Aspectos éticos de los Proyectos de Investigación Europeos

Horizon 2020
European Union Funding
for Research & Innovation

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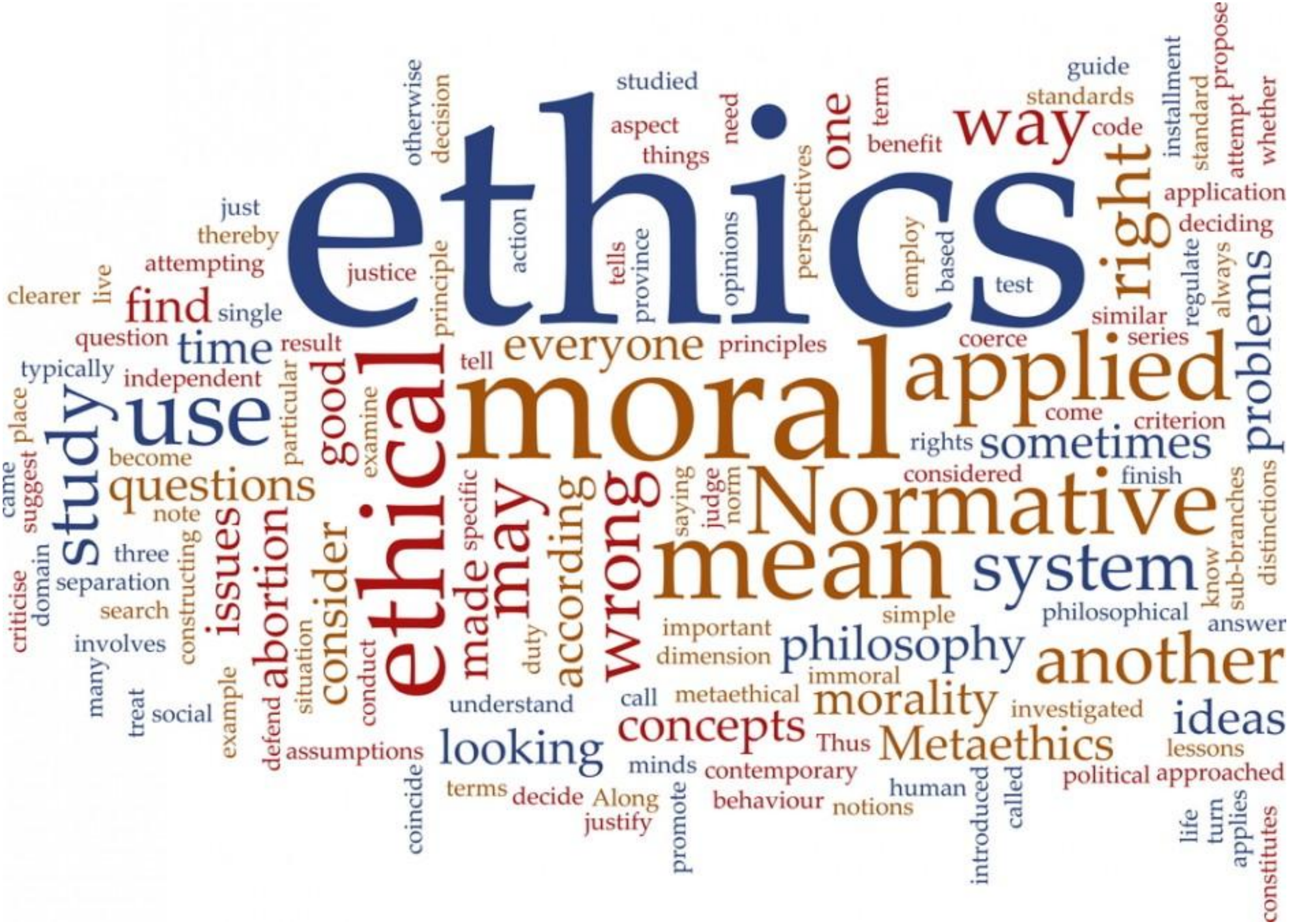
ERC and H2020 Ethics Panels
National Centre for Biotechnology (CNB-CSIC)

erc

Murcia - 28 June 2018

CSIC

CNB
CENTRO NACIONAL DE BIOTECNOLOGIA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Definitions

- **Moral/morality**: what people believe to be right/good or wrong/bad. Set of codes of conduct adopted governing human behavior.

- **Ethics**: is a critical reflection about morality. Provides a systematic way to work through dilemas to determine the best course of action among conflicting choices, a generalized conceptual framework for decision making.

- **Bioethics**: the study of ethical issues arising from health care, in biological and medical sciences.

Basic principles in Bioethics

- Principle of non-maleficence
- Principle of beneficence
- Principle of respect for autonomy
- Principle of justice

Principle of non-maleficence

- **You should not harm any human being**. It implies a careful consideration and evaluation of the **equilibrium between potential benefits and risks** associated to any medical or biomedical intervention

Principle of beneficence

- It is our obligation, **our duty, to do good to be of benefit to the human being**
- However, it does not mean imposing our subjective idea of what is good. We must take into account the freedom and the authorization from the human being (**informed consent**)

Principle of respect for autonomy

- It refers to our due respect to the basic freedom of every human being to decide on any intervention, including biomedical issues, directly affecting him/her (**informed consent**)

Principle of justice

- We must ensure the **equitative access** to potential benefits, biomedical progress and wellbeing to everyone, to all human beings, without restrictions o discriminations of any sort

Ethics also means…

- Safety
- Security
- Privacy
- Respect
- Well-being
- Welfare
- Environment


wiseGEEK


HERO4


CHASE

Ethics issues in H2020/ERC EC-funded Research Projects

Why caring about Ethics?

- **No H2020/ERC EC-funded Research Project can commence without Ethics Approval**
- To ensure full compliance with EU norms and regulations regarding the due respect to humans, animals, plants and environment
- To maximize benefits and minimize risks and harms, while considering the needs associated with each Research Project

Why an Ethics Review?

- To ensures that each ERC grant respects EU ethics principles and EU/national ethical legislation
- Legal requirement
  - *Horizon 2020 Framework Programme — Regulation (EU) No 1291/2013 (art 19) and Rules for participation (art 13): any proposal which contravenes fundamental ethical principles shall not be funded*
  - *Work Programme: proposals shall not be selected and may be excluded from the evaluation, selection and award procedures at any time*
  - *Grant Agreement (article 34): general obligation of beneficiaries to comply with ethical principles*
- To help researchers considering and elaborating on the ethics aspects of their projects

Why Ethics Approval is important?

- Ethics Approvals are **mandatory** by EC
- Ethics approval **protects** the researchers and the research being conducted
- Ethics Approval demonstrates that the Research Project and the Researchers **adhere to the accepted Ethics standards** that are expected by the Society in the EU

Ethics is tke KEY to open the Treasure

Examples of ethics issues

- Use of human Embryonic Stem Cells (hESC)
- Use of Non-Human Primates
- Research Intervention on human beings
- Privacy and use of personal data
- Research on animals
- Research in low income countries & countries at risk
- Dual Use & misuse
- Environmental protection
- Other

EU directives and international references

- **Clinical trials**
  - *Regulation No 536/2014 of the European Parliament*
  - *Commission Directive 2005/28/EC of 8 April 2005*
- **Human genetic material and biological samples**
  - *Directive 2004/23/EC*
- **Animal experimentation**
  - *Directive 2010/63/EU of the European Parliament*
- **Data protection**
  - *Regulation (EU) 2016/679*
- **Developing countries and politically sensitive issues**
  - *Declaration/Charter (EU Fundamental Rights; UN Rights of Child, UNESCO Universal Declaration)*
- **Environment Protection and safety**
  - *Directive 2001/18/EC ; Directive 2009/41/EC ; Regulation EC No 1946/2003; Directive 2008/56/EC; Council Directive 92/43/EEC; Council Directive 79/409/EEC and Council Regulation EC No 338/97*
- **Dual use In the context of security/dissemination**
  - *Council Regulation (EC) No 428/2009*

Related relevant agreements/documents

- **The Universal Declaration of Human Rights** adopted by the UN General Assembly on 10 December **1948** in Paris. The Declaration arose directly from the experience of the Second World War and represents the first global expression of what many people believe to be the rights to which all human beings are inherently entitled

- **Declaration of Helsinki** a set of ethical principles regarding human experimentation developed for the medical community by the World Medical Association (WMA) and widely regarded as the reference document on human research ethics. Initially adopted in **1964**, in Helsinki (Finland), and later modified several times. Last version was adopted in Fortaleza (Brazil), October 2013

- **Asturias (Oviedo) Convention**, The Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (ETS No 164) was initially adopted in **1997** in Oviedo (Spain)

Ethics Self Assessment

- Which ethics issues are relevant for my Project? Describe them in details
- Do I need to obtain permissions?
- Do I have already these permissions?
- Timeplan for obtaining permissions
- Table with permissions obtained, requested and not yet requested
- Copies of all oficial documentation

