Research Ethics Review Committee
Documents to be submitted to IRB before the giving date

- **Check List of Documents submitted For Research Article /Synopsis**

- Application for IRB Approval.
- Written Proposal as Hard copy and softcopy.
- IRB Form
- Questionnaire Performa
- Consent form
- Power point presentation of Research Proposal
- Prior Approval from HOD
- Discuss your project to Dr. Rana Akhtar community medicine HOD

- **Checklist of Documents submitted for Clinical Trial**

- IRB form filled and signed by PI
- Study Protocol
- Informed consent form English & Urdu
- PI to IRB letter mentioning the list of documents submitted for approval
- Site and company agreement
- List of all sites and principal investigators (for multi-center trial)
- Phase 1 and 2 trial results/published data (if phase 3 trial)

Avicenna Medical College & Hospital Institutional Review Board
Research Proposal Cover Sheet

Office Use Only		
IRB approval number:	Date received:	Date approved:

- Please attach 3 copies of synopsis (along with survey/consent form) along with 2 copies of the application form.
- A complete application must be submitted 2 weeks before the tentative date of the meeting.
- If this proposal is to continue a previously IRB-reviewed study, please mention the original approval date and application no. (If yes, your proposal will go through expedited review, but you must still complete all forms.).

Title:

Name of principal investigator (PI):
Purpose of study:

CPSP/UHS/Paper Publication:

Principle Investigator: Faculty:
Staff ___/_____Student___/_____ other (please describe)
Attach a list of all other coworkers if relevant. (however, the permission will be granted to PI& Supervisor specifically)
Email address:

Name of Supervisor (if PI is an UG/PG student):

Department affiliation:

Telephone number of faculty:

Email address of Supervisor:

Research Proposal Summary

Estimated number of participants:

Participant profile (check all that apply): YES/NO (Please specify Inpatient's)
__Students and Faculty Member_
Participants will be (check all that apply):

Adults (at least 18 years of age)

Minors (under age 18)
(Please specify age range) __

Special needs Yes /No __No_____

Animal Experiments Yes/No___No_____

Describe any special characteristics of the participants:

Describe the procedure for recruiting participants:

Describe procedures that will be used to ensure confidentiality of participants.

Describe how photographic and patient records will be preserved.

Summary of Potential Risks and Benefits

Will participants receive any compensation for participating? OBJ
If yes, describe the compensation.

Will deception be used? OBJ
If yes, describe the nature of the deception and a justification for its use

Describe any foreseeable risks to participants, and procedures that will be used to minimize those risks.

Research Proposal Background Information

Describe the background information, including specific aims and hypotheses or research questions. A reference list and copies of pertinent articles can be appended if thought to be of value in the evaluation of the research by the IRB. Attach additional pages if needed.

The aim and objective of the study are:

- The access the knowledge of mothers on oral health of elementary school children
- To access the attitude of mother in maintaining oral health of their elementary school children
- To access the practices adopted by the mothers regarding oral health of their children

Research Proposal Materials and Methods

Provide a detailed description of the research procedure. If applicable, please include a summary of how each variable will be measured and proposed statistical analyses. Attach additional pages if needed.

Materials and Methods

Study design:

Setting:

Population:

Duration:

Sample Size:

Sampling Technique:

Sample Selection:

Inclusion criteria

Exclusion criteria

Methodology:

Written Consent Document

If you do not plan to use a consent form, please include an explanation and justification.

The written consent document should be typed on a separate page and then attached to this application. It should be written simply, so that it can be easily (preferably URDU) understood by the average person. Do not use technical jargon or abbreviations. The following basic elements must be included.

1. A statement that the study involves research, an explanation of the purposes of the research, the expected duration of the participant's involvement in the research, a description of the procedures to be followed, and identification of any procedures that are experimental.

2. A description of any reasonably foreseeable risks or discomforts to the participant.
   No risk and discomfort

3. A description of any benefits that may reasonably be expected from the research.
   Identification and development of understanding regarding integration in an integrated modular curriculum among the students and faculty.

4. A description of how the participant's privacy will be protected. Will the data be kept confidential? Anonymous?
   The names and identities of students and faculty will not be revealed to the public (in any written or verbal form).
5. A statement that participation is voluntary, that the participant may refuse to participate, and that either the participant or the researchers may discontinue the study at any time with no adverse consequences.
   Participants will be voluntary and if the participants refuse, they will not be forced to participate.

6. A statement advising participants that if they have any questions about the research, or their rights, they may contact you. Your name and telephone number must be included.
   Yes, this information will be provided.

7. Signature lines should be included for the participant, the participant's parent or guardian if

For Supervisor of Student Research

International guidelines mandate that research be of sufficient merit to justify the participation of human subjects. The IRB prefers to confer most of the responsibility for determining merit to supervisors. Please sign below and check a box to help us evaluate the merit of the student application.

I have discussed the proposed research with the student applicant named above and find the research to be of sufficient merit to justify the use of human subjects.

I will supervise the preservation of rights of participants and ensure that no harm will come to the participants regardless of the age/sex/race/religion.

No coercion/incentives undeclared to A-IRB/withholding of information will be used during the study in order for the subjects to lose their free will to participate or dissociate from the study.

Animal rights will be respected as per International norms.

Supervisor Name & signature _____ Date _____

Justification of proposed study			
Discrimination denied			
Funding Adequate			
Medico legally Safe			
Religiously/Morally permissible			
Study design is practical			
Practical Applications of study			
Socially acceptable			
Press advertisement (copy attached)			
Consent Process (form attached)			
Permission for Photographs will be taken			

DECISION:

A-IRB Decision

Item	Approved	Revision	Responsible
Study Design Scientifically acceptable			
Ethical Aspects preserved			
Patient Privacy preserved			
Patient Safety ensured			
Justification of proposed study			
Animal rights preserved			
Discrimination denied			
Funding Adequate			
Medico legally Safe			
Religiously/Morally permissible			
Study design is practical			
Practical Applications of study			

Socially acceptable			
Press advertisement (copy attached)			
Consent Process (form attached)			
Permission for Photographs will be taken			

DECISION:

O Approved as such O Approved-Conditionally O Deferred to be resubmitted O Rejected

Remarks_____

_____

_____

Chairperson Co-chairman Secretary:

Prof. Dr. Gulfreen Waheed Dr. Faisal Nazir Hussain Dr. Muntiha

Vote of Members:

1. 2. 3.

4. 5. 6.

7.