



Challenges facing developing and transition countries in establishing an effective system of research ethics infrastructure (panel discussion)

👉 **Latin-American perspective**

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Ministry of Health of Chile

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## EULABOR :

👉 European and Latin American Ethical Regulation Systems of Biomedical Research : Comparative Analysis of its Pertinence and Application for Human Subject Protection

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## EULABOR :

- 👉 Funded by a € 300.000 grant of the European Commission under the 6th Framework Programme (Science and Society).
- 👉 INSERM (France) acts as co-ordinator, represented by Dr Eugenia Lamas.
- 👉 Participant countries: Argentina, Brazil, Chile, and Mexico/Spain, France, and Germany.



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## EULABOR :

- 👉 Argentina (Juan Carlos Tealdi - Fundación BioSur)
- 👉 Brazil (Roland Schramm - Fundación FioCruz)
- 👉 Chile (Sergio Zorrilla - Universidad de Santiago)
- 👉 Mexico (Dafna Feinholz - CNB)
  
- 👉 France (Eugenia Lamas - INSERM)
- 👉 Germany (Michael Fuchs - IWE)
- 👉 Spain (Alex Bota - Fundación EPSON)

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## EULABOR (objectives) :

- ☞ To describe and compare the adequacy and appropriateness of research ethics regulatory systems in a number of countries in Latin-America and Europe, in respect of the protection of people participating in biomedical research.
- ☞ To get empirical data in order to elaborate practical proposals for improving research governance and designing training programmes.



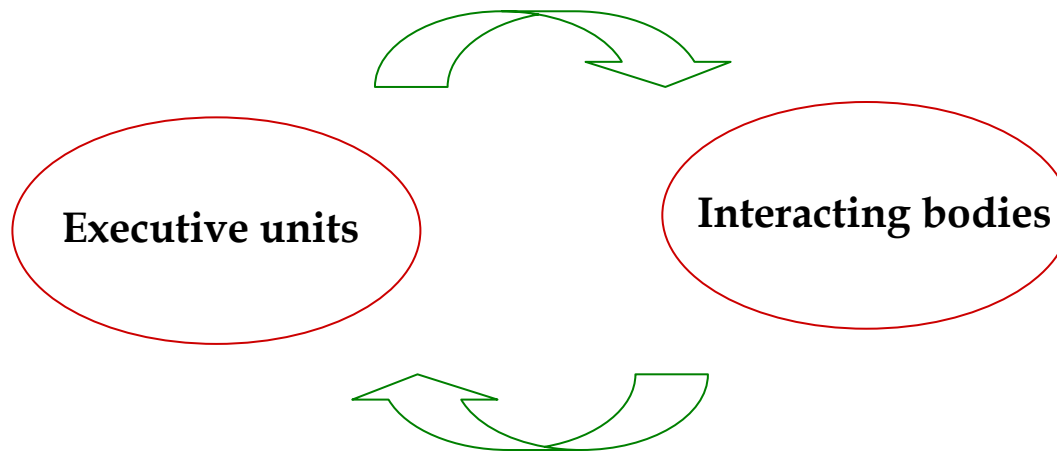
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# EULABOR (research framework) :