Proposal ID Acronym

4 - Ethics issues table

1. HUMAN EMBRYOS/FOETUSES		Page
Does your research involve Human Embryonic Stem Cells (hESCs)?	○ Yes ◉ No	
Does your research involve the use of human embryos?	○ Yes ◉ No	
Does your research involve the use of human foetal tissues / cells?	○ Yes ◉ No	
2. HUMANS		**Page**
Does your research involve human participants?	○ Yes ◉ No	
Does your research involve physical interventions on the study participants?	○ Yes ◉ No	
3. HUMAN CELLS / TISSUES		**Page**
Does your research involve human cells or tissues (other than from Human Embryos/ Foetuses, i.e. section 1)?	○ Yes ◉ No	
4. PERSONAL DATA		**Page**
Does your research involve personal data collection and/or processing?	○ Yes ◉ No	
Does your research involve further processing of previously collected personal data (secondary use)?	○ Yes ◉ No	
5. ANIMALS		**Page**
Does your research involve animals?	◉ Yes ○ No	1
Are they vertebrates?	◉ Yes ○ No	1
Are they non-human primates?	○ Yes ◉ No	
Are they genetically modified?	◉ Yes ○ No	1
Are they cloned farm animals?	○ Yes ◉ No	
Are they endangered species?	○ Yes ◉ No	
6. THIRD COUNTRIES		**Page**

Ethics Issues Table
Part A

Correctly completing this table is ESSENTIAL

Proposal ID Acronym

In case non-EU countries are involved, do the research related activities undertaken in these countries raise potential ethics issues?	◉ Yes ○ No	1
Trinidad and Tobago		
Do you plan to use local resources (e.g. animal and/or human tissue samples, genetic material, live animals, human remains, materials of historical value, endangered fauna or flora samples, etc.)?	◉ Yes ○ No	1
Do you plan to import any material - including personal data - from non-EU countries into the EU?	◉ Yes ○ No	1
Do you plan to export any material - including personal data - from the EU to non-EU countries?	○ Yes ◉ No	
In case your research involves low and/or lower middle income countries, are any benefits-sharing actions planned?	○ Yes ◉ No	
Could the situation in the country put the individuals taking part in the research at risk?	○ Yes ◉ No	
7. ENVIRONMENT & HEALTH and SAFETY		Page
Does your research involve the use of elements that may cause harm to the environment, to animals or plants?	○ Yes ◉ No	
Does your research deal with endangered fauna and/or flora and/or protected areas?	○ Yes ◉ No	
Does your research involve the use of elements that may cause harm to humans, including research staff?	○ Yes ◉ No	
8. DUAL USE		Page
Does your research involve dual-use items in the sense of Regulation 428/2009, or other items for which an authorisation is required?	○ Yes ◉ No	
9. EXCLUSIVE FOCUS ON CIVIL APPLICATIONS		Page
Could your research raise concerns regarding the exclusive focus on civil applications?	○ Yes ◉ No	

European Commission - Research - Participants
Proposal Submission Forms
European Research Council Executive Agency

Proposal ID Acronym

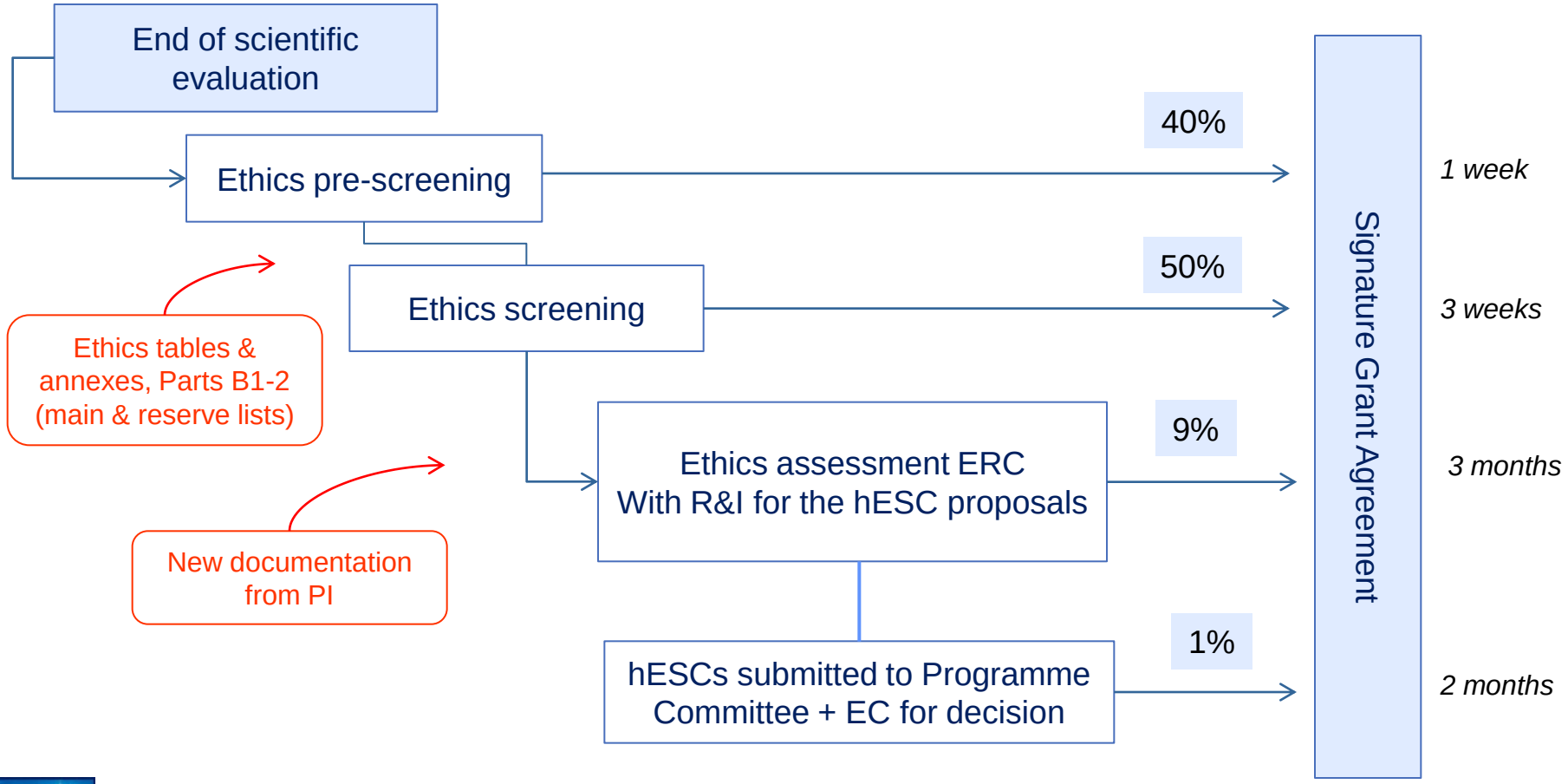
10. MISUSE		Page
Does your research have the potential for misuse of research results?	○ Yes ◉ No	
11. OTHER ETHICS ISSUES		Page
Are there any other ethics issues that should be taken into consideration? Please specify	○ Yes ◉ No	

I confirm that I have taken into account all ethics issues described above and that, if any ethics issues apply, I will complete the ethics self-assessment and attach the required documents. ☒

How to Complete your Ethics Self-Assessment

European Research Council

Ethics clearance process



Ethics issues in EC-funded Research Projects

1. Use of Human Embryos/Foetuses
2. Involvement of Human Beings
3. Use of Human Cells/Tissues
4. Protection of Personal Data
5. Use of Animals
6. Non-EU countries
7. Environment, Health and Safety
8. Dual Use
9. Exclusive focus on Civil Applications
10. Misuse

Use of Human Embryos/Foetuses

The following activities are **not eligible** for funding in H2020/ERC research projects:

- Human cloning for reproductive purposes
- Heritable changes in the human genome
- Creating human embryos for research only
- Research leading to the destruction of human embryos

Use of Human Embryos/Foetuses

Does your research involve… ?

- Human Embryonic Stem Cells (existing, created de novo)
- Human Embryos (will they be destroyed?)
- Human Foetal Tissues / Cells

- Ethics Approvals / Informed Consents required

Involvement of Human Beings

Does your research involve human participants?

