INTRODUCTION

Clinical trials can provide several benefits to the population, the health system, the scientific community and the local economy (Table 1). The introduction of the National Ethics Committee (CONEP) represented a breakthrough for clinical research in Brazil in ethical terms; however, adjustments of the ethics system are required. The framework of ethics evolved over time in different countries in order to follow the new advances in scientific research on rare diseases, since they allow for samples that are representative of the target population and the planning and development of healthcare policies in Brazil.

Our proposal has four main recommendations: review of the responsibilities of local IRBs and the IRB review process for multicenter studies (see Figure 1), standardization of knowledge, implementation of certification and harmonization of regulatory policies (Table 2).

METHODS

We retrieved and reviewed the guidelines and regulations regarding the submission and approval of clinical trials in the following countries, as indicated in Figure 2:

- Australia (National Health and Medical Research Council - NHMRC)
- Canada (Institutional Review Boards - IRB) (Pan-Canada)
- Canada (Ontario Ministry of Health and Long-Term Care - OMLTC)
- Australia (National Health and Medical Research Council - NHMRC)
- Canada (Institutional Review Boards - IRB) (Pan-Canada)
- UK (Central Office for Research Ethics Committees - COREC)
- USA (2000)
- USA (2015)
- Canada Institutional PRE or Panel
- Canada (Institutional Review Boards - IRB) (Pan-Canada)
- USA (2000)
- USA (2015)
- Canada Institutional PRE or Panel
- Canada (Institutional Review Boards - IRB) (Pan-Canada)
- USA (2000)
- USA (2015)