

Spanish Regulations

- ETS 164, October 1997 **Convention on Human Rights and Biomedecine** (Oviedo Convention)
- Royal Decree 2132/2004, requirements and procedures for the development of **research projects for the establishment of embryonic stem cells** (IVF surplus embryos) (BOE 30 octubre)
- Law 14/2006, **Assisted Reproduction Techniques**
- Law 14/2007, **Biomedical Research**

Convention on Human Rights and Biomedecine (Oviedo Convention)

Article 13 – Interventions on the human genome

An intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants

Article 18 – Research on embryos in vitro

1 Where the law allows research on embryos in vitro, it shall ensure adequate protection of the embryo.

2 The creation of human embryos for research purposes is prohibited.

Law 14/2006 Assisted Reproduction Techniques

- Clinical ART
- Research in human embryos

Possible options for use of supernumerary
cryopreserved human embryos

- Use for the couple or patient
- Donation to other couples or single women
- Donation for research
- Discard

Law 14/2006 Assisted Reproduction Techniques

Chapter IV

Article 15

Research with human gametes and embryos

Requirements

- Informed consent
- Development <14 days
- Authorised centers
- Qualified personnel
- Project authorised by competent authorities + CNRHA (or Guarantees Commission)
- Follow up

Law 14/2006 Assisted Reproduction Techniques

Chapter III

Article 13. **Therapeutic techniques in the preembryo**

1. Therapeutic techniques with the aim of **treating a disease and preventing transmission.**

2. Requirements

a) Informed consent

b) Well diagnosed diseases with a severe or very severe prognosis and adequate chances of success.

c) No modification of non pathologic traits (avoid eugenics)

d) Authorised centers, skilled professionals.

3. Authorisation by competent authority and National Commission for ART

IN CONTRADICTION WITH OVIEDO CONVENTION

Couples' opinions regarding the fate of surplus frozen embryos

	<i>Embryos frozen > 10 years</i>	<i>Embryos frozen for between 5 and 10 years</i>	<i>Embryos frozen for between 2 and 4 years</i>	<i>Total</i>
Donation for research	60 (35.7) ^a	128 (34.9) ^a	48 (19.1) ^b	236 (30.0)
Donation for reproduction	47 (28.0)	84 (22.9)	28 (11.2)	159 (20.2)
Disposal	28 (16.7) ^c	40 (10.9) ^d	13 (5.2) ^d	81 (10.3)
Maintain embryos frozen	14 (8.3)	90 (24.5)	158 (62.9)	262 (33.3)
Undecided	19 (11.3)	25 (6.8)	4 (1.6)	48 (6.1)

Couples choices regarding the fate of cryopreserved embryos stored for >2 years

Luna et al, 2009

Couples' opinions regarding the fate of surplus frozen embryos

	<i>Donation for research</i>	<i>Donation for reproduction</i>	<i>Disposal</i>	<i>Total</i>
No. own gametes (%)	156 (56.9) ^b	64 (23.4) ^c	54 (19.7)	274
No. donated gametes ^a (%)	36 (42.9) ^d	40 (47.6) ^e	8 (9.5)	84

Distribution of responses in relation to the origin of gametes

Luna et al, 2009

National Commission for Assisted Reproduction

The **National Commission for ART** is a permanent and consultive collegiate body dependent on the Ministry of Health with the aim of giving advice about the use of ART techniques, including related scientific activities.

