

# Ethics Committee of the French Society of Stomatology, Maxillofacial Surgery and Oral Surgery



Pr Christophe MEYER  
President

Pr Gwenaël RAOUL  
Member

Dr Jean-Philippe FOY  
Member

Pr Narcisse ZWETYENGA  
Member

Notification number: CETH-SCOMFS 003/2026 Date: 07/05/2026

Project Title: **Distalisation en masse assistée par minivis : comparaison des effets dentaires, dentoalvéolaires et squelettiques entre aligneurs et multi-attaches. Une étude rétrospective comparative**

Investigator's Name(s): BRIERE Edwige – CHAUTY Sarah

Involved Structure(s): **Unité fonctionnelle d'Orthopédie dento-faciale, Centre de Traitements dentaires, Hospices civils de Lyon, 6-8 place Depéret, 69365 Lyon cedex 03, France**

Document(s) Provided by the Applicant: **Consentement éclairé – Etude BRIERE Edwige (pdf fine); Protocole d'étude Comité d'éthique (word file)**

Maître Georges LACOEUILHE  
Lawyer

Dr Michèle MAGREMANNE  
Representative of a scientific partner society (Royal Belgian Society of Stomatology and Maxillofacial Surgery)

Dr Lotfi BEN SLAMA  
General Secretary

After reviewing the request and analyzing the documents provided, it has been determined that:

- This is a research study not involving the human being (classified as RIPH 3) as defined by the French Research Regulation Authorities, also referred to as a "research project outside the Jardé law" (retrospective non-interventional observational study based on routine care data / review of medical records; no interventions or changes to care; no additional tests or appointments)
- Patients are well informed, and appropriate consent will be properly obtained from them (*informed consent form included in the available documents*)
- Regulatory requirements include
  - compliance with MR-004 (CNIL) (*not specified in the provided data and therefore to be checked by the investigators*)
  - data anonymization (*appears to be planned—to be checked by the investigators*)
- The scientific value of the study is satisfactory
- The protocol used does not raise ethical concerns
- The composition of the research team is satisfactory

✓ For all these reasons, the Ethics Committee of the French Society of Stomatology, Maxillofacial Surgery and Oral Surgery (SFSCMFCO) issues a **favorable opinion** for this research project.

**This opinion in no way exonerates the person in charge of the research project from carrying out any necessary regulatory procedures (approval from the National Commission for Information Technology and Liberties (CNIL), appointment of a Data Protection Officer (DPO), registration of the project on the Health Data Hub, declaration of the study on the clinicaltrials.gov website, etc.) before the start of the study..**

The project lead is also required to sign the commitment below:

I, the undersigned: (Name: \_\_\_\_\_ First name(s): \_\_\_\_\_ date of birth: \_\_\_\_\_ title: \_\_\_\_\_  
Professional address: \_\_\_\_\_ Phone number: \_\_\_\_\_  
Email : \_\_\_\_\_

As the principal investigator/research project lead, I hereby commit to:

1. Requesting the opinion of the SFSCMFCO Ethics Committee for any protocol modifications made following this opinion
2. Informing the SFSCMFCO Ethics Committee of the study's progress
3. Notifying the SFSCMFCO Ethics Committee of the study's conclusion and submitting the final report and/or resulting article(s)
4. Acknowledging this opinion in the publication(s) and thanking the SFSCMFCO in the publication(s)

Date, location, signature

**Approved projects by the Ethics Committee will be recorded in the research directory for stomatology, maxillofacial surgery, and oral surgery, available on the SFSCMFCO website.**