- Volunteers for social/human sciences
- Unable to give informed consent
- Vulnerable individuals or groups
- Children/minors
- Patients
- Healthy volunteers for medical studies
- Physical interventions? Invasive techniques? Collection of biological samples?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fMRI

Non-invasive
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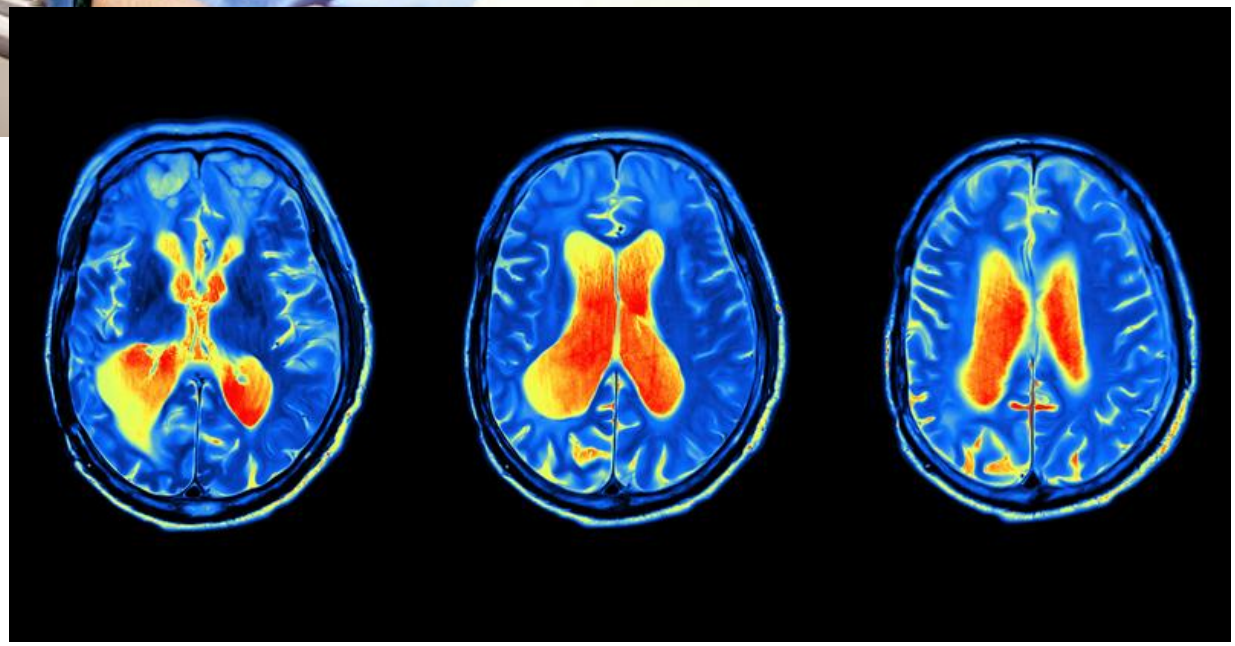

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RISK
BENEFIT

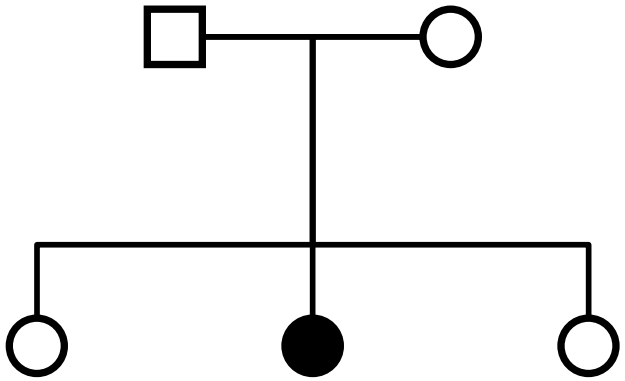
Ethics in research involving human subjects

- Who do we want to protect? **The human subject, the patient**
- What do we have to regulate? **The use of human samples (biological and also data) in research**
- **We must ensure respect for people and for human dignity**, and a fair distribution of the benefits and burden of research, while protecting the values, the rights and interests of participants

Informed Consent

- Introduction, aims of the specific research to be conducted (plain words)
- Describing the procedures that will be applied
- What type of human biological samples / data will be taken or used (and the burden associated)
- What needs to be done with biological sample/data upon finishing the experiment? (keep/anonymize/destroy)
- Benefits and risks of participating
- What, how and who will be contacted concerning results obtained? (**incidental findings**, right to know/not-know)
- Confidentiality, rights for accessing to data and rights to modify consent
- Right to revoke consent

Right to know and Right NOT to know



Use of Human Cells or Tissues

- Available commercially
- Obtained within the research project
- Obtained from another research Project
- Obtained from a biobank

- Ethics Approvals / Informed Consent

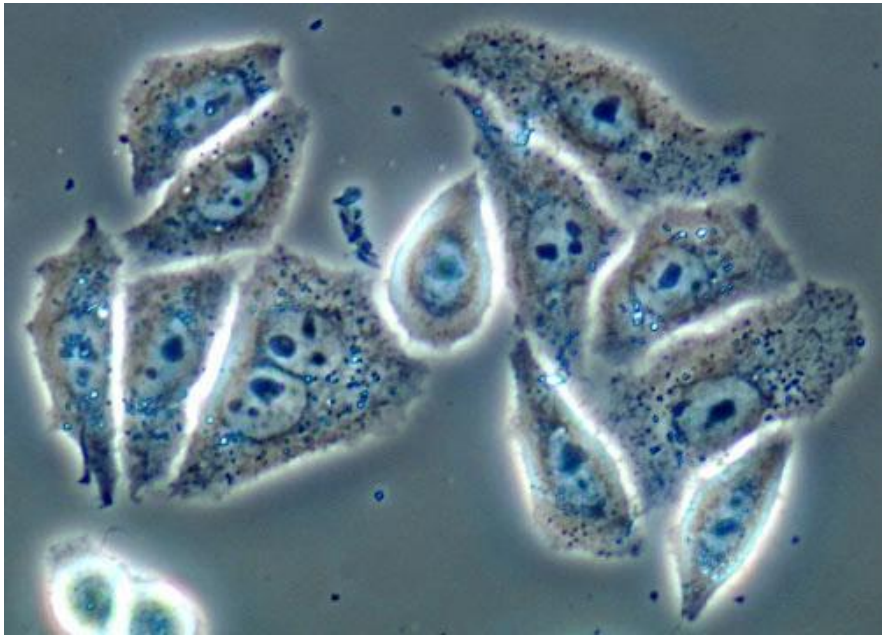
BioBank

Patient/Donor

Collection

Researcher

Research involving human subjects



- **HeLa cells**

- Cervical cancer
- 1951 HeLa cells established
- >60.000 scientific publications
- >10.000 patents

HeLa = **He**nrietta **La**cks

Henrietta Lacks (1920-1951)

Research involving human subjects

In 2013 Hela cells genome was released (Landry et al. Genes, Genomes, Genet.)

The descents of Henrietta Lacks complained because nobody asked them permission and they claimed this was private information

Eventually Henrietta Lacks' relatives agreed to release HeLa genome partially and under strict restrictions