AIMS

Development and follow-up of ART techniques

Guidelines

Gamete donors and patients

Genetic diseases for PGD

Authorisation and certification of ART centres

Services and SOPs

Results

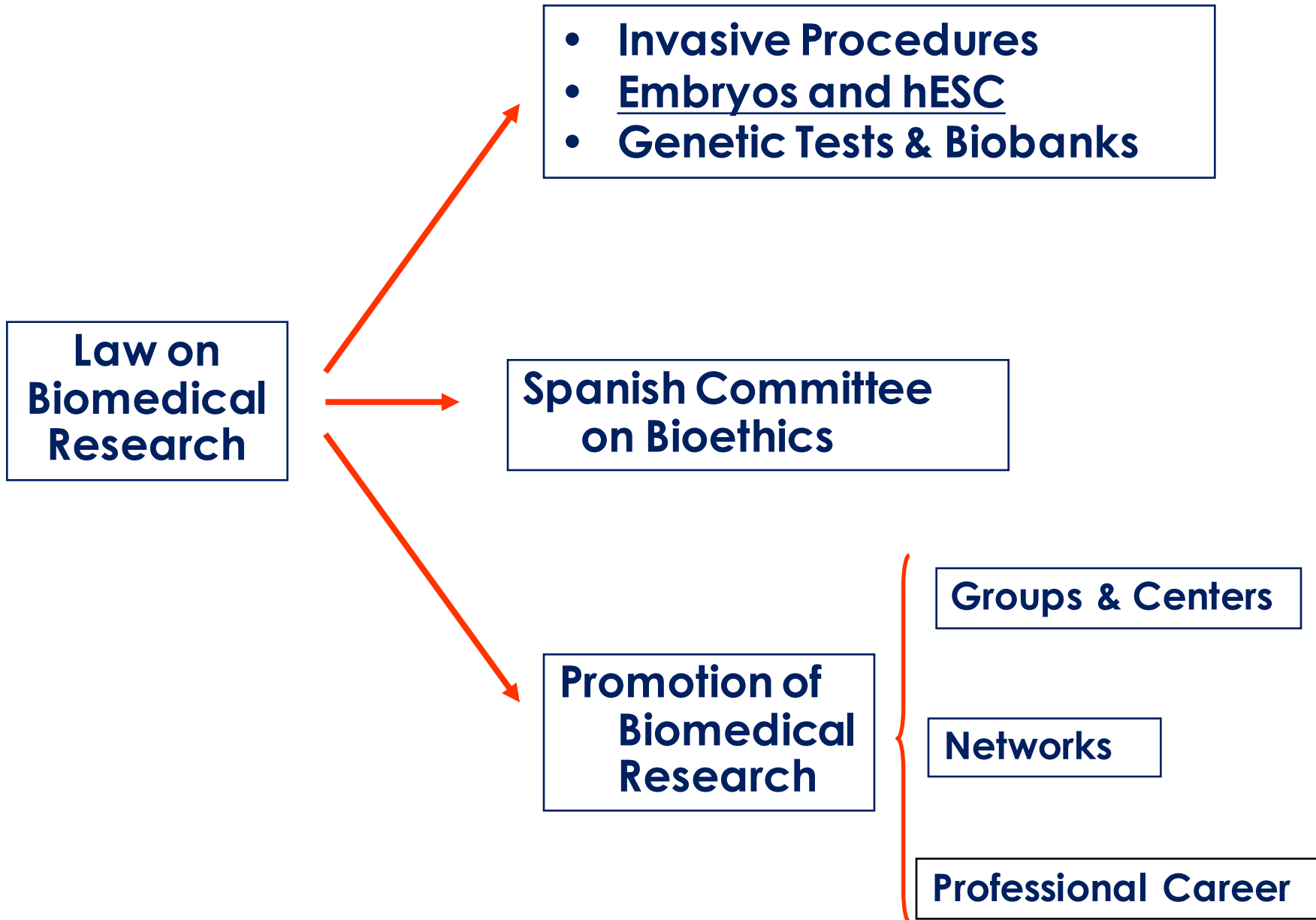
Evaluation of authorised research projects

