

Signed Informed Consent Form(s) or Document(s)

Throughout the study, the national and international guidelines of the Code of Ethics and the Helsinki Declaration were followed, as well as the legal regulations on data confidentiality as provided for in Organic Law 3/2018, of 5 December, on the Protection of Personal Data and the guarantee of digital rights, and Regulation (EU) No 2016/679 of the European Parliament and of the Council of 27 April 2016 on data protection (RGPD).

The study did not require any new intervention and was limited to retrospective data collection through medical history and anonymized record for further analysis. Data were collected securely and stored with a code for each subject for further analysis. The principal investigator was the only one who had access to the encoding file using a password.

The study data was only accessible to the research team and ethics committee staff upon request.

As stated in the Institutional Review Board Approval Form, the use of written informed consent in this study was not necessary given the nature of the study (retrospective).