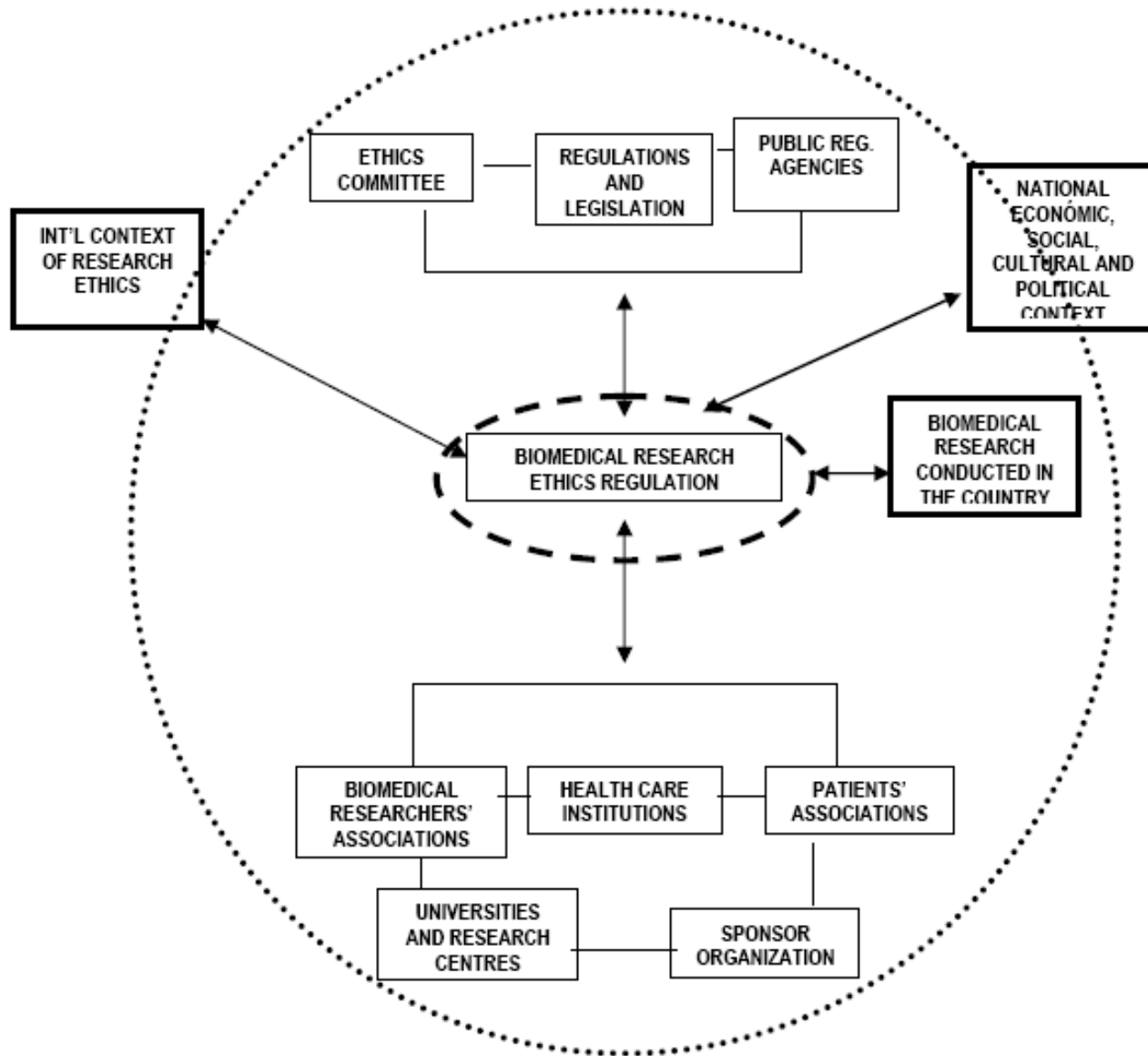


What do we understand by a regulatory system for biomedical research?

... is the group of actors, institutions, codes, and laws, involved in overseeing the ethics of biomedical research in humans, interacting as a system



# EULABOR (research framework) :



## EULABOR (preliminary results) :

300	ETHICAL REGULATION SYSTEM: REGULATIONS AND CURRENT LEGISLATION	LATINAMERICA				EUROPE		
		ARGENTINA	BRAZIL	CHILE	MÉXICO	GERMANY	SPAIN	FRANCE
301	Are there any regulations or legislation	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	<b>DOES CURRENT LEGISLATION INCLUDE THE FOLLOWING TYPES OF RESEARCH? (Say yes/no, Describe briefly only if necessary)</b>							
302	Pharmacological	Yes	Yes	Yes	Yes	Yes	Yes	Yes
303	Pharmacological on non-registered drugs	Yes	Yes	Yes	Yes	No	Yes	Yes
304	Epidemiological	Yes	Yes	No	Yes	Yes, in some states	Yes	Yes
305	Cell therapy	No	Yes	No	No	Yes	No	Yes
306	Psychosocial / Social	No	Yes	No	No	Yes, at universities	No data	Yes
307	Pharmacogenetic	No	Yes	No	No	Yes	No	Yes
308	Biological Manipulation samples	Yes	Yes	No	No	Yes	Yes	Yes
309	Protection of significant personal, clinical, genetic data	Yes	Yes	No	No	No in process	Yes	Yes
310	Medical devices	Yes	Yes	No	Yes	Yes	Yes	Yes



## EULABOR (preliminary results) :

- 👉 All countries have a regulatory framework targeting biomedical research. These are, however, heterogeneous in their scope and legal status.
- 👉 There are differences, also, in the responsible bodies for regulating biomedical research. In some of them the MoH is in charge, in others the Ministry of Justice or the Drug Regulatory Agency. Grey areas exist.
- 👉 Only Brazil and Argentina have some involvement of patients organisations in the overseeing of biomedical research.

## EULABOR (preliminary results) :

- ☞ There is heterogeneity, also, in the local translation of international agreements and codes.
- ☞ Only in Mexico there is a working National Bioethics Commission.
- ☞ Only in Brazil and Chile the responsibilities for evaluating research protocols resides in research ethical committees.

## EULABOR (preliminary results) :

- 👉 In Brazil, Argentina, and Chile, the committees evaluate both ethical and scientific aspects of the protocols.
- 👉 Only Brazil has a formal accreditation process for the committees.
- 👉 Argentina and Brazil have organised networks.
- 👉 Members do not receive salary for their work in evaluating research protocols.



## **EULABOR (the way forward) :**

👉 This project and its preliminary results in Latin-America are proposed as a tool to be replicated and improved, to collect empirical data on the functioning of ethics regulatory systems in different countries, to inform policy making and research governance.

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## EULABOR (the way forward) :

👉 Ačiū

Muchas gracias

Thank you

Merci

Danke schön



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