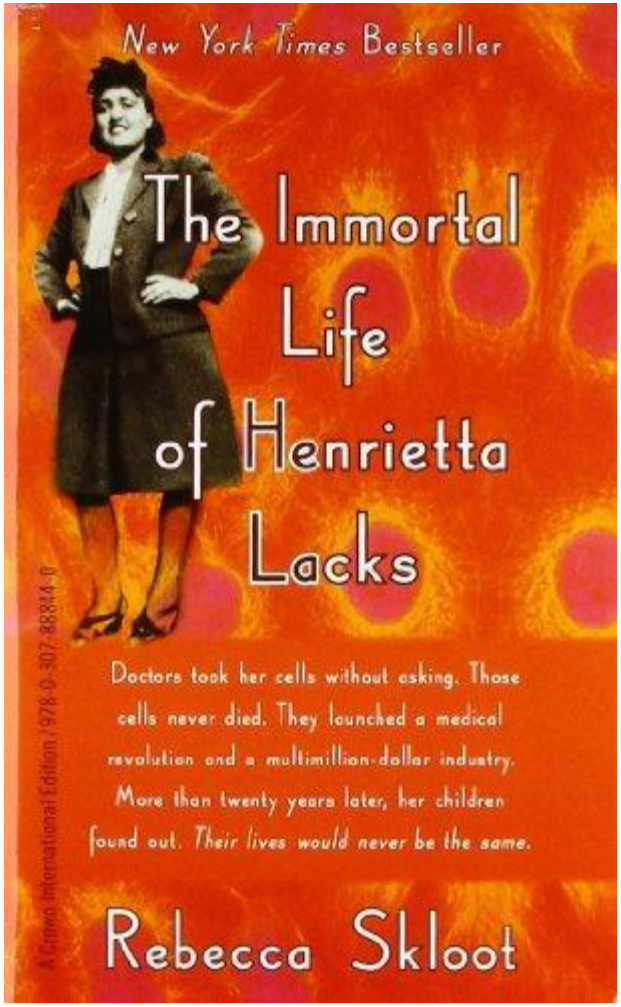
SCIENCE

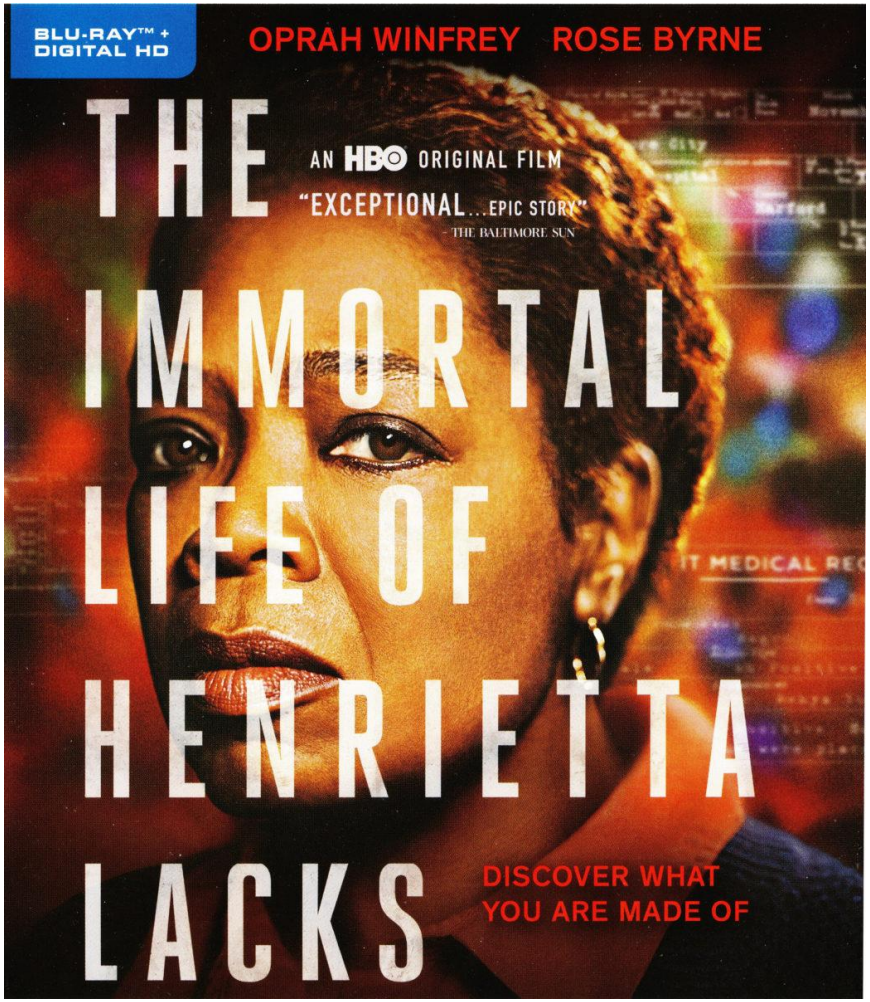
A Family Consents to a Medical Gift, 62 Years Later

By CARL ZIMMER AUG. 7, 2013

The New York Times

Research involving human subjects





Protection of Personal Data

Does your research involves **personal data collection and/or processing**?

- Sensitive data (religion, ethnicity, politics…)
- Genetic information
- Tracking or observing participants
- Further processing of previously collected personal data (**secondary use**)
- Collect only data that are required

EUGDPR.org | The Regulation | The Process | Our Partners

GDPR Portal: Site Overview

Quick Links

www.eugdpr.org

New GDPR Regulation (EU) 2016/679

- **Replaces** Data Protection Directive 95/46/EC
- **Approved** in April 2016, entered into force 25 May 2018
- The aim of the GDPR is to **protect all EU citizens** from privacy and data breaches in an increasingly data-driven world
- Increased **Territorial Scope** (extra-territorial applicability)
- **Breach of GDPR can be fined** up to 4% of annual global turnover or €20 Million (whichever is greater)
- **Consent**: provided in an intelligible and easily accessible form, using clear and plain language. It must be as easy to withdraw consent as it is to give it. Opt-in

New GDPR Regulation (EU) 2016/679

- **GDPR Breach mandatory** in all member states within 72 hours
- Right for data subjects to obtain from the data controller confirmation as to whether or not personal data concerning them is being processed, where and for what purpose. Further, the controller shall provide a copy of the personal data, free of charge, in an electronic format. This change is a dramatic shift to data **transparency and empowerment of data subjects**.

New GDPR Regulation (EU) 2016/679

- **Right to be Forgotten**: Data Erasure, the right to be forgotten entitles the data subject to have the data controller erase his/her personal data, cease further dissemination of the data, and potentially have third parties halt processing of the data
- **Data Portability**: the right for a data subject to receive the personal data concerning them, which they have previously provided in a 'commonly use and machine readable format' and have the right to transmit that data to another controller.

New GDPR Regulation (EU) 2016/679

- **Privacy by Design**: inclusion of data protection from the onset of the designing of systems, rather than an addition. Controllers to hold and process only the data absolutely necessary for the completion of its duties (data minimisation), as well as limiting the access to personal data to those needing to act out the processing.
- **Data Protection Officers**: internal record keeping requirements

New GDPR and Informed Consents

- **Informed Consents** must contain now:
- the details of the person the participant may contact at the site should there be a question or the need to exercise any of the rights detailed in the data privacy clause.
- the Data Protection Officer at the research institution.
- the express reference to the fact that the participant may also lodge a complaint with Data protection authorities should the study participant feel the need to do so.

Use of animals

Does your research involve **animals**?

- Vertebrates
- Non-Human Primates
- Genetically Modified
- Cloned Farm Animals
- Endangered Species

Animal Research

- Who do we want to protect? **The animals**
- What do we have to regulate? **The use of animals for research and teaching purposes**
- What do we intend to preserve? **Animal welfare, minimizing any harm, pain or discomfort caused by a given research procedure**
- **Which are the underlying principles?**

New European Directive

DIRECTIVE **2010/63/EU** OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 September 2010 **on the protection of animals used for scientific purposes**

Mandatory to all EU member states

Must be adopted and transposed to National regulations by 10 Nov 2012

Came into force on **1 January 2013**

20.10.2010 EN Official Journal of the European Union L 276/33

DIRECTIVES

DIRECTIVE 2010/63/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 22 September 2010
on the protection of animals used for scientific purposes
(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

Having regard to the opinion of the European Economic and Social Committee [1],

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure [2],

Whereas:

(1) On 24 November 1986 the Council adopted Directive 86/609/EEC [3] in order to eliminate disparities between laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes. Since the adoption of that Directive, further disparities between Member States have emerged. Certain Member States have adopted national implementing measures that ensure a high level of protection of animals used for scientific purposes, while others only apply the minimum requirements laid down in Directive 86/609/EEC. These disparities are liable to constitute barriers to trade in products and substances the development of which involves experiments on animals. Accordingly, this Directive should provide for more detailed rules in order to reduce such disparities by approximating the rules applicable in that area and to ensure a proper functioning of the internal market.

(2) Animal welfare is a value of the Union that is enshrined in Article 13 of the Treaty on the Functioning of the European Union (TFEU).

(3) On 23 March 1998 the Council adopted Decision 1999/575/EC concerning the conclusion by the Community of the European Convention for the protection of vertebrate animals used for experimental and other scientific purposes [4]. By becoming party to that Convention, the Community acknowledged the importance of the protection and welfare of animals used for scientific purposes at international level.

(4) The European Parliament in its resolution of 5 December 2002 on Directive 86/609/EEC called for the Commission to come forward with a proposal for a revision of that Directive with more stringent and transparent measures in the area of animal experimentation.

(5) On 15 June 2006, the Fourth Multilateral Consultation of Parties to the European Convention for the protection of vertebrate animals used for experimental and other scientific purposes adopted a revised Appendix A to that Convention, which set out guidelines for the accommodation and care of experimental animals. Commission Recommendation 2007/526/EC of 18 June 2007 on guidelines for the accommodation and care of animals used for experimental and other scientific purposes [5] incorporated those guidelines.

(6) New scientific knowledge is available in respect of factors influencing animal welfare as well as the capacity of animals to sense and express pain, suffering, distress and lasting harm. It is therefore necessary to improve the welfare of animals used in scientific procedures by raising the minimum standards for their protection in line with the latest scientific developments.

(7) Attitudes towards animals also depend on national perceptions, and there is a demand in certain Member States to maintain more extensive animal-welfare rules than those agreed upon at the level of the Union. In the interests of the animals, and provided it does not affect the functioning of the internal market, it is appropriate to allow the Member States certain flexibility to maintain national rules aimed at more extensive protection of animals in so far as they are compatible with the TFEU.

[1] OJ C 277, 17.11.2009, p. 51.
[2] Position of the European Parliament of 5 May 2009 (OJ C 212 E, 5.8.2010, p. 170), position of the Council of 13 September 2010 (not yet published in the Official Journal) and position of the European Parliament of 8 September 2010 (not yet published in the Official Journal).
[3] OJ L 358, 18.12.1986, p. 1.
[4] OJ L 222, 24.8.1999, p. 29.
[5] OJ L 197, 30.7.2007, p. 1.

New European Directive

(10) While it is desirable to replace the use of live animals in procedures by other methods not entailing the use of live animals, the use of live animals continues to be necessary to protect human and animal health and the environment. However, this Directive represents an important step towards achieving the final goal of full replacement of procedures on live animals for scientific and educational purposes as soon as it is scientifically possible to do so. To that end, it seeks to facilitate and promote the advancement of alternative approaches. It also seeks to ensure a high level of protection for animals that still need to be used in procedures. This Directive should be reviewed regularly in light of evolving science and animal-protection measures.

