Research and clinical trials what are the rights of patients?

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Disclosures

Company name	Research support	Employee	Consultant	Stockholder	Speakers bureau	Advisory board	Other
University of the Basque Country	Enerca Project	x					

This talk is applicable for:		
	Definite	Probable
Thalassemia's	x	
Sickle cell disease	x	
Membrane disorders (e.g. sferocytosis)	x	
Enzym defects (e.g. PKD, G6PD)	x	
PNH	x	
Other forms of hemolytic disease	x	

THE LEGAL FRAMEWORK

Regulation 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use.

Direct **effect** in national legal systems.

Transparency and information.

Speed procedures (one position by country and coordination between countries).

Entry into force: when the **EU Portal and the EU Data Base** achieve full functionally. Not earlier than 28 May 2016.

EU Portal

EU Database. Notification of the recruitment, of the conditions of the trial, of the results.

DEFINITIONS AND PRINCIPLES

A clinical trial is a clinical study realted to the effect of a medicinal product in humans in addition to normal clinical practice.

•The rights, safety, dignity and well-being of subjects should be **protected.**

•The **data** generated should be reliable and robust.

•The interests of the subjects should always take **priority** over all other interests.

•Clinical trials should be subject to prior **authorisation**

Administrative authorisation.

Ethics review.

•Clinical trials for the development of **orphan** medicinal products and of medicinal products addressed to diseases affecting no more than one person in 50.000 in the Union (**ultra-rare diseases**) should be **fostered**.

THE PROCEDURE

Sponsor	Submitts the application to the European Portal Selects a reporting MS
Reporting MS	Initial assessment
Other MS involved	Revision

(Recital 4: future clinical trials will **target more specific patients pulations**, such subgroups identified through genomic information. In order to include a sufficient number of patients it may be necessary **to involve many or all MS**)

Reporting MS	Consideration of all the revisions

NATIONAL REVISION

- Compliance with the requirements for **informed consent.**
- Compliance of the arrengments for **rewarding or compensating** subjects.
- Compliance of the arrangements for **recruitment** of subjects.
- Compliance with **data** protection rules.
- **Qualification** of persons involved in conducting the trial.
- **Sustainability** of the clinical trial sites.
- Compliance with the applicables rules for the collection, storage and future use of biological **samples.**

THE PROTECTION OF SUBJECTS' RIGHTS

NATIONAL REVISION

•Information and consent

•Data protection

•Rights related to the samples

•Compensation and rewarding

(There is no a right to participate in a clinical trial as a right to medical treatment)

PARTICIPATION IN THE EVALUATION AND ACCESS TO RESULTS

•The national body in charge of the ethical evaluation should involve lay persons, in particular patients or patients' organisations

•The sponsor should sumbit a summary of the results understandable to a layperson.

FREE ACCESS TO THE PRODUCTS IN THE TRIAL

•Subjects should not have to pay for medicinal products and procedures required in the protocol.

THE PROTECTION OF SUBJECTS' RIGHTS

Information and consent

•Comprehensive, concise, clear, relevant and understandable to a lay person informaation

Nature, objectives, benefits, implications and risks
Possible treatments alternatives
Protection of rights
Conditons of the clinical trials (place, duration…)
(of course in the language of the patient)

•Prior interview

•Free decision

THE PROTECTION OF SUBJECTS' RIGHTS

Data and samples

•The withdrawal of the consent shall not affect the activities already carried out and the use of data obtained.

•Data can be used for other research if the subject consents (broad consent. Art. 28.2).

•Directive 95/46/EC: Proposal of a new Regulation. Includes samples in its scope (but this could be problematic taking into account national regulations).

•Eurordis Statement on the EP report on the Regulation for the protection of personal data (2013): it is vital that the EU strikes an approriate balance between facilitating the safe and secure use of patient data for health research and the rights and interests of all individuals.

THE PROTECTION OF SUBJECTS' RIGHTS

Genetic data

•No **binding** international regulation:
UNESCO International Declaration on human genetic data 2003.
Recomendation of the CE on research with human material, 2006.
Protocol to the CE Biomedicine Convention on genetic analysis in the healthcare system, 2008 (nhas not entered into force).

•Confidentiality (also regarding family members) and non discrimination.

•Right to know / to ignore (very relevant regarding NGS).

•Right to genetic counselling (acreditated professional and center, assesment about treatments or other decisions).

THE PROTECTION OF SUBJECTS' RIGHTS

Minors

•The subjects should represent the population groups that are likely to use the product investigated.

•The clinical trial is intented to investigate conditions related to minors or is essential to validate data.

•A direct benefit or a benefit for the population represented by the minor is expected.

•The rules concerning the determination fo the legal representation are national.

•The minor has the right to received information adapted to his / her age and mental maturity.

•The explicit opinion of a minor capable of forming an opinion should be respected.

•The minor should consent when reaches the age of legal competence.

CONCLUSIONS

Moving forward…

- Harmonization.
- Transparency.
- Efficiency.
- Recognition of the relevance of some particular conditions in the legal instruments.

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THANKS!

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