

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



Pr Christophe MEYER
President

Pr Gwenaél RAOUL
Member

Dr Jean-Philippe FOY
Member

Pr Narcisse ZWETYENGA
Member

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

Notification number: CETH-SCOMFS 001/2025

Date: 17/03/2025

Project Title: **Orbital emphysema after zygoma and orbital floor fractures:**

Implications for aeromedical evacuation?

Investigator's Name: **Dr Jean-Baptiste CARUHEL**

Involved Structure(s): **Hopital d'Instruction des Armées (HIA) Sainte-Anne – Toulon - France**

Document(s) provided by the Applicant: **evaluation request, research protocol, patient information notice**

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

- This is a research study not involving the human being (as defined by the French Research Regulation Authorities), referred to as a "research project outside the Jardé law" (study using data typically collected for the type of care described, no additional patient questionnaire)
- Patient's personal data (clinical and paraclinical examinations) are processed in compliance with regulations
- Patients agreed to take part in the study
- 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:

the undersigned: (Name:
title:
Phone number:

First name(s):
Professional address:
Email :

date of birth:

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.

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