Final goal: full replacement of procedures on live animals

New European Directive

3. This Directive shall apply to the following animals:

(a) live non-human vertebrate animals, including:

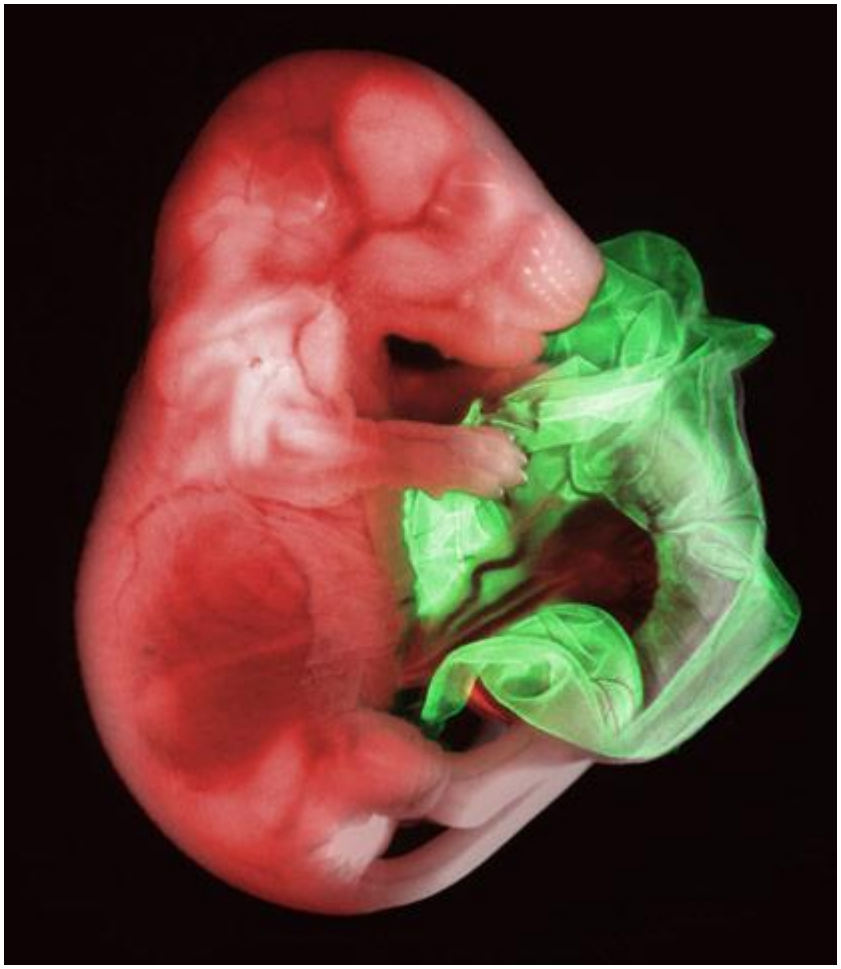
(i) independently feeding larval forms; and

(ii) foetal forms of mammals as from the last third of their normal development;

(b) live cephalopods.

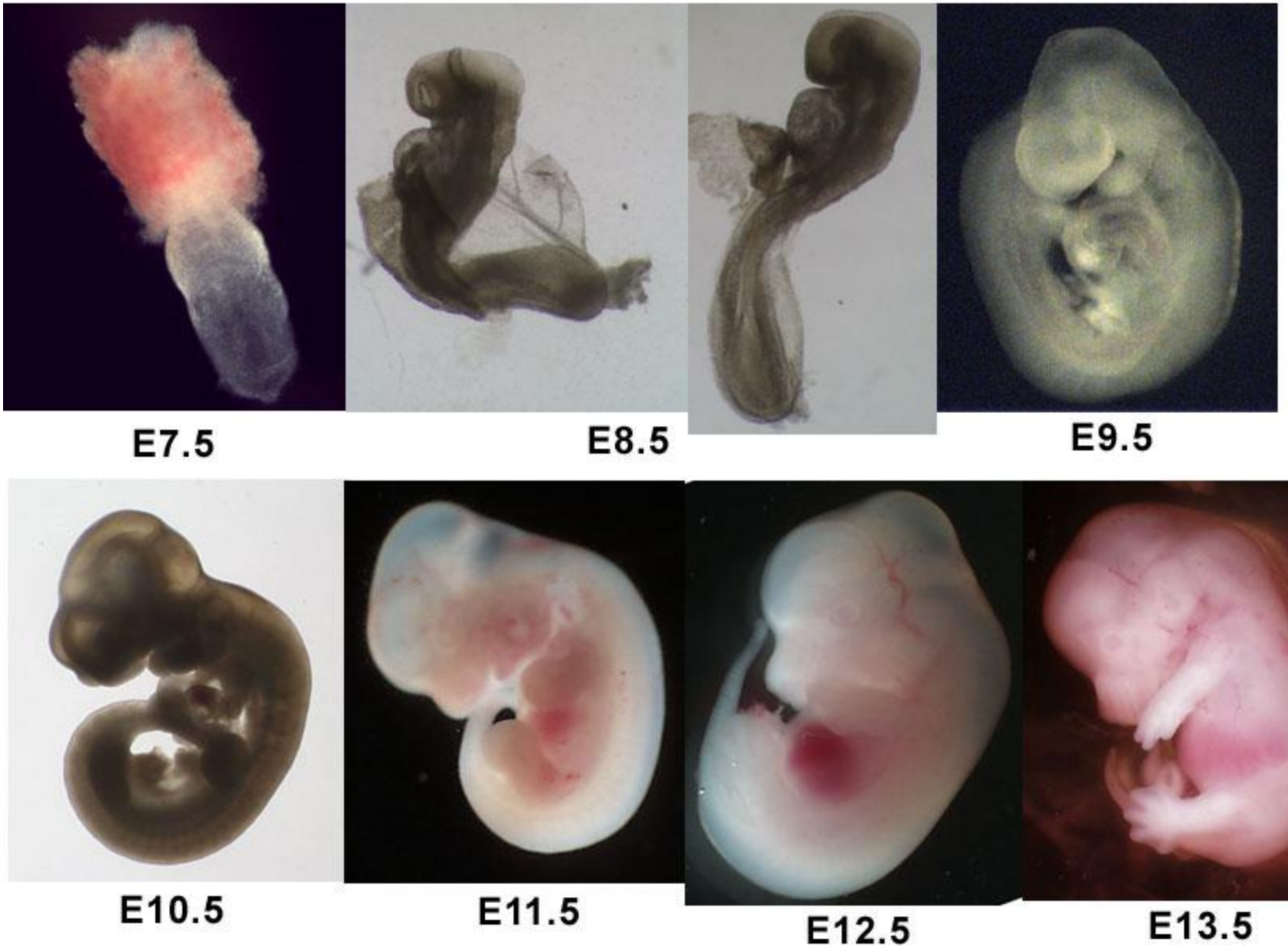
Arbitrary new definition of what is a research animal

+14.5 dpc



+18.5 dpc

These ARE research animals



These are NOT research animals

New European Directive

These ARE research animals

New European Directive

Drosophila

<36 h zebrafish embryo

These are NOT research animals

New European Directive

tadpole

Trout fries

These ARE research animals

New European Directive

1. 'procedure' means any use, invasive or non-invasive, of an animal for experimental or other scientific purposes, with known or unknown outcome, or educational purposes, which may cause the animal a level of pain, suffering, distress or lasting harm equivalent to, or higher than, that caused by the introduction of a needle in accordance with good veterinary practice.

   This includes any course of action intended, or liable, to result in the birth or hatching of an animal or the creation and maintenance of a genetically modified animal line in any such condition, but excludes the killing of animals solely for the use of their organs or tissues;

2. 'project' means a programme of work having a defined scientific objective and involving one or more procedures;

