of institution, that necessary support and facilities and independence will be provided to Ethics Committee and their records will be maintained as long as required.
22. Ethics Committee may undertake the review and monitoring of clinical trial protocols of other investigator(s) and site(s) who do not have their IEC, subject to the condition that the other sites are within the loco- regional and community settings similar to that of the registered Ethics committee. The approving ethics committee must be willing to accept their responsibilities for the study at such trial site(s) and the trial site(s) willing to accept such an arrangement.
23. Ethics Committee shall review and approve the suitability of the investigator and trial site for the proposed trial. The ethics committee shall undertake proper causality assessment of SAE's with the help of subject experts where required, for deciding relatedness and compensation, as per condition no (3) mentioned above.

Yours faithfully,

(Dr. S. Eswara Reddy)
Drugs Controller General (I) & Licensing Authority

Drugs Controller General (India)
Dte. General of Health Services
Ministry of Health and Family Welfare
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