

STATEMENT

Ref. n.º 14/2019 (CE-IST)
Date: 10/07/2019

Name of the PI: Prof. Mónica Oliveira
 Project name: MEDI-VALUE (Developing HTA tools to consensualise MEDical devices' VALUE through multicriteria decision analysis).

Dear Prof.ª Mónica Oliveira,

The Ethics Committee of Instituto Superior Técnico (EC-IST) reviewed your application to obtain ethical assessment for the above mentioned project. The following documents have been reviewed:

No.	Documents	Version & date
1	Form CE-IST	14/05/2019
	190110 IMPACT HTA_WP7_DC_ Consent Form _FINAL.pdf 190110 IMPACT HTA_WP7_DC_Info Sheet_FINAL.pdf CF_ Decision conferencing.pdf CF_ stakeholder panel selection.pdf CF_ Web-Delphi process.pdf Figure 1 Outline of the research proposal.pdf IS_ stakeholder panel selection.pdf IS_ Decision conferencing.pdf IS_ Web-Delphi process.pdf MEDI-VALUE cronogram.pdf UIC1239_ autorizacao_CA.pdf	

The following members of the EC-IST participated in the ethical assessment:

Name	Role in Ethics Committee	Qualification	Gender	Affiliation to IST (Yes/No)
António Pinheiro	Presidente	Professor	M	Y
Mário Gaspar da Silva	Member	Professor	M	Y
Isabel Sá Correia	Member	Professor	F	Y
Isabel Trancoso	Member	Professor	F	Y
Rui Medeiros	Member	Professor	M	N

This EC-IST is working accordance to ICH-GCP, Schedule Y and ICMR guidelines, the EC-IST regulation and other applicable regulation.

None of the researchers participating in this study took part in the decision making and voting procedure for this assessment.

Based on the review of the above mentioned documents, the EC-IST states a an unanimous favourable ethical opinion about the request / trial as submitted.

The EC-IST expects to be informed about the progress of the study, any Serious Adverse Events occurring in the course of the study, any revision in the protocol and in the participants' information/informed consent, and requests to be provided a copy of the final report.

The EC-IST recommends that the procedure to keep the information be analyzed in detail with the Data Protection Officer (DPO) of the University of Lisbon (ULisboa) and requests to be informed about the recommendations issued by the DPO.



Prof. António Pinheiro

President of Ethics Committee of Instituto Superior Técnico (EC-IST)