SEHAT Trial Informed Consent Form

Official Title:

Evaluating the Impact of Novel Oral Health Promotion Program "SEHAT" among Adolescents in Pakistan's Resource-Constrained Settings – A Cluster Randomized Trial

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Informed Consent Form

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Confidentiality Statement:

This document contains confidential information related to the SEHAT trial. It is intended solely for regulatory review and research purposes. Names of participants are not included.

School Head/Principal Consent Form

Study Title: Evaluating the Impact of Novel Oral Health Promotion Program "SEHAT" among adolescents in Pakistan's Resource-Constrained Settings – A Cluster Randomized Trial

IRB Approval No: 128 - 26

1. Study Overview & Rationale

This study evaluates the impact of the "SEHAT" (School-based Education for oral Health awareness using Advanced Telecommunication technology) program, a novel health promotion initiative designed for adolescents. While the program is framed within the context of general well-being and healthy daily routines, its primary objective is to empower students with sustainable oral health and hygiene practices. Your school has been invited to participate as a "cluster" unit. Classrooms within the school will be assigned to different educational formats to compare their effectiveness over a 12-month period. The educational sessions will be delivered independently by researchers, ensuring the program integrates into the school day with zero workload for teachers.

2. Procedures & Duration

The study involves four phases: Baseline Assessment, Intervention Delivery, Early Reinforcement (3-6 months), and Longitudinal Tracking (12 months).

- Qualified dentists will conduct non-invasive clinical check-ups.
- Students will engage in virtual or conventional learning sessions.
- All sessions are designed to fit within the school timetable (approx. 40 minutes per session).

3. School's Role

By signing this form, the principal agrees to:

- Accept the random assignment of classrooms to either the experimental or conventional study arms.
- Facilitate a private space for clinical examinations and classroom access for virtual sessions.
- Appoint a school focal person (e.g., a teacher) to assist in scheduling and following up on student attendance.

4. Human Subjects & Ethics

- While the school provides "cluster-level" permission, individual participation remains voluntary. We will obtain parental informed consent and student assent before any data collection begins.
- The school or individual students may withdraw at any time without penalty or impact on their academic standing.

5. Data Privacy & Safeguarding

- School and student names will be replaced with unique ID codes. Data will be stored on a secure, encrypted drive accessible only to the research team.

- All researchers have undergone background checks and will adhere to the Shifa College of Dentistry Child Protection Policy. No student will be left alone with a researcher without a school staff member in the vicinity.

6. Compensation & No Cost

There is no financial cost to the school. As a benefit, the research team will provide Oral Hygiene Kits (toothbrush & toothpaste) to all participating students and provide a summary report of the school's overall oral health status to the administration.

7. Declaration of Consent

I confirm that I have read the information provided and have had the opportunity to ask questions. I understand the school's role in this study.

Principal's Name: _____ Signature & Official Stamp: _____

School Name: _____ Date: _____

Parental/Guardian Consent Form

Study Title: Evaluating the Impact of Novel Oral Health Promotion Program "SEHAT" among adolescents in Pakistan's Resource-Constrained Settings – A Cluster Randomized Trial

IRB Approval No: 128 - 26

1. Study Overview

Your child's class has been selected to participate in the SEHAT study. This initiative focuses on improving adolescent oral health and hygiene routines through innovative digital and classroom-based sessions. The goal is to empower students with sustainable habits, to prevent tooth decay and promote overall well-being.

2. What will your child do?

If you allow your child to participate, they will:

- Attend short, interactive classroom sessions (approx. 40 minutes) led by our research team.
- Receive a brief, non-invasive dental check-up by a qualified dentist to observe plaque levels and gum health.
- Answer simple questions about their daily brushing habits and oral health knowledge.
- Use a small diary to track their progress at home.

3. Confidentiality & Data Safety

Your child's name will never be used in any report. All information will be assigned a unique ID code and stored on a secure, encrypted drive. For research purposes and potential publication in medical journals, data will only be reported in an anonymized, group format.

4. Voluntary Participation & Risks

Participation is entirely voluntary. There are no medical procedures, injections, or physical risks involved. You or your child may choose to stop participating at any time without any penalty or impact on their school grades.

Student Assent Section (To be read with the child)

- What is this for? We want to help you keep your teeth strong and your smile bright!
- What will I do? A friendly dentist will look at your teeth to see how healthy they are. You will also get to join fun classroom sessions and use a "Healthy Teeth Diary."

- Does it hurt? No. The dentist will only look inside your mouth. There are no needles or "scary" tools.
- Do I have to? Only if you want to! If you feel shy or want to stop, just tell us.

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5. Permission Statement (Circle your answer)

1. Do you understand what this project is about? Yes / No
2. Do you understand that a dentist will look at your/your child's teeth? Yes / No
3. Are you happy for your child to participate? Yes / No

Child's Name: _____ Parent/Guardian Name: _____
Child's School:_____ Signature: _____
Child's Grade: _____ Date: _____

Teacher Facilitation & Consent Form

Study Title: Evaluating the Impact of Novel Oral Health Promotion Program "SEHAT" among adolescents in Pakistan's Resource-Constrained Settings – A Cluster Randomized Trial

IRB Approval No: 128 - 26

1. Study Overview & Rationale

This study evaluates the impact of a health promotion program aimed at improving the oral hygiene habits of adolescents. Your classroom has been selected as a study unit. The educational sessions will be delivered independently by researchers, without interrupting the core academic curriculum.

2. Role of Facilitating Teacher

To ensure the trial's scientific rigor, your role is strictly limited to administrative facilitation. You are not required to teach, assess, or lead any part of the intervention. Your support involves:

- Helping the research team identify a suitable 40-minute slot in the weekly timetable.
- Assisting in the distribution and collection of Parental Consent Forms to ensure high response rates.
- Allowing the research team access to the classroom and staying present during sessions to satisfy school safeguarding protocols.
- Informing the researchers of school holidays, exams, or unplanned closures that might affect the 12-month follow-up timeline.

3. Commitment to the Teacher

The research team guarantees:

- We will provide all equipment (laptop, projectors, power bank etc), stationery, and dental kits.
- We will manage all student questions and clinical assessments independently.
- If a session conflicts with an urgent academic requirement, the session will be rescheduled immediately.

4. Confidentiality & Professional Safety

- Your name and professional performance will not be evaluated or mentioned in any publication.
- Your decision to facilitate this study is voluntary. Choosing not to participate will have zero impact on your professional standing or relationship with the school administration.

5. Recognition of Contribution

In recognition of your time spent coordinating the study, the research team will provide you with a "Certificate of Research Facilitation" from Shifa College of Dentistry, which may be used for your professional portfolio.

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6. Consent Statement

I understand that my role is to facilitate the logistics of the SEHAT study within my classroom. I have been informed that all intervention activities will be handled by the research team.

Teacher's Name: _____
School Name: _____
Class/Grade: _____
Signature: _____
Date: _____