INFORMED CONSENT FORM FOR PARTICIPATION IN RESEARCH OF THE SCHOOL OF HEALTH SCIENCES, DEPARTMENT OF DENTISTRY,
OF THE NATIONAL AND KAPODISTRIAN UNIVERSITY OF ATHENS (EKPA)

Research Approval Number: _____

Program Title: Clinical efficacy of various irrigation parameters in the reduction of intracanal microbiota
School/Department: Department of Dentistry, EKPA / Endodontics Laboratory
Principal Investigator (Name and Contact Number): Giorgos Tzanetakis - 6944326268
Research Associates: Agapi Zervaki, Nikos Kerezoudis, Maria Georgopoulou

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You are invited to participate in a research program supported by EKPA. The following information is provided to help you decide whether you wish to participate.

1. Purpose

The purpose of this research is:

- To evaluate whether two different concentrations (2.5% and 5%) of the antimicrobial sodium hypochlorite solution, used for root canal irrigation, have different antimicrobial effects. Specifically, to determine which of the two concentrations reduces the number of microbes in the root canal more effectively.
- To assess whether a higher volume of this solution results in additional microbial reduction.

2. Procedures

Your participation in this research involves the following:

- A total of 44 patients will be included in the study, each randomly assigned to one of the two tested concentrations (2.5% and 5%) of the antimicrobial solution.
- Both concentrations are commonly used in clinical practice and are well-documented in scientific literature.
- To participate, you must have at least one single-rooted tooth with a single canal, confirmed as necrotic through sensitivity tests, and with a periapical lesion visible on an X-ray.
- Eligible teeth must be fully developed.
- Each patient will visit the clinic three times:
    - **First visit:** Clinical examination, initial X-ray, and explanation of study procedures (30 minutes).
    - **Second visit:** Endodontic treatment, during which microbiological samples will be collected (1 hour 30 minutes).
    - **Third visit (one year later):** Follow-up clinical and radiographic examination (15 minutes) to assess treatment outcome and tissue healing at the root tip.

During endodontic treatment, four samples will be collected from the same tooth using paper cones inserted at the root canal:

1. Initial sample after access opening.
2. Sample after mechanical cleaning with small instruments.
3. & 4. Samples taken after two cycles of antimicrobial solution application using a syringe and fine needle.

All procedures will follow standard clinical practice, with the only difference being microbiological sample collection.

3. Exclusions

You cannot participate if:

- You have taken antibiotics in the last three months.
- You require chemoprophylaxis for dental procedures, as this could alter the study results.

4. Risks and Discomforts

There are no expected risks associated with participation in this study.

If endodontic treatment fails (regardless of participation in the study), three treatment options are available:

1. Retreatment if improvement is possible.
2. Surgical intervention if retreatment is not viable.
3. Tooth extraction if neither option is acceptable to you.

Any of the above treatments will be decided in agreement with the treating dentist, and the cost will be covered by the regular fees at the Dental School.

5. Research Costs

There is no additional cost beyond the standard fees of the Department of Dentistry. Endodontic treatment expenses are included in these fees.

6. Benefits

- The necessary endodontic treatment will be performed.
- While there is no direct benefit to society, the study results may help improve antimicrobial treatment protocols, increasing the success rate of endodontic therapy.

7. Payment

No payment will be provided for participation in this study.

8. Alternative Treatments

The recommended treatment for your condition is endodontic therapy.

9. New Findings

If new information emerges during the study that may affect your decision to continue participation, you will be informed accordingly.

10. Confidentiality

All records will remain confidential. However, there is no guarantee that this information cannot be disclosed in a court or other legal proceedings. In such cases, your name will not appear in any reports or publications.

11. Limited Liability

All research involves risks, including potential physical harm. Despite precautions, complications may arise. If complications occur, the researchers will assist with medical or dental care, but the cost will be your responsibility or covered by your insurance. EKPA does not have a budget for compensation in case of injury or medical complications. Signing this form does not waive your legal rights.

12. Right to Withdraw

You can withdraw from the study at any time without affecting your right to receive treatment at the Department of Dentistry or any other privileges. Refusal to participate will not impact your access to care.

The principal investigator reserves the right to terminate your participation if unexpected reactions occur, instructions are not followed, or the study is discontinued.

13. Assurance of Answered Questions

If you have further questions about the study, you may contact the principal investigator, Giorgos Tzanetakis, on 6944326268.

This program has been reviewed and approved by the Research Ethics Committee of the Department of Dentistry at EKPA. For questions regarding the committee, you may contact the Department Chair via Ms. E. Koumoutsea at 210-746-1114.

I have read the above information and agree to participate in this research. I acknowledge that I will receive a copy of the signed consent form.

Participant or Legal Guardian Signature: _____
Date: _____

Researcher Receiving Consent Signature: _____
Date: _____