## **Submission to Healthcare Ethics Committees in Portugal: Our Experience**

# Submissão às Comissões de Ética para a Saúde em Portugal: A Nossa Experiência

Keywords: Clinical; Ethics Committees; Portugal; Research Palavras-chave: Clínica; Comissão de Ética; Investigação; Portugal

Dear Editor,

Ethics Committees in health care are instrumental in upholding ethical standards within the life sciences, ensuring the protection of human dignity and integrity. However, they encounter challenges pertaining to time constraints and limited logistical resources. In Portugal, since 2018, the mandate for an Ethics Committee in human research institutions has introduced a degree of variability in resource allocation and methods of ethical evaluation. This has led to increased complexity in national-level projects, which often require approvals from several local ethics committees. Furthermore, with the implementation of local health units, the number of ethics committees is set to rise from five to potentially 39 across mainland Portugal.

In this letter, we describe the procedures and response times experienced when submitting an identical protocol to the five ethics committees of the regional health administrations in mainland Portugal. The study in question was a European cross-sectional survey, endorsed by the European General Practice Research Network and previously approved by an Ethics Committee at the University of Zagreb. Our goal was to gather a representative sample of Portuguese family physicians, considering recruitment through their institutional email, thus requiring approval from each respective regional ethics committee.

We provide a comparative analysis of the ethics committees' submission processes and response times in Table 1.

Each committee's website provided submission guidelines, but these often lacked clarity, leading to ambiguities. A notable challenge was the diversity in submission rules, protocol structures and required documents across committees. Additionally, many required submissions in Portuguese, complicating matters further for international studies. Predicting response times was often challenging due to the non-publication of meeting dates or the absence of contact emails. Response times varied, frequently exceeding the national 31.3-day average,<sup>3</sup> but the feedback received was detailed and provided valuable insights.

Based on our experience, we recommend researchers conducting nationwide studies in primary health care allocating a minimum of 120 days for the ethics committee approval process. For the committees, we advocate for standardized submission procedures and procedures for mutual recognition of decisions. This streamlining is crucial, given the dual research and clinical duties of most researchers. Furthermore, we suggest institutions enhance their support for ethics committees, ensuring they have adequate secretarial support and allocated time for members. This is particularly relevant at a time when there is a reorganization of the Portuguese National Health Service, which is transitioning from five regional administrations to a multitude of local health units.

#### **AUTHOR CONTRIBUTIONS**

DIR, CS: Literature search, writing of the manuscript.

GP: Critical review of the manuscript.

JA: Writing of the manuscript.

BH: Study design, critical review of the manuscript.

All authors approved the final version to be published.

## **COMPETING INTERESTS**

BH was a consultant for the Healthcare Ethics Committee of the Lisbon and Tagus Valley Region.

All other authors have declared that no competing interests exist.

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Table 1 - Comparative analysis of the Ethics Committees' submission processes and response times

Ethics Committee	Northern Region	Center Region	Lisbon and Tagus Valley Region	Alentejo Region	Algarve Region
Submission	Online platform (only accessible through PC/laptop)	E-mail	E-mail	E-mail	E-mail
Does it accept the protocol in English?	No	Yes	Yes, with a mandatory abstract in Portuguese	No	No
Time until approval	79 days (Submission on 05/11/2022, approval on 23/01/2023)	47 days (Submission on 05/11/2022, approval on 22/12/2022)	40 days (Submission on 04/12/2022, approval on 13/01/2023)	419 days (Submission on 23/12/2022, approval on 15/02/2024)	53 days (Submission on 05/11/2022, Ethics Committee approval on 28/12/2022; Executive Board approval on 12/06/2023)

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