Legislation update

Experimental techniques authorisation

Research (infertility, gamete and embryo) project authorisation

Donor compensation



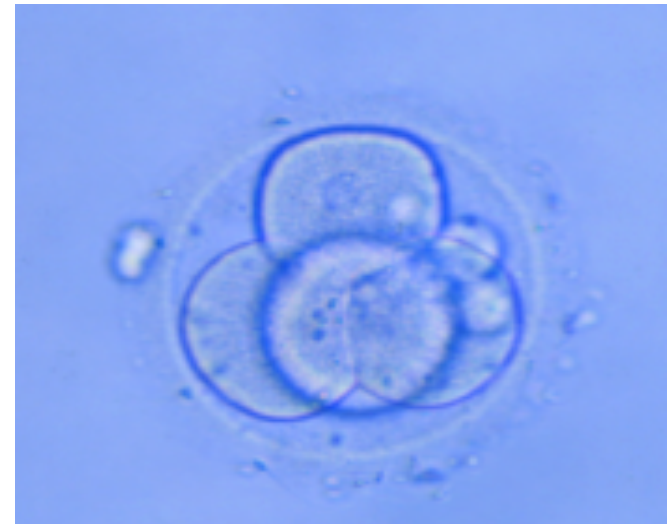
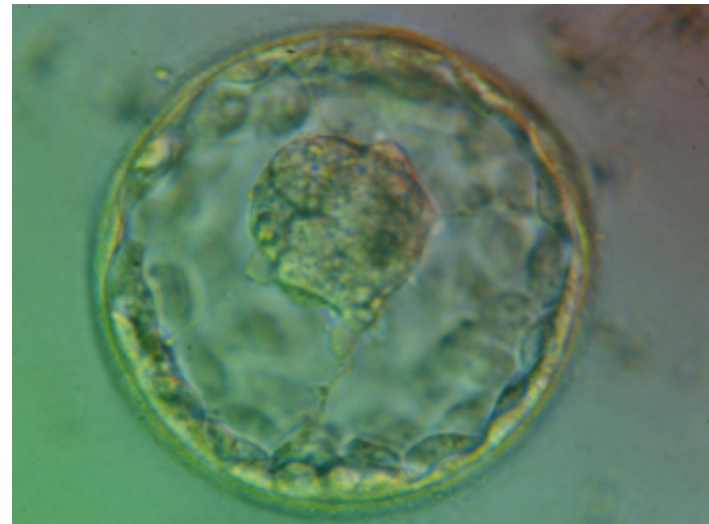
Law 14/2007, Biomedical Research

- **Allows SCNT** and other techniques for hESC derivation
- **No** generation of human embryos solely for research purposes allowed (Oviedo Convention). Definition of “embryo”
- **National Guarantees Commission** created for the control of embryo and hESC research.

National Guarantees Commission

Review and approval needed for

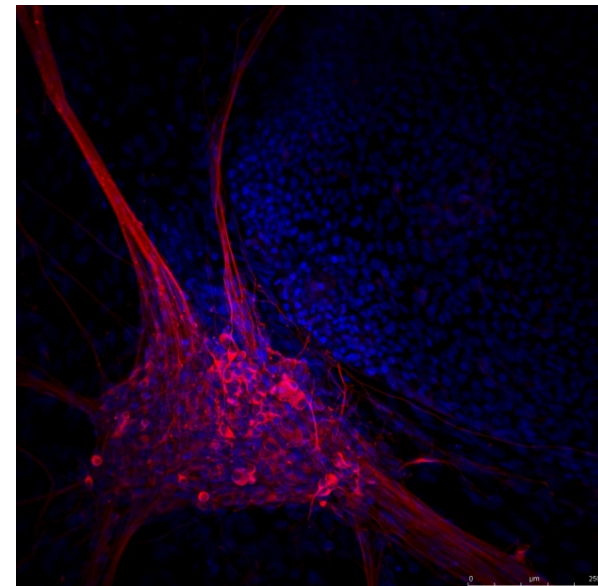
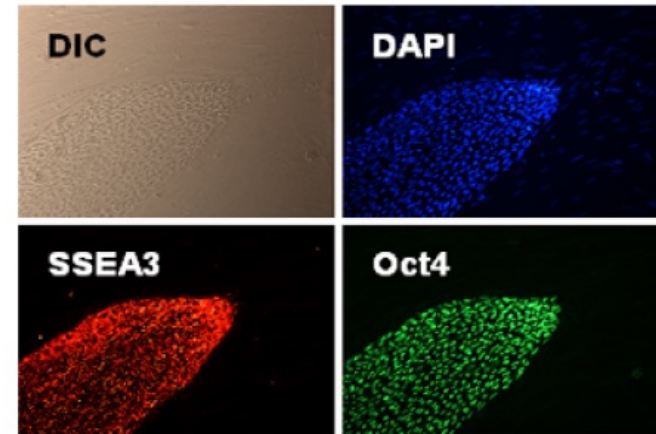
- Research with human embryos intended for hESC derivation and for other uses except for research related to ART
- Research with hESC and hiPS
- Research in oocyte activation for SCNT
- Research with human samples that aim to obtain pluripotent stem cells



National Guarantees Commission

Review and approval needed for

- Research involving cells from embryonic/fetal origin
- Research with pluripotent stem cells from other countries



Germline Genome Editing

- No research projects involving germline genome editing submitted for review and authorisation to the Spanish National Commission for Assisted Reproduction.