# INFORMED CONSENT FORM (ICF)

**Official Title:** *Effect of Menstrual Cycle on Postoperative Sensitivity and Rebound Pain in Posterior Composite Restorations: A Double-Blind Split-Mouth Clinical Study*

**Unique Protocol ID:** FIRAT-DENTISTRY ADEMGOK-001

**NCT ID:** .....

**Date:** *01.09.2022*

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## Participant Information and Consent Form

Dear Participant,

You are invited to participate in a clinical research study investigating the effect of menstrual cycle phases on postoperative sensitivity (POS) and rebound pain (RP) following direct posterior composite restorations.

Your participation in this study is completely voluntary. Please read the following information carefully before deciding whether to participate.

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## Purpose of the Study:

This study aims to evaluate whether hormonal fluctuations during different menstrual cycle phases affect postoperative sensitivity and rebound pain after dental restorations.

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## Study Procedure:

- You will receive two composite restorations on two different occasions—one during your menstrual phase and one during your ovulatory phase.
- The same local anesthesia (Inferior Alveolar Nerve Block, IANB) and composite filling material (Clearfil Majesty Posterior) will be used for both restorations.
- Your pain and sensitivity levels will be assessed using a Visual Analog Scale (VAS, 0-10) at the following time points:
    - For postoperative sensitivity (POS): 24hour, 48hour, and 72hour after the procedure.
    - For rebound pain (RP): 4hour, 8hour, and 12hour after anesthesia wears off.

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## Potential Risks and Side Effects:

- Temporary numbness due to local anesthesia.
- Mild sensitivity or pain after the filling procedure.
- Rare cases of allergic reactions or unexpected pain increase.

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## Confidentiality and Data Protection:

- All collected data will be kept strictly confidential and anonymized.
- Your personal information will not be shared with third parties.
- Data will be used only for scientific research purposes.

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## Voluntary Participation and Withdrawal Rights:

- Your participation is entirely voluntary, and you may withdraw from the study at any time without providing a reason.
- Withdrawing from the study will not affect your dental treatment in any way.

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## Contact Information for Questions or Concerns:

If you have any questions about the study, please contact:

🔑 **Dr. Adem GOK**

🏢 **Firat University Faculty of Dentistry**
📧 **mail** agok@firat.edu.tr
📞 **Phone:** +905444142458

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## Participant Consent:

✅ I have read and understood the information provided in this form.
✅ I understand that my participation is **voluntary**, and I can **withdraw at any time**.
✅ I agree to participate in this study.

**Participant's Name:** ✍ _____
**Signature:** ✍ _____
**Date:** 📅 ____ / ____ /

**Researcher's Name:** ✍ _____
**Signature:** ✍ _____
**Date:** 📅 ____ / ____ /