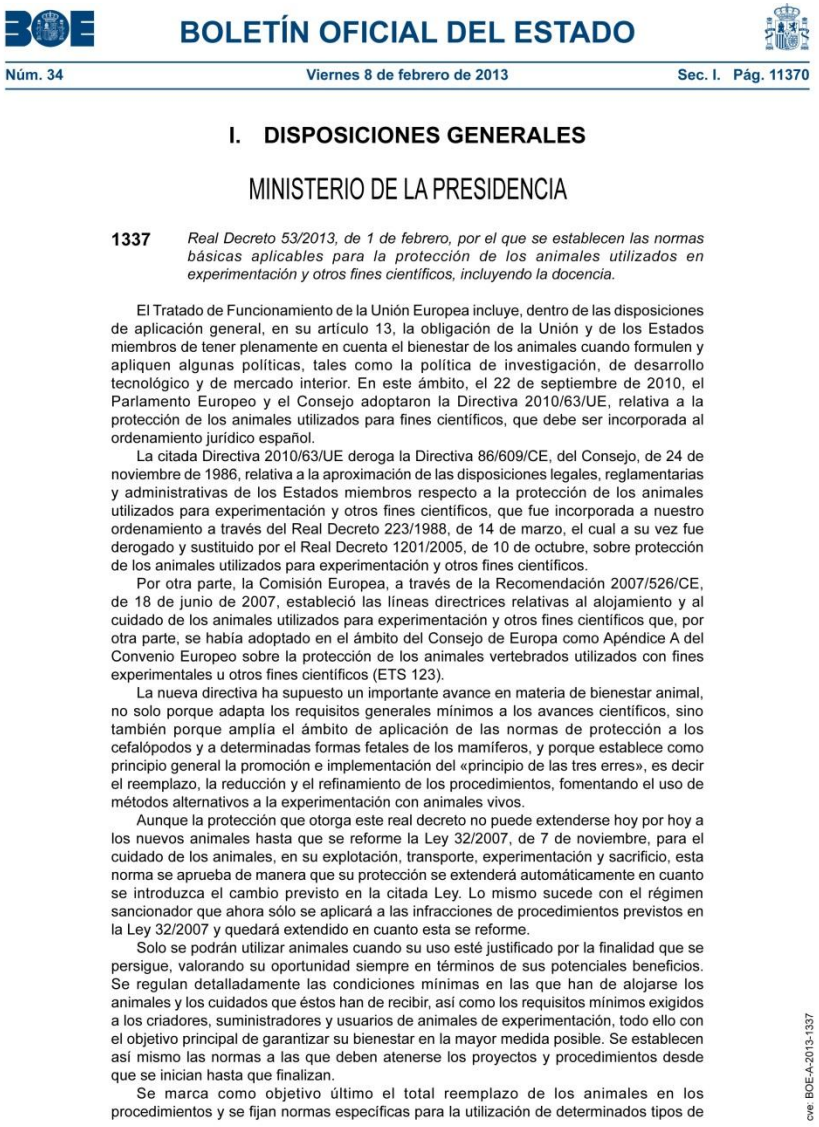
New definitions of PROCEDURE and PROJECT

New European Directive

- **Severity of procedures**: non-recovery, mild, moderate, severe
- **Reusing animals** in different procedures is encouraged but regulated
- **Retrospective analysis** (at the end of the project)
- Further limitations to the use of non-human primates for research purposes (only when justified and for avoiding, preventing, diagnosing or treating debilitating or **life-threating clinical conditions** in human beings)
- **Inspections** and **data reporting on uses of animals** to local, national and EU authorities

Transposition of EU Directive to Spain

La Nueva Directiva Europea 2010/63/UE fue finalmente traspuesta al ordenamiento jurídico español a través del **Real Decreto 53/2013**, de 1 de febrero, por el que se establecen las normas básicas aplicables para la protección de los animales utilizados en experimentación y otros fines científicos, incluyendo la docencia, publicado en el B.O.E. el 8 de febrero de 2013



BOLETÍN OFICIAL DEL ESTADO

Núm. 34 Viernes 8 de febrero de 2013 Sec. I. Pág. 11370

I. DISPOSICIONES GENERALES

MINISTERIO DE LA PRESIDENCIA

1337 *Real Decreto 53/2013, de 1 de febrero, por el que se establecen las normas básicas aplicables para la protección de los animales utilizados en experimentación y otros fines científicos, incluyendo la docencia.*

El Tratado de Funcionamiento de la Unión Europea incluye, dentro de las disposiciones de aplicación general, en su artículo 13, la obligación de la Unión y de los Estados miembros de tener plenamente en cuenta el bienestar de los animales cuando formulen y apliquen algunas políticas, tales como la política de investigación, de desarrollo tecnológico y de mercado interior. En este ámbito, el 22 de septiembre de 2010, el Parlamento Europeo y el Consejo adoptaron la Directiva 2010/63/UE, relativa a la protección de los animales utilizados para fines científicos, que debe ser incorporada al ordenamiento jurídico español.

La citada Directiva 2010/63/UE deroga la Directiva 86/609/CE, del Consejo, de 24 de noviembre de 1986, relativa a la aproximación de las disposiciones legales, reglamentarias y administrativas de los Estados miembros respecto a la protección de los animales utilizados para experimentación y otros fines científicos, que fue incorporada a nuestro ordenamiento a través del Real Decreto 223/1988, de 14 de marzo, el cual a su vez fue derogado y sustituido por el Real Decreto 1201/2005, de 10 de octubre, sobre protección de los animales utilizados para experimentación y otros fines científicos.

Por otra parte, la Comisión Europea, a través de la Recomendación 2007/526/CE, de 18 de junio de 2007, estableció las líneas directrices relativas al alojamiento y al cuidado de los animales utilizados para experimentación y otros fines científicos que, por otra parte, se había adoptado en el ámbito del Consejo de Europa como Apéndice A del Convenio Europeo sobre la protección de los animales vertebrados utilizados con fines experimentales u otros fines científicos (ETS 123).

La nueva directiva ha supuesto un importante avance en materia de bienestar animal, no solo porque adapta los requisitos generales mínimos a los avances científicos, sino también porque amplía el ámbito de aplicación de las normas de protección a los cefalópodos y a determinadas formas fetales de los mamíferos, y porque establece como principio general la promoción e implementación del «principio de las tres erres», es decir el reemplazo, la reducción y el refinamiento de los procedimientos, fomentando el uso de métodos alternativos a la experimentación con animales vivos.

Aunque la protección que otorga este real decreto no puede extenderse hoy por hoy a los nuevos animales hasta que se reforme la Ley 32/2007, de 7 de noviembre, para el cuidado de los animales, en su explotación, transporte, experimentación y sacrificio, esta norma se aprueba de manera que su protección se extenderá automáticamente en cuanto se introduzca el cambio previsto en la citada Ley. Lo mismo sucede con el régimen sancionador que ahora sólo se aplicará a las infracciones de procedimientos previstos en la Ley 32/2007 y quedará extendido en cuanto esta se reforme.

Solo se podrán utilizar animales cuando su uso esté justificado por la finalidad que se persigue, valorando su oportunidad siempre en términos de sus potenciales beneficios. Se regulan detalladamente las condiciones mínimas en las que han de alojarse los animales y los cuidados que éstos han de recibir, así como los requisitos mínimos exigidos a los criadores, suministradores y usuarios de animales de experimentación, todo ello con el objetivo principal de garantizar su bienestar en la mayor medida posible. Se establecen así mismo las normas a las que deben atenerse los proyectos y procedimientos desde que se inician hasta que finalizan.

Se marca como objetivo último el total reemplazo de los animales en los procedimientos y se fijan normas específicas para la utilización de determinados tipos de

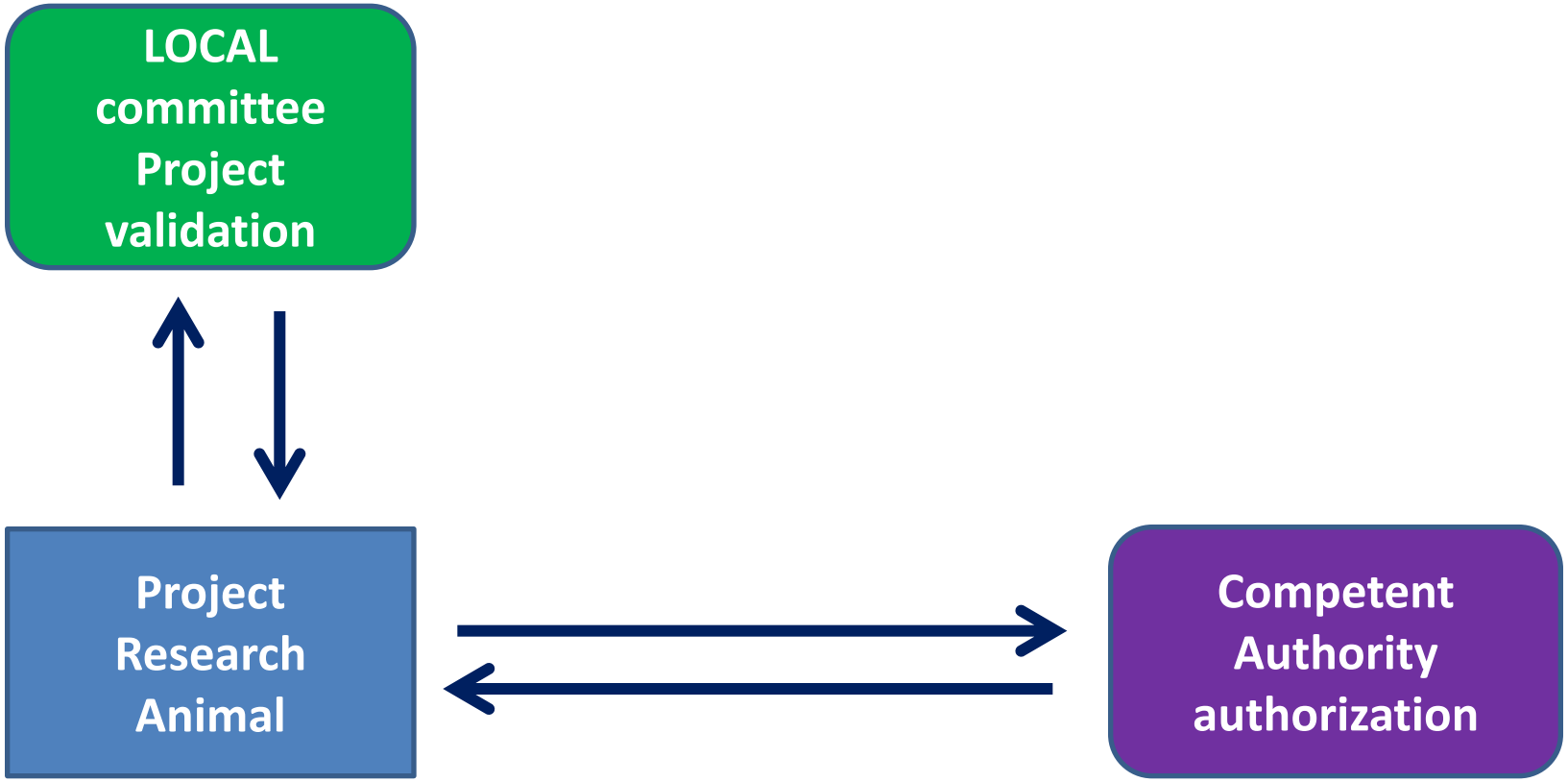
cve: BOE-A-2013-1337

Transposition of EU Directive to Spain

Summary:

