CRISPR-Cas9 research in ERCEA Ethics Process

Filipa Ferraz de Oliveira
ERCEA Scientific Officer

Fostering Responsible Research With CRISPR-Cas9, Paris, March 2016
CRISPR-Cas9 research in ERCEA Ethics Process

1. Introduction: CRISPR-Cas9 in the EC ethics review
   i. Ethics review process in ERCEA
   ii. Research with hESC – ethics process
   iii. CRISPR-Cas9 ethics recommendation

2. CRISPR-Cas9 ethics issues
   i. Reshaping animals
   ii. Engineering plants
   iii. Human genetic therapy
   iv. Environmental release
   v. Misuse

3. CRISPR-Cas9 in ERC research projects
   i. Some quantitative information
CRISPR-Cas9 in EC ethics review

Ethics review process in ERCEA

1. Programme Committee and 2. EC for decision

End of evaluation

1 week

3 weeks + answer from PI

3 months + answer from PI

6 months + voting and EC decision

Signature of Grant Agreements

Ethics Pre-Screening
(40% proposals cleared)

Ethics Screening
(50% proposals cleared)

Ethics Assessment ERCEA or R&I
(9% proposals cleared)

Ethics Assessment R&I
(hESC) 1. Programme Committee and 2. EC for decision

ALL SUBMISSION DOCS

ALL SUBMISSION DOCS + new documentation
CRISPR-Cas9 in EC ethics review

Research with hESC – ethics process

When...

1. The proposal has all ethics documentation needed and
2. Project and cell lines are registered at Human Pluripotent Stem Cell Registry (hPSCreg)

The proposal is sent to:

1. Programme Committee (representatives of all Member States) votes for approval of funding
2. After the voting of the Committee the European Commission should adopt a decision
CRISPR-Cas9 in EC ethics review

Research with hESC – ethics process

Cannot be financed under Horizon 2020:

• research activities aiming at human cloning for reproductive purposes

• research activity intended to modify the genetics of human beings that could make such changes heritable

• research activities intended to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.
CRISPR-Cas9 in EC ethics review

CRISPR-Cas9 ethics recommendation
CRISPR-Cas9 research in ERCEA Ethics Process

1. Introduction: CRISPR-Cas9 in the EC ethics review
   i. Ethics review process in ERCEA
   ii. Research with hESC – ethics process
   iii. CRISPR-Cas9 ethics recommendation

2. CRISPR-Cas9 ethics issues
   i. Reshaping animals
   ii. Engineering plants
   iii. Human genetic therapy
   iv. Environmental release
   v. Misuse

3. CRISPR-Cas9 in ERC research projects
   i. Some quantitative information
CRISPR-Cas9 ethics issues

Reshaping animals

Gene editing experiments producing genetic modified creatures as:

- Flies, mosquitos, worms capable of resisting the transmission of certain diseases
- Mice and extra muscular ferrets
- Cows without horns

- **Animal protection**
  (Directive 2010/63/EU of the European Parliament)

- **GMO production**
  (GMO Directive 2009/41/EC)
CRISPR-Cas9 ethics issues

Engineering plants

Gene editing experiments producing genetic modified plants as:

• Gene-edited potato
• Corn resistant to weed killers

• GMO production
   (GMO Directive 2009/41/EC and the Cartagena Protocol on Biosafety)
CRISPR-Cas9 ethics issues

Human genetic therapy

Gene editing experiments with human cells

- Gene therapy in adults or children
- Editing genes in human embryonic stem cells

- hESC compliance with EU and national law
  (Statement of the Commission related to research activities involving human embryonic stem cells)
- Human cells and tissues in general
CRISPR-Cas9 ethics issues

Environmental release

"Gene drive" technology or installing gene-editing machinery in a living being

- Mosquitoes resisting malaria and capable to reproduce
- Environmental changes hard to undo

- Precautionary principle and the legislation on nature conservation and pollution control
  *(Cartagena Protocol on Biosafety)*
CRISPR-Cas9 ethics issues

Misuse

Gene editing experiments allowing the production of dangerous bio-elements

• Easy accessible technology – low price
• Uncontrolled experiments

• Research that has other potential for terrorist or criminal abuse
  (Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction)
CRISPR-Cas9 research in ERCEA Ethics Process

1. Introduction: CRISPR-Cas9 in the EC ethics review
   i. Ethics review process in ERCEA
   ii. Research with hESC – ethics process
   iii. CRISPR-Cas9 ethics recommendation

2. CRISPR-Cas9 ethics issues
   i. Reshaping animals
   ii. Engineering plants
   iii. Human genetic therapy
   iv. Environmental release
   v. Misuse

3. CRISPR-Cas9 in ERC research projects
   i. Some quantitative information
CRISPR-Cas9 in ERC research projects

- Projects referring to Tandem repeats and/or CRISPR-Cas technology being used
- First project using CRISPR-Cas in StG14
- In AdG15 all 26 projects refer to the use of CRISPR technology
CRISPR-Cas9 in ERC research projects

**Scientific domain**

- SH: 3%
- PE: 5%
- LS1: 6%
- LS2: 3%
- LS3: 16%
- LS7: 24%
- LS8: 24%
- LS9: 19%

**Type of cell involved**

- Bacteria and Fungi: 2
- Insect: 1
- Plant: 4
- Animal: 18
- Human: 16
- hESC, hiESC, aESC: 12

LS1 - Molecular and Structural Biology and Biochemistry
LS2 - Genetics, Genomics, Bioinformatics and Systems Biology
LS3 - Cellular and Developmental Biology
LS7 - Diagnostic Tools, Therapies and Public Health
LS8 - Evolutionary, Population and Environmental Biology
LS9 - Applied Life Sciences and Non-Medical Biotechnology
CRISPR-Cas9 in ERC research projects

Projects with ethics issues flagged by the PI

- Yes
- No

Ethics issues found in the "not flagged" projects

- Human cells
- GM animals or insects
- GM plants
- Environment/staff protection
- Misuse
- No ethics issues

Ethics issues found in the "flagged" projects

- hESC
- Genetic samples
- Human cells
- Personal data
- H. volunteers
- Patients
- Children
- Non-EU countries
- Environment/staff protection
- Animals and insects
- Virus
THANK YOU...

QUESTIONS?