Fondazione Policlinico Universitario Agostino Gemelli IRCCS
Università Cattolica del Sacro Cuore

Informative and Consent for the Processing of Personal Data for Scientific Research Purposes in Adults
(Articles 13 and 14 of the EU GDPR 2016/679)

Sponsor: Fondazione Policlinico Universitario Agostino Gemelli IRCCS, Largo Francesco Vito, No. 1 – 00168 – Rome (hereinafter referred to as "Fondazione")
Study Title: Prospective monocentric study of a cohort of patients affected by Oral Lichen Planus: Cardiovascular and prothrombotic risk in patients affected by Oral Lichen Planus (OLP)
Principal Investigator for the Sponsor:
Prof. Carlo Lajolo, UOC Dental Clinic
Version 1, dated 15/04/2025

The Fondazione, as the Data Controller:

- in accordance with the responsibilities established by Good Clinical Practice (Legislative Decree 211/2003);
- in compliance with the provisions of:
  - Regulation (EU) 2016/679 of the European Parliament and of the Council on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (hereinafter GDPR EU 2016/679);
  - Legislative Decree of 30 June 2003, No. 196, as amended by Legislative Decree No. 101 of 10 August 2018;
  - The Italian Data Protection Authority's provisions concerning the processing of special categories of data under Article 21(1) of Legislative Decree No. 101/2018;
  - The Data Protection Authority's resolution "Guidelines for the processing of personal data in the context of clinical trials of medicinal products" of 24 July 2008 and subsequent amendments,

will process personal data to pursue the objectives of the study.

DATA CONTROLLER (Art. 13, para. 1, lett. a of the GDPR)
The Sponsor's contact details are as follows:

- Largo Francesco Vito, No. 1 – 00168 – Rome
- Tel: 06 30151
- Certified Email (PEC): protocollo.generale.gemelli@pec.it

DATA PROTECTION OFFICER (DPO) (Art. 13, para. 1, lett. b of the GDPR)
The Data Protection Officer appointed by the Data Controller under Article 37 of the GDPR can be contacted at the Sponsor's registered office or by email

at: dpo@policlinicogemelli.it or via certified email (PEC): dpo.gemelli@pec.it.
It is noted that the Sponsor will only process pseudonymized data of enrolled subjects.

LEGAL BASIS AND PURPOSE OF DATA PROCESSING (Art. 13, para. 1, lett. c of the GDPR)
Personal data (any information relating to an identified or identifiable natural person) and special categories of data (Article 9 of the GDPR) relating to health status will be processed based on informed consent as the lawful basis under Articles 6(1)(a) and 9(2)(a) of the GDPR.
Specifically, the data will be processed for the following purposes:

- Medical research, including clinical trials of medicinal products based on a project with a favorable opinion from the competent Ethics Committee (prospective/interventional study);
- Conducting a study using data previously collected for healthcare or prior research projects, or biological samples previously obtained for healthcare purposes, with a favorable opinion from the competent Ethics Committee (retrospective/observational study);
- X Scientific and statistical research aimed at protecting public health in the medical, biomedical, and epidemiological fields, surveys (prospective observational study);
- Establishment, integration, and/or maintenance of a Registry, in line with the study title on page 1.

PROVISION OF DATA (Art. 13, para. 1, lett. e of the GDPR)
Participation in the study is voluntary and requires consent; refusal to consent to data processing for study participation will prevent enrollment.
Data may be shared among parties acting as independent Data Controllers involved in the study, to the extent necessary for study execution. Personal data will not be disclosed, except in anonymized and/or aggregated form that prevents identification of the data subject.
As required by clinical trial regulations, your data may also be transmitted to the Ethics Committee and competent authorities, using methods that ensure confidentiality.

If necessary for the study, data may be transferred to non-EU countries. In such cases, data transfer will comply with Chapter V of the GDPR (Articles 44 et seq.), ensuring adequate data protection through contractual safeguards, including standard contractual clauses.

DATA PROCESSING METHODS (Art. 13, para. 1, lett. f of the GDPR)
Data processing will involve various operations (collection, recording, storage, consultation, and modification of personal data, etc.) using manual and digital tools, strictly aligned with the study's objectives and ensuring data security, confidentiality, integrity, and availability throughout.
Technical and organizational measures are adopted to ensure a level of security appropriate to

the risk, including authentication and authorization systems, pseudonymization techniques, and access controls based on personnel roles and responsibilities.

Data collected by the Investigational Center will be labeled with an alphanumeric code that replaces the subject's name, so that only the physician and authorized personnel can link the code to the subject's identity (pseudonymization).

Data will be processed exclusively by authorized personnel subject to professional secrecy and legal confidentiality obligations, respecting the rights and dignity of the data subjects. External parties designated as "Data Processors" under Article 28 of the GDPR may process data on behalf of the Controller within the scope of the study.

DATA RETENTION (Art. 13, para. 2, lett. a of the GDPR)
Data will be retained for no longer than necessary to achieve the study objectives and, in any case, for 7 years (in the case of observational studies) from the end of the study.
At the end of this period, the data will be deleted.

DATA SUBJECT RIGHTS (Art. 13, para. 2, lett. b of the GDPR)
Under Articles 15, 16, 17, 18, and 21 of GDPR EU 2016/679, the data subject:

a) has the right to request from the Data Controller access to, rectification, integration, erasure, restriction, or objection to the processing of personal data, where applicable;

b) has the right to lodge a complaint with the Italian Data Protection Authority by following the procedures and guidance on the official website: www.garanteprivacy.it.

The data subject may exercise these rights at any time by contacting the Data Controller or its Data Protection Officer using the contact details provided.

The Data Controller undertakes to inform the subject of any changes that may occur in the data processing operations described. The data subject may withdraw consent at any time without justification and discontinue participation in the study. In such cases, no further data will be collected, although previously collected data may still be used to determine study results, without alteration. Withdrawal of consent does not affect the lawfulness of processing based on consent before its withdrawal.

RIGHT TO LODGE A COMPLAINT WITH A SUPERVISORY AUTHORITY (Art. 13, para. 2, lett. d of the GDPR)
Pursuant to Article 77 of the GDPR, and without prejudice to any other administrative or judicial remedy, if the data subject considers that the processing of personal data concerning them infringes the GDPR, they have the right to lodge a complaint with the competent

supervisory authority, identified in Italy as the Garante per la protezione dei dati personali, as per Article 153 of Legislative Decree 196/03, as amended by Legislative Decree 101/18. For details, see the institutional website: www.gpdp.it.

Consent to Data Processing for Scientific Research Purposes (Adults)
Pursuant to Article 7 of the GDPR

Having read the information provided under Article 13 of the GDPR, of which this form is an integral part,

I, the undersigned,
First Name: _____
Last Name: _____
Tax Code: _____
Phone: _____
As the Data Subject

☑ give my consent ☑ deny my consent
for the processing of my personal data for the purposes of the Research, as described in the information sheet.

☑ give my consent ☑ deny my consent
for the results of the analyses and any incidental findings emerging during the study to be communicated to:

☑ myself

☑ a family member (Name and Surname: _____)
Contact: _____

☑ spouse/partner (Name and Surname: _____)
Contact: _____

Signature of the Data Subject: _____
Date: _____