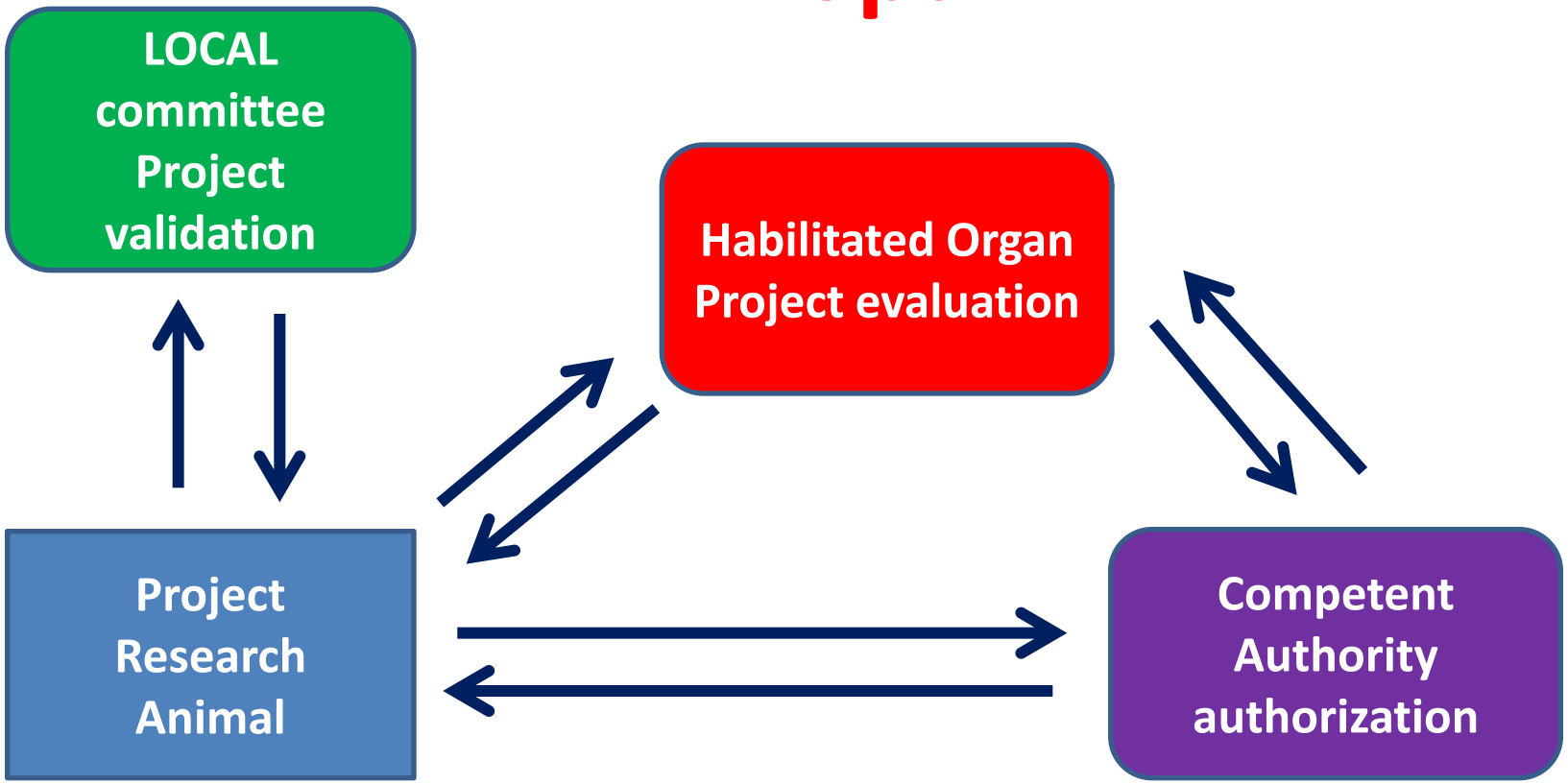
A set of regulations aiming to permit animal experimentation **ONLY** in **registered centres**, by **competent personnel**, **adequately educated** and after obtaining the corresponding **authorization**

New European Directive



New European Directive

in Spain



Principles of Animal Research

- The fundamental principles regulating animal research were described in 1959 by W. M. S. **Russell** and R. L. **Burch** and are commonly known amd referred as “the **3Rs**”
- **R**eplacement
- **R**eduction
- **R**efinament

- EU Directive 2010/63/EU

Replacement

- The use of animals for research purposes **must be avoided if alternative methods not involving animals are available** allowing to undertake such experimentation and to reach the same aims

- **Researchers must check and review** the existence of possible alternative methods allowing to avoid using research animals unnecessarily

- **Researchers must use the "lowest" animal** permiting to reach the expected conclusions

Replacement

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European Commission

JOINT RESEARCH CENTRE

European Union Reference Laboratory for Alternatives to Animal Testing (EURL ECVAM)

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- Latest News
- About EURL ECVAM
- EURL ECVAM Strategy Papers
- EURL ECVAM Recommendations
- EURL ECVAM Status Reports
- Validation & regulatory acceptance
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The **European Union Reference Laboratory for alternatives to animal testing (EURL-ECVAM)** has been formally established in 2011, due to the increasing need for new methods to be developed and proposed for validation in the European Union. **EURL ECVAM** is hosted by the Joint Research Centre located in Ispra, Italy.

EURL ECVAM has a long tradition in the validation of methods which reduce, refine or replace the use of animals for safety testing and efficacy/potency testing of chemicals, biologicals and vaccines. Research laboratories are able to submit to **EURL ECVAM** for scientific validation the alternative methods to animal testing that they have developed.

EURL ECVAM also promotes the development and dissemination of alternative methods and approaches, their application in industry and their acceptance by regulators.

The European Commission's involvement in activities targeted to the validation of alternative approaches to animal testing started in 1991, with the launch of **ECVAM** (the European Centre for the Validation of Alternative Methods), hosted by the **Joint Research Centre**. As from 2011, ECVAM's tasks are assigned to **EURL ECVAM.**

EURL ECVAM
European Union Reference Laboratory for Alternatives to Animal Testing

Photo: Cell culture under sterile conditions in the EURL ECVAM microbiology laboratory. Copyright EU 2012.

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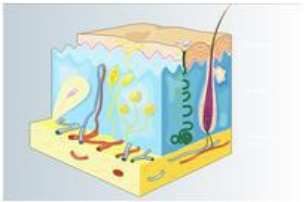

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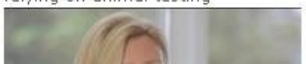


Replacement

Reduction

- Researchers must use the **minimum number of animals allowing to reach significant conclusions**

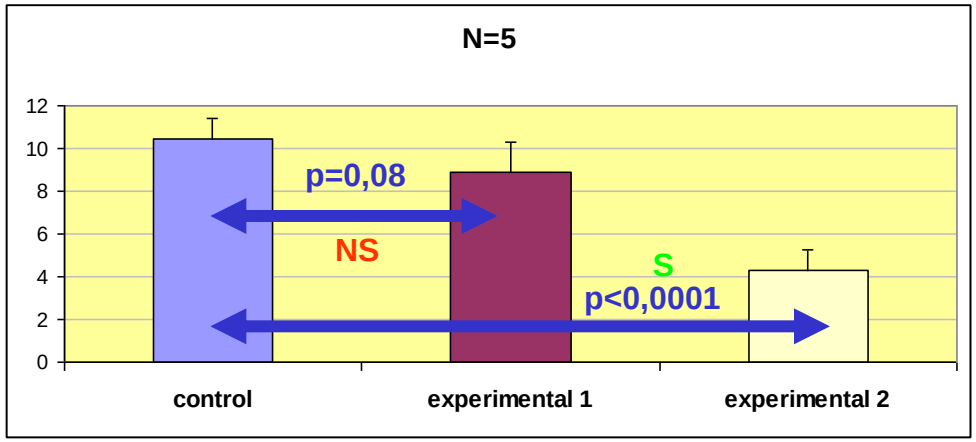
- Often wrongly confounded by forcing to use the smallest possible number of animals

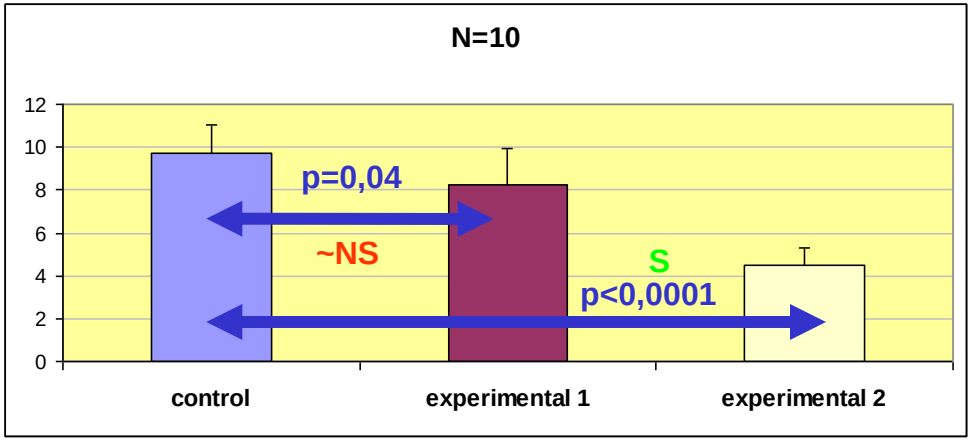
- It refers also to **avoid repeating animal experiments unnecessarily**, aiming at obtaining the maximum number of data from each experiment, **sharing and adequately documenting the results**, so that other colleagues can use them and do not have to repeat the same experiment

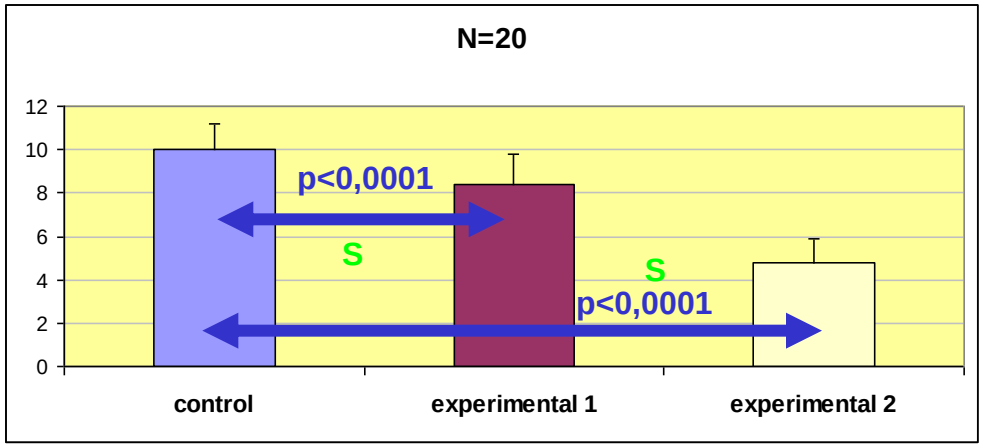
Reduction

- **Experimental design**
- Experimental and control **groups**, blocks
- **Adequate number of individuals** per experimental group, according to expected differences, technical and biological variability
- Defining the correct number of individuals (**sample size**)

CALCULATING SAMPLE SIZE







Let's assume the parameter we are measuring varies +/- 20% in the populations to be analyzed

Experimental 1:

Difference between experimental and control group is about 20%

We will need N=20 for significant results

Experimental 2:

Difference between experimental and control group is about 50%

It is enough with N=5 for significant results

$$Sample\ Size = \frac{\frac{z^2 \times p(1-p)}{e^2}}{1+(\frac{z^2 \times p(1-p)}{e^2 N})}$$

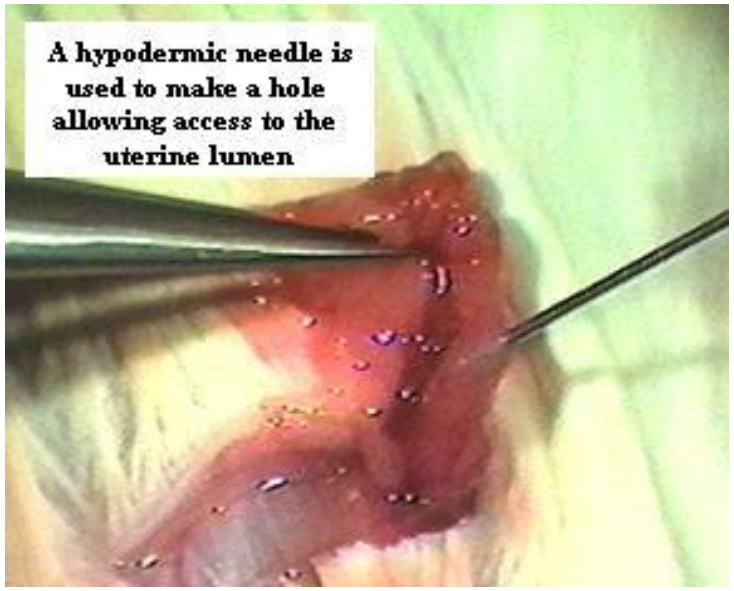
Refinement

- Researches must **use always the most advanced, optimized methods and equipments for research animals** aiming to reduce or alliviate, to the minimum, the harm, pain and discomfort caused by the experimental procedures

- Surgical anesthesia, post-surgical analgesia

- **Developing new methods**, more efficient, allowing to reach similar conclusions through the use of lesser number of animals

Refinement



Uterine embryo transfer

NSET

Non-surgical embryo transfer

Non-EU countries

- Research is conducted, partially or totally, in a non-EU country
- Participants or resources come from a non-EU country
- Materials (Data) is imported from or exported to a non-EU country
- Must **ensure compliance with EU Ethics Standards regardless of the country** where the research is to be conducted


Atlantic Ocean
South Africa
Copyright © Ontheworldmap.com

Non-EU countries

- Research undertaken in a non-EU country raise **potential Ethics issues**?
- Planning to use **local resources**? (UN Convention on Biological Diversity, Nagoya Protocol Access permission, benefit sharing agreement)
- Importing/Exporting Materials/Data
- Low and Middle-Income countries (benefit sharing actions planed)
- Local participants put at risk

The Nagoya Protocol on ABS

- The Nagoya Protocol on Access and Benefit-sharing
- The Nagoya Protocol on **Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization** to the Convention on Biological Diversity is an international agreement which aims at sharing the benefits arising from the utilization of genetic resources in a fair and equitable way (October 2014)

www.cbd.int/abs/

Environment, Health and Safety

- Research may cause **harm to humans**, including research staff
- Research may cause **harm to the environment, animals or plants**
- Research deals with **endangered/protected flora or fauna**

- Specific permissions, required health and safety authorizations

Dual use

- Your research may have military applications
- Your research may contribute to the proliferation of weapons of mass destruction
- EU export control regulation 482/2009
- Export licenses required, ensure compliance, avoid negative implications

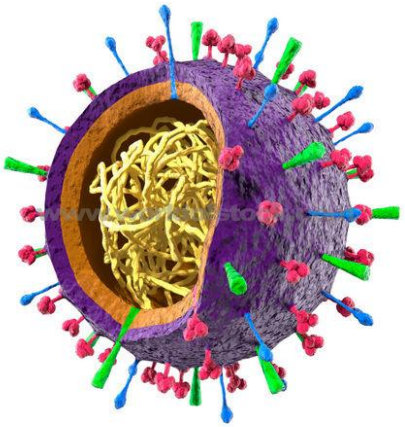

GALILEO

Exclusive use on civil applications

- **H2020: Only research that has an exclusive focus on civil applications is eligible for funding**
- Military partners/subcontrators might be involved, for dual-use technologies, as long as the research itself has a clear focus on civil applications

Misuse

- **Your research has a potential for misuse of research results.** Your research, materials, methods and knowledge generated may:
- applied for malevolent/criminal/terrorist use
- harm humans, animals or the environment
- end up in the wrong hands
- serve purposes other tan those intended
- Conduct risk assessment, legal requirements national, EU, international
- take all measures to prevent misuse



1918-1919
H1N1 serotype

~500 Million infected
~50 Million deaths

Other Ethics issues

- Robotics, artificial intelligence
- Nanotechnology
- Neurobiology
- Xenotransplants
- Animal-human chimeras/embryos
- 3D-bioprinted human organs
- Genetic enhancement
- Inmigration, War conflicts
- …

Ethics issues → Recommendations

- Get help/advice from your institutional (and/or external) Ethics experts/committees
- Appoint an **Ethics advisor**
- Organize an **Ethics Advisory Board**
- Involve your Ethics advisor/board in the monitoring of research activities
- Have your Ethics advisor/board writing an Ethics report on your research activities

Lluís Montoliu's laboratory at CNB-CSIC

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